COMPILATION OF VARIOUS LEGAL PROVISIONS ON EXCEPTIONS REGARDING FARMERS' AND/OR BREEDERS' USE OF PATENTED INVENTIONS

COMPILATION DE DIVERSES DISPOSITIONS JURIDIQUES RELATIVES AUX EXCEPTIONS CONCERNANT L'UTILISATION PAR LES AGRICULTEURS ET LES OBTENTEURS D'INVENTIONS BREVETÉES

COMPILACIÓN DE DIVERSAS DISPOSICIONES JURÍDICAS SOBRE EXCEPCIONES RELATIVAS A LA UTILIZACIÓN POR LOS AGRICULTORES Y/O LOS FITOMEJORADORES DE INVENCIONES PATENTADAS

تجميع لأحكام قانونية متنوعة بشأن الاستثناءات المتعلقة باستخدام المزارعين و/أو مستولدي النباتات للاختراعات المحمية ببراءة

关于农民和/或育种者使用专利发明例外的各种法律条款汇编

ПОДБОРКА РАЗЛИЧНЫХ ПРАВОВЫХ ПОЛОЖЕНИЙ ОБ ИСКЛЮЧЕНИЯХ, КАСАЮЩИХСЯ ИСПОЛЬЗОВАНИЯ ЗАПАТЕНТОВАННЫХ ИЗОБРЕТЕНИЙ СЕЛЬСКОХОЗЯЙСТВЕННЫМИ ПРОИЗВОДИТЕЛЯМИ И/ИЛИ СЕЛЕКЦИОНЕРАМИ

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Articles 38 e) and 38 ë), and Article 50.2 of the Law on Industrial Property № 9947 of July 7, 2008 (as amended up to Law № 96/2021 of July 7, 2021)

Article 38. Limitation of the Effects of the Patent

The rights conferred by the patent shall not extend to:

[…]

e) the use by a farmer of the product of his crop for propagation or multiplication on his own holding, provided that the reproductive vegetable material was sold or otherwise commercialized by the holder of the patent or with his consent to the farmer, for agricultural purposes.

ë) the use by a farmer of protected livestock for farming purposes, on condition that the breeding animals or other animals reproductive material was sold or otherwise commercialized to the farmer by the holder of the patent or with his consent. Such use includes the provision of the animal or other animal reproductive material for the purposes of his agricultural activity, but not the sale as part of or for the purpose of commercial reproductive activity.

Article 50 Compulsory Licenses

[…]

2. Based on the request, for a non-exclusive use of the patent protected invention or the plant species protected by this right, the court is entitled to grant a compulsory licence in respect of a first patent to the patent owner or right holder on the plant species, who cannot use the second patent or right on a plant species without infringing the first patent, by making a payment established by an expert appointed by the court, provided that:

a) the invention claimed in the second patent or the protected plant species involves a technical advance of considerable economic significance in relation to the invention claimed in the first patent;

b) they have requested to the patent or right holder on the plant species, the right to be provided with a contractual licence and have not been provided with the same."

2/a. The court, for a non-exclusive use of the protected invention, takes any measure it deems necessary to verify the existence of such a situation.

2/b. In the case of a compulsory licence, as provided under paragraph 2 of this Article, the owner of the first patent or the holder of the right on a plant species shall be entitled to use the subsequent patented invention or protected plant species under a combined licence on reasonable terms.

[…]

4. The type of use covered and the conditions to be met shall be specified by the court. The following conditions shall apply:

a) The scope and duration of the exploitation shall be limited to the purpose for which it was authorized;

b) The exploitation shall be non-exclusive;

c) The exploitation shall be non-assignable. In the case of a compulsory licence, as provided by paragraph 2 of this Article, the authorised exploitation regarding the first patent shall be non-assignable, except with the assignment of the second patent or plant species.

[…]

ANDORRA

Articles 33.1 g) and 34 of the Law on Patents № 26/2014 of October 30, 2014

33. Límits dels drets de les patents

1. Els drets conferits per una patent no s'estenen a:

[…]

g) Actes relatius a la matèria biològica obtinguda per reproducció o multiplicació d'una matèria biològica protegida objecte de la patent, després que aquesta matèria hagi estat posada al mercat en el territori al qual es refereix la lletra a d'aquest apartat pel titular de la patent o amb el seu consentiment, quan la reproducció o la multiplicació sigui el resultat necessari de la utilització per a la qual hagi estat comercialitzada la matèria biològica esmentada, i a condició que la materia obtinguda no s'utilitzi posteriorment per a noves reproduccions o multiplicacions.

[…]

34. Supòsits especials

1. No obstant el que disposen els articles anteriors, la venda o qualsevol altra forma de comercialització de material de reproducció vegetal efectuada pel titular de la patent o amb el seu consentiment a un agricultor per a la seva explotació agrícola, implica el dret d'aquest últim a utilitzar el producte de la seva collita per a una reproducció o multiplicació ulterior efectuada per ell mateix en la seva explotació.

2. No obstant el que disposen els articles anteriors, la venda o qualsevol altra forma de comercialització d'animals de cria o de material de reproducció animal efectuada pel titular de la patent o amb el seu consentiment a un agricultor o ramader, implica l'autorització a aquests últims per utilitzar el bestiar protegit amb fins agrícoles o ramaders. Això inclou la posada a disposició del bestiar o d'un altre material de reproducció animal perquè l'agricultor o ramader pugui prosseguir la seva activitat agrícola o ramadera, però no la venda en el marc d'una activitat de reproducció comercial o amb aquesta finalitat.

ARMENIA

Articles 25 and 73 of the Law on Patents, Law No. HO-108-N

25. Արտոնագրից բխող բացառիկ իրավունքի խախտում չհամարվող գործողությունները

[…]

3. Սույն օրենքի 24-րդ հոդվածի 4-6-րդ մասերով սահմանված դրույթները չեն տարածվում վերարտադրման կամ բազմացման միջոցով ստացված կենսաբանական նյութի վրա, որն արտոնագրատիրոջ կողմից կամ նրա համաձայնությամբ քաղաքացիական շրջանառության մեջ է դրվել Հայաստանի Հանրապետությունում, երբ վերարտադրումը կամ բազմացումը անհրաժեշտաբար բխում է այն կիրառությունից, որի համար կենսաբանական նյութը շուկա է հանվել, պայմանով, որ ստացված նյութը հետագայում չի օգտագործվի այլ վերարտադրման կամ բազմացման համար:

4. Որպես սույն օրենքի 24-րդ հոդվածի 4-6-րդ մասերի բացառություն՝ գյուղատնտեսական օգտագործման նպատակով բույսի վերարտադրման նյութի վաճառքը ֆերմերին կամ այլ ձևով դրա առևտրայնացումն արտոնագրատիրոջ կողմից կամ նրա համաձայնությամբ, իրավունք է տալիս ֆերմերին վերարտադրման կամ բազմացման նպատակով օգտագործելու իր բերքի արդյունքն իր հողամասում:

5. Որպես սույն օրենքի 24-րդ հոդվածի 4-6-րդ մասերի բացառություն՝ բազմացող ընտանի կամ այլ կենդանիների վերարտադրության նյութի վաճառքը ֆերմերին, կամ այլ ձևով դրա առևտրայնացումը արտոնագրատիրոջ կողմից կամ նրա համաձայնությամբ իրավունք է տալիս ֆերմերին այդ նյութով վերարտադրված կենդանին օգտագործելու գյուղատնտեսական նպատակներով: Սա ներառում է կենդանուց կամ դրա բազմացումից ստացված արգասիքը գյուղատնտեսական նպատակներով օգտագործելու հնարավորությունը, բացառությամբ առևտրային շրջանակներում կամ այդ նպատակներով բազմացման գործունեության:

73. Հարկադրական լիցենզիայի տրամադրման պայմանները

[…]

6. Եթե սելեկցիոները չի կարող բույսի սորտի նկատմամբ իրավունք ձեռք բերել՝ առանց խախտելու ավելի վաղ առաջնություն ունեցող գյուտի արտոնագիրը, ապա կարող է դիմել արտոնագրով պահպանվող գյուտի ոչ բացառիկ օգտագործման հարկադրական լիցենզիա ստանալու համար այն ծավալով, որն անհրաժեշտ է պահպանվող բույսի սորտի օգտագործման համար:

7. Եթե կենսատեխնոլոգիական գյուտի արտոնագրատերը չի կարող գյուտն օգտագործել՝ առանց խախտելու բույսի սորտի նկատմամբ ավելի վաղ իրավունքը, ապա նա կարող է դիմել այդ իրավունքով պահպանվող բույսի սորտի օգտագործման հարկադրական ոչ բացառիկ լիցենզիա ստանալու համար:

8. Սույն հոդվածի 6-րդ և 7-րդ մասերում նշված հարկադրական լիցենզիաները տրամադրվում են՝ կիրառելով սույն օրենքի 72-74-րդ հոդվածների դրույթները մութաթիս մութանդիս (mutatis mutandis):

AUSTRIA

Sections 22c., 36 and 37 of the Patent Act 1970 (as amended up to Federal Law published in the Federal Law Gazette BGBI.I No. 186/2023)

§ 22c. (1) Der im § 22b vorgesehene Schutz erstreckt sich nicht auf das biologische Material, das durch generative oder vegetative Vermehrung von biologischem Material gewonnen wird, das im Europäischen Wirtschaftsraum vom Patentinhaber oder mit dessen Zustimmung in Verkehr gebracht wurde, wenn die

generative oder vegetative Vermehrung notwendigerweise das Ergebnis der Verwendung ist, für die das biologische Material in Verkehr gebracht wurde, vorausgesetzt, dass das so gewonnene Material anschließend nicht für andere generative oder vegetative Vermehrung verwendet wird.

(2) Abweichend von § 22b beinhaltet der Verkauf oder das sonstige Inverkehrbringen von pflanzlichem Vermehrungsmaterial durch den Patentinhaber oder mit dessen Zustimmung an einen Landwirt zum landwirtschaftlichen Anbau dessen Befugnis, sein Erntegut für die generative oder vegetative Vermehrung durch ihn selbst im eigenen Betrieb zu verwenden, wobei Ausmaß und Modalitäten dieser Ausnahmeregelung denjenigen des Artikels 14 der Verordnung (EG) Nr. 2100/94 entsprechen.

(3) Abweichend von § 22b beinhaltet der Verkauf oder das sonstige Inverkehrbringen von Zuchtvieh oder von tierischem Vermehrungsmaterial durch den Patentinhaber oder mit dessen Zustimmung an einen Landwirt dessen Befugnis, das geschützte Vieh zu landwirtschaftlichen Zwecken zu verwenden. Diese Befugnis erstreckt sich auch auf die Überlassung des Viehs oder anderen tierischen Vermehrungsmaterials zur Fortführung seiner landwirtschaftlichen Tätigkeit, jedoch nicht auf den Verkauf mit dem Ziel oder im Rahmen einer gewerblichen Viehzucht. Für diese Befugnis ist eine angemessene Entschädigung zu zahlen.

(4) § 22b gilt nicht für biologisches Material, das im Bereich der Landwirtschaft zufällig oder technisch nicht vermeidbar gewonnen wurde. Daher kann ein Landwirt nicht in Anspruch genommen werden, wenn er nicht diesem Patentschutz unterliegendes Saat- oder Pflanzgut angebaut hat.

Zwangslizenzen

§ 36. (1) Kann eine patentierte Erfindung nicht verwertet werden, ohne eine mit besserem Zeitrang patentierte Erfindung (älteres Patent) zu verletzen, hat der Inhaber des jüngeren Patentes Anspruch auf eine nicht ausschließliche Lizenz an dem älteren Patent, wenn die mit dem jüngeren Patent geschützte Erfindung gegenüber der mit dem älteren Patent geschützten Erfindung einen wichtigen technischen Fortschritt von erheblicher wirtschaftlicher Bedeutung darstellt. Im Falle der Lizenzeinräumung hat auch der Inhaber des älteren Patentes Anspruch auf eine nicht ausschließliche Lizenz am jüngeren Patent.

(2) Kann ein Pflanzenzüchter ein Sortenschutzrecht nicht erhalten oder verwerten, ohne eine mit besserem Zeitrang patentierte Erfindung (älteres Patent) zu verletzen, hat er Anspruch auf eine nicht ausschließliche Lizenz an dem Patent, soweit die Pflanzensorte einen bedeutenden technischen Fortschritt von erheblichem wirtschaftlichen Interesse gegenüber der patentgeschützten Erfindung darstellt und soweit diese Lizenz zur Verwertung der zu schützenden Pflanzensorte erforderlich ist.

(3) Wird dem Inhaber eines Patentes für eine biotechnologische Erfindung eine nicht ausschließliche Lizenz für eine durch ein mit besserem Zeitrang erteiltes Sortenschutzrecht (älteres Sortenschutzrecht) geschützte Pflanzensorte erteilt, weil er die biotechnologische Erfindung nicht verwerten kann, ohne ein älteres Sortenschutzrecht zu verletzen, dann hat der Inhaber des älteren Sortenschutzrechtes Anspruch auf eine nicht ausschließliche Lizenz an dem jüngeren Patent zur Verwertung der geschützten Erfindung.

§ 37. (1) Verweigert der zur Einräumung einer Lizenz gemäß § 36 Berechtigte deren Einräumung, obwohl sich der Lizenzwerber bemüht hat, die Zustimmung innerhalb einer angemessenen Frist zu angemessenen geschäftsüblichen Bedingungen zu erhalten, so entscheidet auf Antrag des Lizenzwerbers das Patentamt in dem für die Anfechtung von Patenten vorgeschriebenen Verfahren. Im Fall der Lizenzeinräumung ist eine angemessene Vergütung zu bestimmen, wobei der wirtschaftliche Wert der Lizenz in Betracht zu ziehen ist. Die gegebenenfalls erforderliche Sicherstellung sowie die sonstigen Bedingungen der Benützung sind unter Berücksichtigung der Natur der Erfindung und der Umstände des Falles

festzusetzen. Umfang und Dauer der Lizenz gemäß § 36 werden vorwiegend für die Versorgung des inländischen Marktes gestattet und sind auf den Zweck zu begrenzen, der sie erforderlich gemacht hat. […]

(5) Bei Verfahren über die Einräumung oder Aufhebung von Lizenzen gemäß § 36 Abs. 2 und 3 hat jedem Senat der Nichtigkeitsabteilung ein Mitglied anzugehören, das auf Vorschlag des Bundesministers für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft vom Bundesminister für Verkehr, Innovation und Technologie ernannt worden ist.

[…]

BELGIUM

Articles XI. 34. § 1er. and XI.37. § 1er. of the Law of April 19, 2014, on the Insertion of Book XI 'Intellectual Property' to the Code of Economic Law, and Specific Provisions to the Book XI in Books I, XV and XVII of the Code (as amended up to July 28, 2024)

XI. 34. § 1er. Les droits conférés par un brevet ne s'étendent à aucun des actes suivants

[…]

c) l'utilisation de matériel biologique en vue de créer ou de découvrir et de développer d'autres variétés végétales ;

[…]

i) l'utilisation par un agriculteur du produit de sa récolte pour reproduction ou multiplication sur sa propre exploitation, pour autant que le matériel de reproduction végétale ait été vendu ou commercialisé sous une autre forme à l'agriculteur par le titulaire du brevet ou avec son consentement à des fins d'exploitation agricole. L'étendue et les conditions d'une telle utilisation correspondent à celles fixées à l'article 14 du Règlement (CE) n° 2100/94 du Conseil du 27 juillet 1994 instituant un régime de protection communautaire des obtentions végétales ;

j) l'utilisation par un agriculteur de bétail protégé pour un usage agricole, pour autant que les animaux d'élevage ou autre matériel de reproduction animal aient été vendus ou commercialisés sous une autre forme à l'agriculteur par le titulaire du brevet ou avec son consentement. Une telle utilisation comprend la mise à disposition de l'animal ou autre matériel de reproduction animal pour la poursuite de l'activité agricole de l'agriculteur, mais non la vente de ceux-ci dans le cadre ou dans le but d'une activité de reproduction commerciale ;

[…]

l) la matière biologique obtenue par reproduction ou multiplication d'une matière biologique mise sur le marché sur le territoire d'un Etat membre de l'Union européenne par le titulaire du brevet ou avec son consentement, lorsque la reproduction ou la multiplication résulte nécessairement de l'utilisation pour laquelle la matière biologique a été mise sur le marché, pourvu que la matière obtenue ne soit pas utilisée ensuite pour d'autres reproductions ou multiplications.

[…]

XI.37. § 1er. Le ministre peut octroyer, conformément aux articles XI.40 à XI.42, une licence d'exploitation d'une invention couverte par un brevet :

[…]

3° lorsqu'un obtenteur ne peut obtenir ou exploiter un droit d'obtention végétale sans porter atteinte à un brevet antérieur, dans la mesure où cette licence est nécessaire pour l'exploitation de la variété végétale à protéger et pour autant que la variété représente un progrès technique important d'un intérêt économique considérable par rapport à l'invention revendiquée dans le brevet et à condition que cette licence soit octroyée principalement pour l'approvisionnement du marché national;
4° au titulaire d'un droit d'obtention végétale, lorsque le titulaire d'un brevet concernant une invention biotechnologique a, conformément aux dispositions de la loi sur la protection des obtentions végétales, obtenu une licence obligatoire pour l'exploitation non-exclusive de la variété végétale protégée par ce droit d'obtention végétale parce qu'il ne peut exploiter l'invention biotechnologique sans porter atteinte à ce droit d'obtention végétale antérieur et à condition que cette licence soit octroyée principalement pour l'approvisionnement du marché national.

BOLIVIA

The Decision № 486 of September 14, 2000 of the Commission of the Andean Community applies (Refer to the provision below)

BOSNIA AND HERZEGOVINA

Articles 75 and 79 of the Law on Patents as of May 28, 2010

75. (Limitations of Effects in Respect of the Patents in the Field of Biotechnology)

(1) The exclusive rights deriving from the provision of Article 67 of this Law shall not apply to the biological material obtained from the propagation and multiplication of the biological material marketed in Bosnia and Herzegovina by the patent holder or with his consent, where the propagation and multiplication necessarily result from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for further propagation and multiplication.

(2) By way of derogation from the provision of Article 67 of this Law, by means of the sale or another form of commercialization of the plant propagating material to a farmer by the patent holder or with his consent, for farming purposes, the farmer acquires the authorization to use the products of his harvest for the propagation or multiplication on his farm.

(3) By way of derogation from the provision of Article 67 of this Law, by means of the sale or another form of commercialization of breeding stock or another animal reproductive material to a farmer by the patent holder or with his consent, the farmer acquires the authorization to use the protected livestock for agricultural purposes, including at the same time the availability of the animal or another animal reproductive material for the purpose of carrying out his own farming activities, but not the sale within the framework or for the purpose of commercial reproduction activity.

79. Compulsory License

[…]

(5) At a reasoned request, the Court of Bosnia and Herzegovina may grant a compulsory license for somebody else's patent to the patent holder who cannot exploit his protected invention without infringing somebody else's patent.

(6) The compulsory license referred to in paragraph (5) of this Article may be granted, provided that:

a) a patent owned by the person filing the request referred to in paragraph (2) of this Article involves an important technological advance, which is of considerable economic significance in relation to the invention protected by the patent for which the grant of a compulsory license is requested.

b) the holder of the patent for which the grant of a compulsory license is requested is entitled to a cross license on reasonable terms and conditions.

[…]

(13) The provisions of paragraphs (5), (6) and (12) of this Article shall apply mutatis mutandis to the right to protection of a plant variety.

BOTSWANA

Section 25(1) of the Industrial Property Act, 2010 (Act № 8 of 2010)

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;

[…]

BRAZIL

Article 43.V. and 43.VI of Law No. 9.279 of May 14, 1996 (Law on Industrial Property, as amended up to Law No. 14.200 of September 2, 2021)

43. The provisions of the previous Article do not apply:

[…]

V. 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; and

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.

[…]

BULGARIA

Article 20a and Article 32a of the Law on Patents and Utility Models Registration (SG № 27/1993, as amended up to December 23, 2022)

Exhaustion of Rights

20a.

[…]

(2) The protection referred to in Art. 19, Para 6, 7 and 8 shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market 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.

(3) The protection referred to in Art. 19, Para 6, 7 and 8 shall not extent to 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. The sale or other form of commercialisation implies authorisation for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm.

[…]

(5) The protection referred to in Art. 19, Para 6, 7 and 8 shall not extent to 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, which sale implies authorisation for the farmer to use the livestock or other animal reproductive material for the purposes of pursuing his agricultural activity but not sale within the framework or for the purpose of a commercial reproduction activity.

[…]

Compulsory Cross-License

32a.

(1) When a selectionist cannot acquire or use right in a plant variety without infringement of an earlier patent, he shall be able to request a compulsory license for non-exclusive use of the invention protected by the patent, as far as the license is necessary for the use of the plant variety for the purpose of its legal protection, on the condition that respective compensation is paid. When such license is granted, the holder of the patent shall be entitled to be granted cross-license for use of the protected variety on fair terms.

(2) When a holder of a patent for a biotechnological invention cannot use it without infringing earlier right in a plant variety, he may request a compulsory license for non-exclusive use of the protected plant variety, on the condition that respective compensation is paid. When such license is granted, the holder of the protected variety shall be entitled to be granted cross-license for use of the invention on fair terms.

(3) The person that has requested granting of compulsory license under Para 1 or 2 shall prove that:

1. he has made unsuccessful attempt to be granted a contractual license by the holder of the patent or the plant variety;

2. the plant variety or the invention represent significant technical progress of substantial economical interest in comparison with the invention – subject of the patent, or the protected plant variety.

CABO VERDE

Article 42 of the Industrial Property Code (approved by Legislative Decree No. 4/2007 of August 20, 2007)

42. **Authorization for third parties**

1. The transfer, in any form, by the holder of the patent, or with his consent, of reproductive plant material, for the purposes of agricultural exploitation, shall imply authorization for the acquirer to use the product of his harvest, himself, for reproduction or multiplication on his holding.

2. The assignment, in any form, by the holder of the patent, or with his consent, of livestock or other reproductive animal material, shall imply authorization for the acquirer to use the protected animals for agricultural purposes, said authorization including the making available of the animal, or other reproductive animal material, for the performance of his agricultural activity.

3. The authorization referred to in paragraph 2 above shall not cover any sale, which is intended for reproductive activity for commercial purposes within the scope thereof.

COLOMBIA

The Decision № 486 of September 14, 2000 of the Commission of the Andean Community applies (Refer to the provision below)

CROATIA

Articles 99 and 104 of the Patent Act (NN 16/2020 in force from February 20, 2020)

99. Limitation of effects in respect of patents in the field of biotechnology

(1) The exclusive rights deriving from the provision set out in Article 94 of this Act shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market in the territory of the Republic of Croatia, or a Member State of the European Union or a Contracting Party to the European Economic Area Agreement, 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.

(2) By way of derogation from Article 94 of this Act, 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.

(3) By way of derogation from Article 94 of this Act, 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 agricultural purposes, including making the animal or other animal reproductive material available for the purposes of pursuing his agricultural activity but not for sale within the framework or for the purpose of a commercial reproduction activity.

104. Compulsory Licenses

[…]

(3) The court referred to in Article 103 paragraph (1) may grant a compulsory license in relation to the subject matter of the first patent to the holder of a patent who cannot exploit the subject matter of his patent (second patent) without infringing the first patent, on the following conditions:

1. the subject matter of the second patent involves an important technical advance of considerable economic significance in relation to the subject matter of protection of the first patent;

2. the holder of the first patent shall be entitled, on reasonable terms, to a cross compulsory license to use the subject matter of the second patent; and

3. granted license may be transferred exclusively with a transfer of the second patent.

(4) The provisions referred to in paragraph (3) of this Article shall apply mutatis mutandis in the case where a breeder cannot exercise the right to a protected plant variety without infringing the patent protecting an invention in the field of biotechnology or where the holder of a patent cannot exploit the invention protected by a patent in the field of biotechnology without infringing the breeder's right to a protected plant variety.

[…]

(8) A compulsory license according to paragraphs (3) and (4) of this Article shall be non- transferable except together with a transfer of the second patent or a protected plant variety.

CYPRUS

Articles 27A and 49A of the Patents Law of 1998 (as amended up to Law No. 122(I)/2006)

Έκταση και περιορισμοί των δικαιωμάτων εκ του διπλώματος βιοτεχνολογικής ευρεσιτεχνίας

27Α.—(1)(α) Η προστασία που παρέχει ένα δίπλωμα ευρεσιτεχνίας για βιολογικό υλικό, το οποίο, ως εκ της εφευρέσεως, διαθέτει συγκεκριμένες ιδιότητες, εκτείνεται σε οποιοδήποτε βιολογικό υλικό αποκτάται βάσει του εν λόγω βιολογικού υλικού με αναπαραγωγή ή πολλαπλασιασμό υπό την αυτή ή διαφορετική μορφή, το οποίο διαθέτει τις ίδιες με αυτό ιδιότητες.

(β) Η προστασία που παρέχει ένα δίπλωμα ευρεσιτεχνίας για μέθοδο που επιτρέπει την παραγωγή βιολογικού υλικού, το οποίο, ως εκ της εφευρέσεως, διαθέτει συγκεκριμένες ιδιότητες, εκτείνεται στο βιολογικό υλικό που προκύπτει άμεσα από την εν λόγω μέθοδο καθώς και σε οποιοδήποτε άλλο βιολογικό υλικό προκύπτει με αναπαραγωγή ή πολλαπλασιασμό από το βιολογικό υλικό που έχει προκύψει άμεσα υπό την αυτή ή διαφορετική μορφή και το οποίο διαθέτει τις ίδιες με αυτό ιδιότητες.

(γ) Η προστασία που παρέχει το δίπλωμα ευρεσιτεχνίας σε ένα προϊόν, το οποίο περιέχει ή αποτελείται από γενετικές πληροφορίες, εκτείνεται σε κάθε ύλη, με την επιφύλαξη του εδαφίου (3) του άρθρου 5Α, στην οποία ενσωματώνεται το προϊόν και στην οποία περιέχονται και ασκούν τις λειτουργίες τους οι σχετικές γενετικές πληροφορίες.

(2) Η ως άνω προστασία δεν εκτείνεται στο βιολογικό υλικό, το οποίο προκύπτει διά αναπαραγωγής ή πολλαπλασιασμού βιολογικού υλικού διατιθεμένου στην αγορά στο έδαφος της Κύπρου ή στην αγορά ενός Κράτους Μέλους της Ευρωπαϊκής Ενώσεως, από τον ίδιο τον ιδιοκτήτη του διπλώματος ευρεσιτεχνίας ή με τη συγκατάθεσή του, εφόσον η εν λόγω αναπαραγωγή ή πολλαπλασιασμός απορρέει κατ' ανάγκη από τη χρήση για την οποία διατέθηκε το βιολογικό υλικό στην αγορά, εφόσον το παραχθέν υλικό δε χρησιμοποιείται στη συνέχεια για άλλες αναπαραγωγές ή πολλαπλασιασμούς.

(3) Κατά παρέκκλιση από το εδάφιο (1)—

(α) Η πώληση ή άλλη μορφή εμπορίας φυτικού υλικού αναπαραγωγής από τον ιδιοκτήτη του διπλώματος ευρεσιτεχνίας, ή με τη συγκατάθεσή του, σε γεωργό, με σκοπό τη γεωργική εκμετάλλευση, συνεπάγεται ότι ο γεωργός έχει την άδεια να χρησιμοποιεί το προϊόν της συγκομιδής του για αναπαραγωγή ή πολλαπλασιασμό από αυτόν τον ίδιο στη δική του γεωργική εκμετάλλευση, η δε έκταση και οι προϋποθέσεις της παρεκκλίσεως αυτής περιέχονται στο Παράρτημα.

(β) Η πώληση ή άλλη μορφή εμπορίας ζώων εκτροφής ή άλλου ζωικού υλικού αναπαραγωγής από τον ιδιοκτήτη του διπλώματος ευρεσιτεχνίας ή με την συγκατάθεσή του σε γεωργό, συνεπάγεται ότι ο τελευταίος έχει την άδεια να χρησιμοποιήσει τα προστατευόμενα ζώα για γεωργική χρήση. Η άδεια αυτή περιλαμβάνει την διάθεση του ζώου ή άλλου ζωικού υλικού αναπαραγωγής για την άσκηση της γεωργικής του δραστηριότητας, αλλά όχι την πώληση στα πλαίσια εμπορικής δραστηριότητας αναπαραγωγής ή για το σκοπό αυτό.

Αναγκαστική άδεια για την εκμετάλλευση βιοτεχνολογικής εφεύρεσης

49Α.—(1) Αν ένας δημιουργός φυτικής ποικιλίας δε δύναται να αποκτήσει ή να εκμεταλλευθεί δικαίωμα παραγωγής φυτικής ποικιλίας χωρίς να προσβάλει προγενέστερο δίπλωμα ευρεσιτεχνίας, δύναται να ζητήσει υποχρεωτική άδεια για τη μη αποκλειστική εκμετάλλευση της προστατευόμενης με το εν λόγω δίπλωμα εφευρέσεως, εφόσον η άδεια αυτή είναι απαραίτητη για την εκμετάλλευση της προστατευόμενης φυτικής ύλης, έναντι καταβολής λογικής αμοιβής. Όταν χορηγείται τέτοια άδεια, ο ιδιοκτήτης του διπλώματος ευρεσιτεχνίας δικαιούται αμοιβαία άδεια, υπό λογικούς όρους, προκειμένου να χρησιμοποιήσει την προστατευόμενη ποικιλία.

(2) Αν ο κάτοχος διπλώματος ευρεσιτεχνίας που αφορά βιοτεχνολογική εφεύρεση δε δύναται να την εκμεταλλευθεί χωρίς να προσβάλει προγενέστερο δικαίωμα παραγωγής φυτικής ποικιλίας, δύναται να ζητήσει υποχρεωτική άδεια για τη μη αποκλειστική εκμετάλλευση της προστατευόμενης από αυτό το δικαίωμα παραγωγής φυτικής ποικιλίας, έναντι καταβολής λογικής αμοιβής. Όταν χορηγείται τέτοια άδεια, ο κάτοχος του δικαιώματος παραγωγής φυτικής ποικιλίας δικαιούται αμοιβαία άδεια, υπό λογικούς όρους, προκειμένου να χρησιμοποιήσει την προστατευόμενη εφεύρεση.

(3) Ο αιτητής άδειας σύμφωνα με τα εδάφια (1) και (2) πρέπει να αποδεικνύει ότι—

(α) Έχει απευθυνθεί ματαίως στον κάτοχο του διπλώματος ευρεσιτεχνίας ή το δικαιούχο δικαιώματος παραγωγής φυτικής ποικιλίας για να λάβει συμβατική άδεια,

(β) η ποικιλία ή η εφεύρεση συνιστά αξιόλογη τεχνική πρόοδο σημαντικού οικονομικού ενδιαφέροντος, σε σύγκριση με την εφεύρεση που διεκδικείται στο δίπλωμα ευρεσιτεχνίας ή την προστατευόμενη φυτική ποικιλία.

[…]

CZECH REPUBLIC

Sections 7, 8 and 9 of the Act No. 206/2000 Coll., of June 21, 2000, on the Protection of Biotechnological Inventions

7. Exhaustion of rights

The patent holder is not entitled to prohibit the propagation or multiplication of biological material being subject of the patent, if it has been placed on the market by himself or with his consent, and if the propagation or multiplication necessarily results from the application for which the biological material has been marketed, provided that the obtained material is not subsequently used for other propagation or multiplication.

8. Limitation of rights of patent holder

(1) The person, who has obtained the plant propagating material being subject of the patent from its holder or with his consent, is authorised to use for reproduction during his agricultural activity except commercial exploitation, also the product of his harvest.

(2) The person, who has obtained the animal reproductive material being subject of the patent from its holder or with his consent, is authorised to use this material during his agricultural activity except commercial exploitation; this includes making the animal or other animal reproductive material available.

9. Compulsory licence and compulsory cross-licence

(1) If a breeder cannot obtain or exploit a plant or animal 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. The Office will grant the compulsory licence, if the breeding certificate holder applied unsuccessfully to the holder of the patent to obtain a contractual licence and if the plant or animal variety constitutes significant technical progress of considerable economic interest compared with the invention, protected by the patent. In this case, the holder of the patent will be entitled to a cross-licence to commercial use of

protected variety on the same conditions, as applied for a compulsory licence according to a special legal regulation.

(2) If a compulsory licence to commercial use of protected plant or animal variety has been granted to the holder of the patent according to a special legal regulation, the breeding certificate holder will be entitled to a cross-licence to use the patent of invention.

DENMARK

Sections 3a, 3b and 46a of the Consolidate Patents Act (Consolidate Act № 90 of January 29, 2019)

3a.

[…]

(4) The protection referred to in subsections 1, 2 and 3 shall not extend to biological material obtained through multiplication or propagation of biological material placed on the market within the territory of an EU Member State by the proprietor of the patent or with his consent, if that 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 further multiplication or propagation.

[…]

3b. (1) Notwithstanding the provisions of section 3a(1) to (3), the sale or any other form of commercialisation of plant propagating material by the proprietor of the patent or with his consent to a farmer for agricultural use shall imply an authorisation for the farmer to use the product of his harvest for multiplication or propagation by him on his own farm, the extent and conditions thereof being laid down in Article 14 of Council Regulation (EC) No. 2100/94 on Community plant variety rights.

(2) Notwithstanding the provisions of section 3a(1) to (3), the sale or any other form of commercialisation of breeding stock or other animal reproductive material by the proprietor of the patent or with his consent to a farmer shall imply an authorisation for the farmer to use the animal or other animal reproductive material for the purposes of pursuing his own agricultural activity, but not to sell it within the framework or for the purpose of a commercial reproduction activity. The Minister of Industry, Business and Financial Affairs shall lay down provisions concerning the extent and the conditions of the farmer's exploitation of such breeding stock and animal reproductive materials for the purposes of pursuing his own agricultural activity.

[…]

46a. (1) A breeder who cannot acquire or exploit a plant variety right without infringing a prior patent may apply for a compulsory licence for the exploitation of the invention, provided that the compulsory licence is necessary for the exploitation of the plant variety to be protected, subject to the payment of an appropriate royalty. The compulsory licence shall only be granted if the breeder demonstrates that the variety constitutes significant technical progress of considerable economic importance compared with the invention.

(2) If under the Plant Variety Protection Act a proprietor of a patent has obtained a compulsory licence to exploit a protected plant variety, the breeder shall be entitled on reasonable terms to obtain a cross-licence for the exploitation of the invention.

DOMINICAN REPUBLIC

Article 30(f) of the Law № 20-00 of May 8, 2000, on Industrial Property

30. Limitation and exhaustion of patent rights.

A patent shall not confer the right to prevent:

[…]

(f) 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;

[…]

ECUADOR

The Decision № 486 of September 14, 2000 of the Commission of the Andean Community applies (Refer to the provision below)

ESTONIA

Sections 16 7) and 47 of the Patents Act (consolidated text of August 31, 2023)

§ 16. Acts which do not constitute infringement of exclusive right of proprietor of patent.

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.

§ 47. Compulsory licence

(1) A person who is interested in using a patented invention and is capable of doing so in the Republic of Estonia, may, upon refusal of the proprietor of the patent to grant a licence, file an action with a court for acquiring a compulsory licence if:

[…]

5) the patent hinders the grant of plant variety rights pursuant to the Plant Propagation and Plant Variety Rights Act or the use of the protected variety.

[…]

FINLAND

Sections 3a, 3b and 46a of the Patent Act (Act № 550/1967 of December 15, 1967, as amended up to Act № 717/2016 of August 25, 2016)

Section 3a

[…]

The protection referred to above shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market in the territory of the European Economic Area 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.

Section 3b

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 propragation 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.

More specific regulations concerning the contents and implementation of the derogation provided for in subsection 2 may be decreed by the Government where necessary.

Section 46a Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. 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.

Applicants for the licence referred to in subsection 1 above must demonstrate that they have applied unsuccessfully to the holder of the patent to obtain a contractual licence and that the plant variety constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent.

Provisions concerning the right of a patent holder to obtain a compulsory licence for the exploitation of a plant variety protected by plant breeder's right are laid down by the Act on Plant Breeders' Rights.

FRANCE

Articles L613-2-4, L613-5-1, L613-5-2, L613-5-3 and L613-15-1 of the Intellectual Property Code (consolidated version as of March 13, 2025)

Article L613-2-4

The protection referred to under Articles L613-2-2 and L613-2-3 shall not extend to the biological material obtained from the propagation or multiplication of biological material marketed in the territory of a Member State of the European Union or a State party to the Agreement on the European Economic Area by the holder of the patent, or with his consent, where the propagation or the 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 or multiplication.

Article L613-5-1

By way of derogation from the provisions of Articles L613-2-2 and L613-2-3, the sale or any other form of commercialisation of a plant propagating material to a farmer by the holder of the patent, or with his consent, for agricultural use shall imply authorisation for the farmer to use the product of his harvest for the propagation or multiplication by him on his own farm.

The conditions of this use shall be those provided for by Article 14 of Regulation (EC) No. 2100/94 of the Council of 27 July 1994 of 27 July 1994 on Community plant variety rights.

Article L613-5-2

By way of derogation from the provisions of Articles L613-2-2 and L613-2-3, 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. This authorization shall include making the animal or other animal reproduction available for the purposes of pursuing his agricultural activity but not for sale within the framework of a commercial reproduction activity.

Article L613-5-3

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.

Article L613-15-1

Where a breeder cannot acquire or exploit a plant variety right without infringing a prior right, he may request the licence of this patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected and in so far as the variety constitutes with regard to the invention asserted in this patent an important technical progress and is of considerable economic interest.

Where such a licence is granted, on application brought before the Court, the holder of the patent will be entitled, under equitable conditions, to a cross-licence to use the protected variety.

The provisions of Articles L613-12 to L613-14 shall apply.

GERMANY

Sections 9b and 9c, Section 11, paragraph 2a, and Section 24 of the Patent Act (as amended up to Act of August 30, 2021)

Section 9b

If the proprietor of a patent or a third party having the consent of the proprietor of the patent puts into circulation, in the territory of a Member State of the European Union or in a Contracting Party of the Agreement on the European Economic Area, biological material which possesses specific characteristics as a result of the invention and if further biological material is obtained from this biological material through propagation or multiplication, the effects of section 9 have no effect where the propagation or multiplication of the biological material was the purpose for which it was put into circulation. This does not apply where the material obtained in this way is subsequently used for further propagation or multiplication.

Section 9c

(1) Where plant propagating material is marketed by the proprietor of a patent or by a third party with the consent of the proprietor of the patent to a farmer for agricultural use, the latter is, contrary to sections 9, 9a and 9b sentence 2, entitled to use the product of his or her harvest for propagation or multiplication on his or her own holding. Article 14 of Council Regulation (EC) No 2100/94, as amended, and the implementing rules adopted on that basis apply to the conditions and extent of this entitlement. Where claims arise therefrom for the proprietor of the patent, these claims are to be asserted pursuant to the implementing rules adopted on the basis of Article 14 (3) of Council Regulation (EC) No 2100/94.

(2) Where livestock or animal reproductive material is marketed to a farmer by the proprietor of the patent or by a third party having the consent of the proprietor of a patent, the farmer is, contrary to sections 9, 9a and 9b sentence 2, entitled to use the livestock or the animal reproductive material for agricultural purposes. This entitlement also includes making the livestock or other animal reproductive material available for the purposes of pursuing the farmer's agricultural activity, but not the sale for the purpose or within the framework of a commercial reproduction activity.

(3) Section 9a (1) to (3) does not apply to biological material obtained during agricultural activity by chance or in such manner as to be technically unavoidable. As a rule, a claim cannot therefore be brought on this ground against a farmer if the farmer used seeds or plants which are not subject to such patent protection.

[…]

Section 11

The effect of a patent does not extend to

[…]

2a. the use of biological material for the purpose of breeding, discovering and developing a new plant variety;

[…]

Section 24

(1) The non-exclusive authorisation to commercially use an invention is granted by the Federal Patent Court in an individual case in accordance with the following provisions (compulsory licence) if

1. a licence seeker has, within a reasonable period of time, unsuccessfully attempted to obtain permission from the proprietor of the patent to use the invention on reasonable commercial terms and conditions, and

[...]

(2) Where a licence seeker cannot exploit an invention for which he or she holds protection under a patent with a later filing or priority date without infringing a patent with an earlier filing or priority date, the licence seeker is entitled, in respect of the proprietor of the patent with the earlier filing or priority date, to the grant of a compulsory licence from the proprietor of the patent if

1. the condition under subsection (1) no. 1 is fulfilled, and

2. his or her own invention demonstrates an important technological advance of substantial economic significance compared to that of the patent with the earlier filing or priority date.

The proprietor of the patent can require the licence seeker to grant him or her a cross-licence on reasonable terms and conditions for the use of the patented invention with the later filing or priority date.

(3) Subsection (2) applies accordingly where a plant breeder cannot obtain or exploit a plant variety right without infringing an earlier patent.

[...]

GREECE

Articles 8, 9 and 10 of the Presidential Decree 321/2001

Article 8

The protection referred to in Articles 6 and 7 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 propagation or 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 or multiplication.

Article 9

1. By way of derogation from Articles 6 and 7, 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 6 and 7, 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.

[…]

COMPULSORY LICENSES DUE TO INTERDEPENDENCE

Article 10

1. Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty.

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. 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.

4. The authority responsible for granting the licence referred to in paragraphs 1 and 2 is the Court specified in Article 13, par. 10 of L. 1733/1987. Provisions in Article 13 of L. 1733/1987, shall apply correspondingly. Where a licence for a plant variety can be granted only by the Community Plant Variety Office, Article 29 of Regulation (EC) No. 2100/94.

HUNGARY

Articles 20/A and 32 of the Act XXXIII of 1995 on the Protection of Inventions by Patents (consolidated version as up to September 1, 2024)

Article 20/A

[…]

(4) The exclusive right of exploitation conferred by patent protection referred to in paragraphs (1) to (3) shall not extend to biological material obtained from the propagation or multiplication of biological material put on the market in the territory of the European Economic Area by the patentee or with his express consent, where the propagation or 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 or multiplication.

(5) By way of derogation from paragraphs (1) to (3), the sale or other form of commercialisation of plant propagating material to a farmer by the patentee or with his express consent implies authorisation for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm.

(6) The extent and conditions of derogation to which the farmer is entitled under paragraph (5) shall be governed by the provisions laid down in Article 14 of Council Regulation (EC) No 2100/94 on Community plant variety rights.

(7) By way of derogation from paragraphs (1) to (3), the sale or other form of commercialisation of breeding stock or other animal reproductive material to a farmer by the patentee or with his express consent implies authorisation for the farmer to use the patented livestock for agricultural purpose. This includes the use of the animal or other animal reproductive material for the purposes of pursuing his activity but it shall not extend to sale within the framework or for the purpose of a commercial reproduction activity. The extent and conditions of derogation to which the farmer is entitled shall be governed by the provisions of specific legislation.

Article 32

(1) If the patented invention cannot be exploited without infringing another patent (hereinafter referred to as “the dominant patent”), a compulsory license shall be granted, on request and to the extent necessary for the exploitation of the dominant patent, to the holder of the dependent patent, provided that the invention claimed in the dependent patent involves an important technical advance of considerable economic significance in relation to the invention claimed in the dominant patent.

(2) Where a compulsory license has been granted under paragraph (1) with respect to a dominant patent, the holder of such a patent shall be entitled on reasonable terms to a license to exploit the invention claimed in the dependent patent according to the common provisions on compulsory licenses.

(3) The provisions of Article 33(1) and (2) shall also apply *mutatis mutandis* if the subject matter of a plant variety protection provided for in Chapter XIII cannot be exploited without infringing a patent.

ICELAND

Articles 3a, 3b and 46a of the Patents Act № 17/1991 (as amended up to Act № 1460/2021)

Article 3 a

[…]

A patent as referred to in Paragraph 1-3 does not, however, extend to biological material obtained by propagation or multiplication of biological material marketed in the European Economic Area, in a member state of the incorporation of the European Free Trade Association or in the Faroe Islands by patent holders or with their consent if the propagation or multiplication is a necessary factor in the use for which the biological material was marketed, provided that the material obtained will not be used for further propagation or multiplication.

Article 3 b

Notwithstanding the provisions of Paragraph 1-3 of Article 3 a, sales to and other commercial exchanges with farmers, on the part of the patent holder or by her/his consent, of plant propagating material for agricultural use may be regarded as approval of the farmers' using their harvest themselves for propagation and multiplication on their own land. The scope and conditions for this exemption shall be in accordance with provisions of the Act on Plant Variety Rights, No. 58/2000, as subsequently amended, and with regulations based on that Act.

Notwithstanding the provisions of Paragraph 1-3 of Article 3 a, sales to and other commercial exchanges with farmers, on the part of the patent holder or by her/his consent, of breeding livestock or other animal reproductive material may be regarded as approval of the farmers' being authorised to use the protected livestock in agriculture. This includes, among other things, farmers being allowed to use animals and other materials for reproducing animals in their agricultural operations but not being allowed to sell the animals or the materials as a factor in reproduction activity for commercial reasons or with such an aim. The Minister shall issue a set of regulations on the scope and conditions for farmers' utilising such discoveries protected by patents.

Article 46 a

A holder of a plant variety who can neither acquire nor exploit a plant variety right without infringing a prior patent may request a compulsory licence for a reasonable payment to exploit the invention if the licence is necessary to exploit the variety to be protected. A compulsory licence shall be granted only if the plant variety holder demonstrates that the variety involves technically important progress and leads to considerable financial benefit in comparison to the invention in the patent.

If a patent holder has obtained a compulsory licence on the basis of the Act on Plant Variety Rights, No. 58/2000, to exploit a protected plant variety, the holder of the plant variety is entitled to a compulsory cross-licence on reasonable terms to exploit the invention.

IRELAND

Regulations 9, 10, 11, 12 and 13 of the European Communities (Legal Protection of Biotechnological Inventions) Regulations, 2000

9. The protection referred to in Regulations 7 and 8 shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market in the State by the proprietor of the patent or with the consent of the proprietor, where the propagation or multiplication necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for propagation or multiplication.

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.

11. (1) Where a holder cannot acquire or exploit in the State a plant breeders' right granted by the Controller of Plant Breeders' Rights without infringing a prior patent for a biotechnological invention, and where the holder has applied unsuccessfully to the proprietor of the patent concerned for a contractual licence under the patent, the holder may apply to the Controller for a licence under the patent to the extent necessary for the exploitation of the plant breeders' right concerned:

Provided that the plant variety protected by the plant breeders' right involves an important technical advance of considerable economic significance in relation to the invention claimed in the patent.

(2) When granting a licence on an application under paragraph (1) the Controller shall ensure that the licence is subject to the payment of an appropriate royalty to the proprietor of the patent.

(3) The Controller shall not grant a licence referred to in paragraph (1) unless the holder is able and willing to grant the proprietor of the patent a cross-licence, on reasonable terms, to use the variety protected by the plant breeders' right.

(4) Part IV of the Act of 1992 shall apply with any necessary modifications to applications for licences and licences under this Regulation.

12. (1) Where the proprietor of a patent for a biotechnological invention cannot exploit it in the State without infringing a prior plant breeders' right, and where the proprietor has applied unsuccessfully to

the holder of the plant breeders' right concerned for a contractual licence under the plant breeders' right, the proprietor of the patent may apply to the Controller of Plant Breeders' Rights for a licence under the plant breeders' right to the extent necessary for the exploitation of the patent concerned:

Provided that the patent involves an important technical advance of considerable economic significance in relation to the plant variety protected by the plant breeders' right.

(2) When granting a licence on an application under paragraph (1) the Controller of Plant Breeders' Rights shall ensure that the licence is subject to the payment of an appropriate royalty to the holder of the plant breeders' right.

(3) The Controller of Plant Breeders' Rights shall not grant a licence referred to in paragraph (1) unless the proprietor of the patent is able and willing to grant the holder of the plant breeders' right a cross-licence, on reasonable terms, to use the invention claimed in the patent.

(4) The provisions of section 8 of the Act of 1980 (as amended by section 9 of the Act of 1998) shall apply with any necessary modifications to applications for licences and licences under this Regulation.

13. (1) Where the proprietor of a patent for a biotechnological invention which cannot be exploited in the State without infringing a Community plant variety right has been granted a compulsory exploitation right by the Community Plant Variety Office under Article 29 of the Council Regulation, the holder of the Community plant variety right may apply to the Controller for a cross-licence to use the invention claimed in the patent.

(2) Where an application is made under paragraph (1), the Controller may grant the holder of the Community plant variety right a cross-licence, on reasonable terms, to use the invention claimed in the patent concerned.

(3) Part IV of the Act of 1992 shall apply with any necessary modifications to an application for a cross-licence under this Regulation.

ITALY

Article 68, paragraph 1, letter a-bis, Articles 81-septies and 81-octies, and Article 170-bis, paragraph 5, of the Industrial Property Code, Legislative Decree No. 30 of February 10, 2005 (as amended up to Law No. 102 of July 24, 2023)

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;

[…]

Art. 81-septies (Limitations to the extent of protection)

1. The protection referred to in article 81-sexies does not extend to biological material obtained through reproduction or multiplication of biological material marketed in the territory of the State by the patent holder or with his consent, if the reproduction or multiplication necessarily derives from the use for which the biological material was marketed, provided that the material obtained is not subsequently used for other reproductions or multiplications.

Art. 81-octies (compulsory license)

1. The Italian Patent and Trademark Office also issues a compulsory license to:

a) of the breeder, for the non-exclusive exploitation of the invention protected by the patent, if this license is necessary for the exploitation of a plant variety;

b) of the owner of a patent concerning a biotechnological invention for the use of the patent on a plant variety.

2. The issuing of the license referred to in paragraph 1 takes place according to the procedures and conditions referred to in articles 71 and 72, insofar as they are compatible.

3. In case of granting of the compulsory license, the owner of the patent and the owner of the plant variety right are mutually entitled to a license according to conditions which, in the absence of agreement between the parties, are determined by the Italian Patent and Trademark Office .

4. The issuing of the license referred to in paragraph 1 is subject to demonstration by the applicant:

a) who has turned in vain to the owner of the patent or plant variety right to obtain a contractual licence;

b) that the plant variety or invention constitutes a significant technical progress, of considerable economic interest compared to the invention indicated in the patent or the protected plant variety.

Art. 170-bis (Duties regarding biotechnological inventions)

[…]

5. With regard to biotechnological inventions, the use by the farmer, for the reproduction or multiplication on his own in his company, of patented material of plant origin, takes place in compliance with the provisions of Article 14 of Regulation (EC) n. 2100/94 of the Council, of 27 July 1994.

[…]

LATVIA

Sections 19, 20, 21 and 54 of the Patent Law (as amended up to May 22, 2024*)*

19. Scope of the Exclusive Rights Resulting from Biotechnological Inventions

[…]

(4) If the owner of the patent or somebody else with his or her consent sells or markets otherwise a plant multiplication material to a farmer for agricultural purposes implying also a permission for the farmer to use the produced products for multiplication in the holding thereof, Paragraphs one, two and three of this Section shall not be applied to such a scope and on such conditions which conform with what is specified in Article 14 of Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights or Section 24 of the Plant Varieties Protection Law.

(5) Paragraphs one, two and three of this Section shall not be applied if the owner of the patent or somebody else with his or her consent sells or markets otherwise breeding animals or reproductive material of the animals to a farmer implying also a permission for the farmer to use the domestic animals protected by the patent for agricultural purposes. This permission shall include the offering of an animal or other reproductive material of animals for the performance of agricultural activities but not selling for commercial multiplication or to the purposes thereof.

20. Limitations of the Exclusive Rights Resulting from a Patent

The exclusive rights resulting from a patent shall not be implemented in relation to:

[…]

6) the use of biological material in selection or the discovery and creation of other plant varieties;

[…]

21. Exhaustion of the Rights

[…]

(2) The protection, referred to in Section 19, Paragraphs one, two and three of this Law, shall not apply to the biological material obtained by multiplying such biological material which has been included in the economic circulation in the European Economic Area by the owner of the patent himself or herself or by another person with his or her consent if the multiplication arises directly from the use thereof for the purposes of which the biological material was sold provided that the obtained material shall not be used afterwards for another multiplication.

Section 54. Compulsory Licence

[…]

(2) If the owner of the patent of a biotechnological invention is not able to use it without violating the prior right to a plant variety, he or she may apply for a compulsory licence for the use of such a plant variety which is protected by the referred to right, and pay a compensation determined by the court to the owner. In the case of a grant of such a licence, the owner of the plant variety is entitled to qualify for a cross-licence with justified conditions for the use of the protected invention.

[…]

(9) The holder of a compulsory licence shall pay to the owner of the patenta compensation, the amount of which shall be determined by the court, observing the economic value of the licence, the scope of use of an invention and other circumstances.

LIBERIA

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

§13.11. Rights Conferred by the Patent; Limitations and Exceptions.

[…]

b) The rights under a patent may not be used to prevent:

[…]

vii. the use by a farmer of the product of his harvest for propagation or multiplication by him on his own holding or for exchange with other farmers in the context of traditional or communal practices, where the plant material used by the farmer to produce the harvest was put on the market in accordance with subsection (b) (i) of this Section;

[…]

LITHUANIA

*Articles 35, 39 and 48 of the Patent Law № I-372 of January 18, 1994 (*consolidated version as in force on September 1, 2022*)*

35. Patent proprietor's rights

[…]

5. The sale or other form of commercialisation of plant propagating material to a farmer by the patent proprietor or with his consent for agricultural use shall imply 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 shall be laid down by Article 14 of Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights.

6. The sale or any other form of commercialisation of breeding stock or other animal reproductive material to a farmer by the patent proprietor or with his consent shall imply authorisation for the farmer to use the protected livestock for an agricultural purpose. This shall include 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.

7. The extent and the conditions of application of the derogation provided for in paragraph 6 of this Article may be determined by law.

[…]

Article 39. Scope of legal protection of biotechnological inventions

[…]

4. The legal protection referred to in paragraphs 1, 2 and 3 of this Article shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market of the European Economic Area by or with consent the proprietor of the patent, 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.

Article 48. Compulsory cross-licence when an invention is related to the protected plant variety

1. Where a breeder cannot acquire or exploit a plant variety right without infringing the exclusive rights protected by a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Where such a licence is granted, the patent proprietor will be entitled to a cross-licence on reasonable terms to use the protected variety.

2. Where the proprietor 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. Where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to exploit the protected invention.

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

1) they have applied unsuccessfully to the proprietor of the patent of a biological invention or the holder of the plant variety right to obtain a contractual licence;

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

4. The court shall make a decision regarding the granting of licences referred to in paragraphs 1 and 2 of this Article, the amount of royalty and other conditions and extent of a compulsory licence. If the conditions of grating of a compulsory licence change or disappear, at the request of the proprietor of the patent of a biological invention or the holder of the plant variety right, the court may revoke a compulsory licence or change its conditions.

5. Offices keeping a list of protectable plant varieties and the Patent Register of the Republic of Lithuania shall be responsible for the registration, in the manner prescribed by legal acts, of the licences referred to paragraphs 1 and 2 of this Article.

6. Where a licence for a plant variety can be granted only by the Community Plant Variety Office, Article 29 of Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights shall apply.

LUXEMBOURG

Articles 47quater and 47quinquies of the Law of April 7, 2006, on Amendments to the Amended Law of July 20, 1992, on the Changes in the System for Patents for Invention

Art. 47quater. La protection visée aux articles 47bis et 47ter ne s'étend pas à la matière biologique obtenue par reproduction ou multiplication d'une matière biologique mise sur le marché sur le territoire d'un Etat membre de l'Union européenne par le titulaire du brevet ou avec son consentement, lorsque la reproduction ou la multiplication résulte nécessairement de l'utilisation pour laquelle la matière biologique a été mise sur le marché, pourvu que la matière obtenue ne soit pas utilisée ensuite pour d'autres reproductions ou multiplications.

Art. 47quinquies. 1. Par dérogation aux articles 47bis et 47ter, la vente ou une autre forme de commercialisation de matériel de reproduction végétal par le titulaire du brevet ou avec son consentement à un agriculteur à des fins d'exploitation agricole implique pour celui-ci l'autorisation d'utiliser le produit de sa récolte pour reproduction ou multiplication par lui-même sur sa propre exploitation, l'étendue et les modalités de cette dérogation correspondant à celles prévues à l'article 14 du règlement (CE) N° 2100/94 du Conseil du 27 juillet 1994 instituant un régime de protection communautaire des obtentions végétales.

2. Par dérogation aux articles 47bis et 47ter, la vente ou une autre forme de commercialisation d'animaux d'élevage ou autre matériel de reproduction animal par le titulaire du brevet ou avec son consentement à un agriculteur implique pour celui-ci l'autorisation d'utiliser le bétail protégé à un usage agricole. Ceci inclut la mise à disposition de l'animal ou autre matériel de reproduction animal pour la poursuite de son activité agricole, mais non la vente dans le cadre ou le but d'une activité de reproduction commerciale.

3. Lorsqu'un obtenteur ne peut obtenir ou exploiter un droit d'obtention végétale sans porter atteinte à un brevet antérieur, il peut demander une licence obligatoire pour l'exploitation non exclusive de l'invention protégée par ce brevet, dans la mesure où cette licence est nécessaire pour l'exploitation de la variété végétale à protéger, moyennant une redevance appropriée. Lorsqu'une telle licence est accordée, le titulaire du brevet a droit à une licence réciproque à des conditions raisonnables pour utiliser la variété protégée.

MALTA

Articles 27 and 39 of the Patents and Designs Act (chapter 417) of June 01, 2002 (as amended up to Act XXXV of 2023)

27. Rights conferred by a patent.

[…]

(7) Notwithstanding the provisions of subarticles (3), (4) and (5):

(a) the sale or other form of commercialization of plant propagation material to a farmer by the holder of the patent or with his consent for agricultural use implies authorization for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm;

(b) the sale of any other form of commercialization of breeding stock or other animal reproductive material to a farmer by the holder of the patent or with his consent implies authorization for the farmer to use the protected livestock for an agricultural purpose. Such use includes making the animal or other animal reproductive material available for the purposes of pursuing his agricultural activity. Such use does not include the sale within the framework of or for the purpose of a commercial reproduction activity.

[…]

(9)

[…]

(b) The protection referred to in subarticles (3), (4) and (5) shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market by the holder of a 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.

(c) For the purposes of this subarticle "market" means the market in Malta and from 1st May, 2004, the European Union

39.

[…]

(9) Where a breeder cannot acquire plant variety protection or exploit a plant variety without infringing a prior patent, he may apply to the Civil Court, First Hall, for a compulsory licence for non-exclusive use of the invention protected by the patent in so far as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. 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:

Provided that an applicant for a licence referred to in above shall demonstrate that:

(a) he had applied unsuccessfully to the holder of the prior patent to obtain a contractual licence;

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

[…]

(11) With regard to plant variety protection subarticles (9) and (10) shall only come into force when the relevant form of plant variety protection comes into force as provided in article 4(5)(e).

MEXICO

Article 57 of the Federal Law on the Protection of Industrial Property

57. El derecho que confiere una patente no producirá efecto alguno contra:

[…]

VI.- Un tercero que, en el caso de patentes relacionadas con materia viva, utilice la invención patentada como fuente inicial de variación o propagación para obtener otros productos, salvo que dicha utilización se realice en forma reiterada;

VII.- 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;

[…]

La realización de cualquier actividad contemplada en el presente artículo no constituirá infracción administrativa o delito en los términos de esta Ley.

MONTENEGRO

Articles 51, 77 and 78 of the Law on Patents (Official Gazette of Montenegro, No. 42/2015, 2/2017, 146/2021 and 3/2023)

51. Exceptions from Protection

The protection referred to in Article 50 of this Law shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market by the holder of the patent or with his consent, where the propagation or multiplication necessarily results from the application for which the biological material has been marketed, provided that the material obtained is not subsequently used for other propagation or multiplication.

77. Compulsory Licence Granted to Plant Breeders

(1) Where a plant breeder cannot obtain or exploit a right of protection of plant variety without infringing a prior patent concerning a biotechnological invention, he may file a request with the authority referred to in Article 57 paragraph 1 of this Law for a non-exclusive compulsory licence for the use of the invention protected by the patent insofar as the licence is necessary for the exploitation of the protected plant variety.

(2) If such a compulsory licence referred to in paragraph 1 above is granted, the holder of the patent shall be entitled to a compulsory cross-licence to use the protected plant variety on reasonable terms.

(3) Where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior right of protection of plant variety, he may file a request with the authority under

paragraph 1 above for a non-exclusive compulsory licence for the use of the plant variety protected by that right.

(4) If such a compulsory licence under paragraph 3 above is granted, the holder of the plant variety right shall be entitled to a compulsory cross-licence to use the protected biotechnological invention under reasonable terms.

[…]

78. Limitation of Rights Concerning Biotechnological Material

(1) 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 further propagation or multiplication by him on his own farm, under conditions prescribed by the law on the protection of plant varieties, whereas products obtained thereby may not be used for commercial purposes.

(2) The sale or 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 make 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 commercial reproduction of animals or reproduction materials.

NETHERLANDS (KINGDOM OF THE)

Articles 54c and 57 of the National Patent Act 1995 (Kingdom Act of December 15, 1994, status as of June 1, 2023)

Artikel 54c

De uit een octrooi voortvloeiende rechten zijn niet van toepassing op:

[…]

c. het gebruik van biologisch materiaal voor het kweken, of ontdekken en ontwikkelen van andere plantenrassen;

[…]

i. het gebruik door een landbouwer van de producten van zijn oogst voor de propagatie of vermeerdering door hemzelf op zijn eigen bedrijf, indien het plantaardig propagatiemateriaal door de octrooihouder of met zijn toestemming voor gebruik in de landbouw aan de landbouwer is verkocht of anderszins verhandeld. De reikwijdte en de voorwaarden vo or dit gebruik zijn bepaald in artikel 14 van Verordening (EG) nr. 2100/94 van de Raad van 27 juli 1994 inzake het communautaire kwekersrecht (PbEG 1994, L 227);

j. het gebruik voor agrarische doeleinden, door een landbouwer, van vee dat onder octrooibescherming valt, indien het fokvee of ander dierlijk propagatiemateriaal door de octrooihouder of met zijn toestemming aan de landbouwer is verkocht of anderszins verhandeld. Dit gebruik omvat het beschikbaar

stellen van het dier of ander dierlijk propagatiemateriaal voor zijn eigen gebruik in de landbouw, maar niet de verkoop in het kader van of met het oog op de commerciële fokkerij;

[…]

l. biologisch materiaal dat wordt gewonnen door propagatie of door vermeerdering van biologisch materiaal dat door de octrooihouder of met diens toestemming in Nederland, Curaçao of Sint Maarten, in een lidstaat van de Europese Unie, of in een andere staat die partij is bij de Overeenkomst betreffende de Europese Economische Ruimte in het verkeer is gebracht, indien de propagatie of de vermeerdering noodzakelijkerwijs voortvloeit uit het gebruik waarvoor het biologisch materiaal in het verkeer is gebracht, mits het afgeleide materiaal vervolgens niet voor andere propagaties of vermeerderingen wordt gebruikt.

Artikel 57

[…]

5. De octrooihouder verleent aan een kweker een licentie tegen een redelijke vergoeding, indien de kweker een kwekersrecht op een plantenras niet kan verkrijgen of exploiteren zonder inbreuk te maken op het octrooi van eerdere datum en de licentie noodzakelijk is voor de exploitatie van het te beschermen plantenras, dat een belangrijke technische vooruitgang van aanzienlijk economisch belang vertegenwoordigt ten opzichte van de door het octrooi beschermde uitvinding.

6. Indien aan een octrooihouder een licentie is verleend op grond van artikel 42, tweede lid, van de Zaaizaad- en Plantgoedwet, verleent de octrooihouder aan de houder van het kwekersrecht op diens verzoek onder redelijke voorwaarden een wederkerige licentie om de beschermde uitvinding te gebruiken.

NICARAGUA

Articles 46 and 47 of the Law No. 354 on Patents, Utility Models and Industrial Designs

46. *Limitation of Patent Rights*

A patent shall not confer the right to prohibit the following acts:

[…]

(c) where the patent protects biological material capable of being reproduced, the use of that material as a starting point for producing viable new biological material, except where the production of that material requires repeated use of the patented material;

(d) where the patent protects reproductive or vegetative propagating material, reproduction or propagation by a farmer of the product obtained from the protected material, and the marketing of that product for agricultural and livestock use or for human consumption, insofar as the product has been obtained on that farmer's own farm and the reproduction or propagation takes place also on that farm.

47. Exhaustion of Patent Rights

[…]

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.

NORTH MACEDONIA

Article 96 of the Law on Industrial Property adopted on January 12, 2009

96. Exemption from the infringement of patent right in the field of biotechnology

(1) The person using the plant material for reproduction, on the basis of the consent by the patent holder, shall not infringe the right referred to in Article 90 of this Law relating to the selling or other types of commercial exploitation of plant material for reproduction, if the product of their own harvest is used it for propagation and multiplication for their own needs and for the needs of their own property.

(2) The person that uses the cattle or other animal reproductive material, on the basis of the consent of the patent holder, shall not infringe the right referred to in Article 90 of this Law relating to the selling or other types of commercial exploitation, if the protected cattle is used for agricultural activities, including reproduction of animals and production of other animal reproductive material for the purposes of their agricultural activity, but not for commercial reproductive purposes.

NORWAY

Sections 3a, 3b and 46a of the Patents Act (Act № 9 of December 15, 1967, as amended up to March 1, 2023)

Section 3 a.

[…]

The protection referred to in paragraphs 1-3 shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market within the EEA 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.

Section 3 b. If plant-propagating material is sold or transferred, with the consent of the patent holder, to a farmer for agriculture use this shall imply authorization for the farmer to use the product of his harvest for propagation or multiplication on his own farm notwithstanding section 3 a paragraphs 1-3.

If breeding stock or other animal reproductive material is sold or transferred, with the consent of the patent holder, to a farmer, the farmer shall have the right to use the protected animal or the reproductive material for an agriculture purpose on his own farm notwithstanding section 3a paragraphs 1-3. The last sentence does not provide the right to sell the material referred to as a component of or for the purpose of commercial reproductive activity.

The King may, by regulation, determine the conditions and the extent of the farmer's rights according to this section.

Section 46 a. *Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may, subject to payment of an appropriate royalty, apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for exploitation of the plant variety to be protected. A compulsory licence will only be granted where the applicant can demonstrate that the plant variety constitutes significant technical progress of considerable financial interest in relation to the invention. If a patent holder has been granted a compulsory licence for the exploitation of a protected plant variety according to Act No 32, March 12, 1993 about Plant variety protection Section 28 second paragraph, the holder of the plant variety right is entitled to a compulsory licences of the patented invention on reasonable terms.*

OMAN

Section 11 of the Law on Industrial Property Rights (promulgated by the Royal Decree No. 67/2008)

(11) [..]

4. The rights under the patent shall not extend:

[…]

E) [..]

With respect of patents granted for plants and plant varieties, the rights under those patents shall not extend to:

[…]

c) acts done for the purpose of breeding other varieties, including essentially derived varieties;

F) subject to the safeguarding of the legitimate interests of the patent owner, any acts practiced by farmers to use for propagating purposes, the product of the harvest which they have obtained by planting the patented variety or an essentially derived variety.

POLAND

Articles 82 and 93[5] of the Act of June 30, 2000, on Industrial Property (as amended up to Act of March 9, 2023)

Article 82

1. Patent Office may grant authorisation to exploit a patented invention of another person (a compulsory license), where:

[…]

(iii) it has been established that the patent holder enjoying the right of priority of an earlier application (the earlier patent) prevents, by refusing to conclude a license contract, the meeting of home market demands through the exploitation of the patented invention (the dependent patent), whose exploitation would encroach upon the earlier patent; in such case the holder of the earlier patent may demand that an authorisation be given to him for the exploitation of the invention that is the subject matter of the dependent patent (cross-license).

2. The grant of a compulsory license for the exploitation of an invention in the case referred to in paragraph (1)(iii) shall be conditional upon ascertainment that the exploitation of the invention that is the subject matter of the dependent patent, where the both inventions concern the same subject matter, involves an important technical advance of considerable economic significance. […]

[…]

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 or demands a cross-license to be granted to him by the patent holder.

Article 93[5]

1. 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 by the holder of the patent or with his consent, where the propagation or multiplication necessarily results from the application of the biological material.

2. Any party who has acquired or otherwise obtained the patented biological material from the holder of a patent or with his consent for agricultural use shall be authorised to use it for propagation or multiplication on his own farm, the extent and conditions of this derogation being the same as provided for the use, without the plant breeder's consent, of plant propagating material of the plant variety protected under the provisions of the act of 26 June 2003 on the legal protection of plant varieties.

3. The provision of paragraph (2) shall apply accordingly to breeding stock or other animal reproductive material.

PORTUGAL

Articles 103 and 110 of the Industrial Property Code (approved by Decree-Law № 110/2018 of December 10, 2018 and amended by Decree-Law № 9/2021 of January 29, 2021)

103. Limitation of rights conferred by a patent

1. The rights conferred by a patent do not extend to:

[...]

d) Use of biological material for the purpose of growing or discovering and developing new varieties of plants;

[…]

h) A farmer's use of the product of his or her harvest for reproduction or multiplication purposes in his or her exploitation, as long as the reproduced plant material has been sold or commercialised in another way to the farmer for agricultural purposes by the owner or with his or her consent;

i) Use of protected animals by a farmer for agricultural purposes, as long as the livestock or other animal reproduction materials have been sold or commercialised in another manner to the farmer by the owner or with the latter's consent;

[...]

2. For the purposes stipulated in sub-paragraph i) of the previous number, the use mentioned therein shall include making available the animal or other animal reproduction material for the purposes of agricultural activity, but not the respective sale in view of a reproduction activity for commercial purposes or within the scope of said activity.

3. The protection mentioned in nos. 3 to 5 of article 98. does not cover biological material obtained via reproduction or multiplication of biological material commercialised by the owner or with his or her consent within the European economic area if the reproduction or multiplication necessarily results from the use for which the biological material was placed on the market, as long as the biological material obtained is not subsequently used for other reproductions or multiplications.

110. Dependent Licenses

[…]

4. When a breeder of a variety of plant is unable to obtain or exploit a right for plant breeding without violating a prior patent, he or she may request a compulsory license for nonexclusive exploitation of the invention that is protected by the patent, in so far as that license is necessary for exploiting the same variety of plant, in exchange for payment of appropriate remuneration.

5. Whenever a license of the type provided for in the previous number is granted, the owner shall be entitled to a reciprocal license, under reasonable conditions, in order to use that protected variety.

6. When the owner of a biotechnological invention cannot exploit it without violating a previous plant breeding right pertaining to a variety of plant, he or she may request a compulsory license for non-exclusive exploitation of the variety protected by that breeding right in exchange for suitable payment.

7. Whenever a license of the type stipulated in the previous number is granted, the owner or the breeding right shall be entitled to a reciprocal license with reasonable conditions in order to use the protected invention.

8. The applicants of the licenses mentioned in nos. 4 and 6 shall prove the following:

a) That they have been unsuccessful in their approach of the owner or owner of the plant breeding right in view of obtaining a contractual license;

b) The plant variety or invention represents important technical progress that is of considerable economic interest, with respect to the invention claimed in the patent or the variety of plant that is to be protected.

[…]

PERU

The Decision № 486 of September 14, 2000 of the Commission of the Andean Community applies (Refer to the provision below)

REPUBLIC OF MOLDOVA

Article 23, paragraphs (2) – (4), and Article 28[4] of the Law № 50-XVI of March 7, 2008, on the protection of Inventions (as amended up to Law No. 98 of April 27, 2023)

23. Исчерпание прав

[…]

(2) Охрана, предусмотренная частями (5)–(7) статьи 24, не распространяется на биологический материал, полученный воспроизведением или размножением биологического материала, проданного или предложенного к продаже на территории Республики Молдова патентообладателем или с его согласия, если это воспроизведение или размножение вытекает исключительно из использования, в целях которого биологический материал был поставлен на рынок, при условии, что полученный материал впоследствии не был использован для воспроизведения или размножения.

(3) В отступление от частей (5)–(7) статьи 24 продажа или любой другой вид реализации патентообладателем или с его согласия фермеру материала для воспроизводства растений с целью применения в сельском хозяйстве предусматривает разрешение для фермера использовать продукт полученного им урожая для воспроизводства или размножения для личного пользования.

(4) В отступление от частей (5)–(7) статьи 24 продажа или любой другой вид реализации племенного скота или иного репродуктивного животного материала патентообладателем или с его согласия фермеру предполагает разрешение для фермера использовать его в сельскохозяйственных целях, за исключением коммерческого использования; это включает и использование животных или иного репродуктивного животного материала для осуществления его сельскохозяйственной деятельности.

28[4]. Предоставление принудительной лицензии на патент в случае изобретений в области полупроводниковых технологий и в целях использования зависимых патентов и патентов на сорта растений

(1) Судебная инстанция может предоставить принудительную лицензию на патент в случае изобретений в области полупроводниковых технологий только при условии их публичного использования в некоммерческих целях или необходимости устранения практики, которая в результате административного производства признана антиконкурентной.

(2) Судебная инстанция может предоставить принудительную лицензию на патент в случае зависимых патентов и патентов на сорта растений по заявлению патентообладателя или обладателя патента на сорт растения, который не может применить изобретение или охраняемый сорт

растения (второй патент) без ущерба для другого патента (первого патента), при условии, что изобретение или сорт растения, заявленные во втором патенте, предполагают значительный технический прогресс, представляющий существенный экономический интерес по отношению к изобретению и сорту растения, заявленными в первом патенте. Судебная инстанция может принять любые меры, необходимые для проверки наличия такой ситуации. В случае принудительной лицензии в пользу патента или патента на сорт растения обладатель первого патента имеет право на перекрестную лицензию на разумных условиях для использования запатентованного изобретения или охраняемого сорта растения.

ROMANIA

Article 31, paragraph 10, and Article 44 of the Law No. 64 of October 11, 1991, on Patents (amended up to Law No. 83/2014)

31.

[…]

(10) The protection referred to in paragraphs (7) - (9) shall not extend to the biological material derived by reproduction or multiplication from a biological material sold or offered for sale on the territory of Romania by the patent owner or with his consent, where the reproduction or multiplication necessarily results from the utilization for which the biological material was put on the market, provided that the obtained material has not been used subsequently for other reproductions and multiplications.

44.

(1) Compulsory licenses shall be non-exclusive and shall be granted by the Court of Bucharest, under specific conditions regarding their extent and duration, as well as the amount of royalties to which the right holder is entitled, established in accordance with the commercial value of the licenses granted.

[…]

(3) Compulsory licenses shall be authorized mainly for supplying the market.

(4) The extent and duration of compulsory licenses shall be limited to the purposes for which they have been authorized. […]

(5) When the owner of a plant variety patent cannot exploit the patent without infringing a prior patent, he may request a compulsory license for the invention protected by said patent.

[…]

SAN MARINO

Article 30 of the Law № 79 of 25 May 2005, the Industrial Property Consolidation Law (amended up to February 7, 2014)

30. (Context of exclusive rights and claim interpretations)

[…]

9. The protection set out in paragraphs 6, 7 and 8 does not cover biological material obtained through the reproduction or multiplication of biological material marketed in the territory of a Member State by the patent proprietor or with his consent, if the reproduction or multiplication necessarily derives from the use, which the biological material has been marketed for, as long as the material obtained is not subsequently used for other reproductions or multiplications.

10. Notwithstanding paragraphs 6, 7 and 8 above, the sale or other form of marketing of reproduction material of vegetal origin, by the patent owner or with his consent, to a farmer for the purpose of agricultural exploitation implies the authorization for the farmer to use the product of the harvest for reproduction or multiplication on his own and within his own business; the context and the ways of this exception correspond to those provided for in article 14 of Regulation (EC) No. 2100/94.

11. Notwithstanding paragraphs 6, 7 and 8, the sale or other form of marketing of livestock or other reproduction material of animal origin, by the patent owner or with his consent, to a farmer implies the authorization for the farmer to use the protected livestock for agricultural use. Such authorization includes the provision of the animal or other reproduction material of animal origin for the continuation of his agricultural activity, but not the sale in the context or for the purpose of commercial reproduction.

SAO TOME AND PRINCIPE

Article 101, paragraph 6, Article 107, paragraph 2, and Article 113 of the of the Intellectual Property Code (approved by Decree-Law № 23/2016)

101. Scope of Protection

[…]

6. Notwithstanding the provisions of paragraphs 3 to 5 of this Article:

a) The sale or other form of marketing, by the patentee or with his consent, of plant-propagating material to a farmer, for the purpose of agricultural use, requires authorization for the farmer to use the product of his harvest to proceed himself with the reproduction or multiplication in his activities;

b) The sale or other form of marketing, by the patentee or with his consent, of breeding stock or other animal reproductive material to a farmer requires authorization for the farmer to use the protected livestock for agricultural purposes, including 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

[…]

107. Exhaustion of Rights

[…]

2. The protection referred to in Articles 101, paras.3 to 5 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 patent owner 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.

113. Dependent Licences

[…]

4. If a plant breeder cannot obtain or exploit a plant securing right without infringing a prior patent, he may request for a compulsory licence for the non-exclusive use of the invention protected by the patent inasmuch as this licence is necessary to exploit the same plant variety, subject to payment of an appropriate sum.

5. Whenever a licence of the type provided for in the previous paragraph is granted, the patentee is entitled to a reciprocal licence, on reasonable terms, to use the protected variety.

[…]

SERBIA

Articles 25 and 29 of the Law on Patents of January 4, 2012 (Official Gazette of the Republic of Serbia № 99/2011, 113/2017, 95/2018, 66/2019 and 123/2021)

Limitations of Rights Concerning Biological Material

25.

By acquiring protected plant propagating material from the owner of a patent or with his consent, a farmer shall obtain authorization to use the product of said propagating material for further propagation or multiplication on his own farm, under conditions prescribed by the law on the protection of, plant breeders' rights.

By acquiring protected animal reproductive material or breeding stock from the owner of a patent or with his consent, a farmer shall obtain authorization for use protected livestock or for reproductive material for the purpose of his own agricultural activities, but not for sale within the framework or for the purpose of a commercial reproduction activity.

Cross Compulsory License Granted to Plant Breeders and Patent Holder relating to Biotechnological Invention

29.

Where a plant breeder cannot obtain or exploit a protected plant breeders' rights without infringing prior patent, he may file the request for the grant of a compulsory license to the government authority competent for the Agriculture for the use of the invention protected by the patent inasmuch as the license is necessary for the exploitation of the plant variety to be protected.

If such a license is granted, the owner of the patent shall be entitled to a compulsory cross-license to use the plant variety protected, on reasonable terms.

Where the owner of a patent concerning a biotechnological invention cannot exploit it without infringing a prior protected plant breeders' rights, he may file the request for the grant of a compulsory license to the government authority competent for the Agriculture, that cannot be exclusive, for the use of the plant variety protected.

If compulsory license is granted, the holder of the plant breeders right is entitled to a compulsory cross-license to use the protected invention on reasonable terms.

Compulsory license from paragraph 1 and 3 shall not be exclusive.

A requester for the compulsory license referred to in paragraphs 1 and 3 of this Article must demonstrate that:

1) he has unsuccessfully made efforts to obtain a contractual license;

2) 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.

The compulsory license referred to in paragraphs 1 and 3o f this Article may only be assigned with the manufacturing plant that exploits the invention for which the license has been granted.

For compulsory license referred to in paragraph 1 and 3 of this Article, the licensee shall pay appropriate royalty.

SLOVAKIA

Sections 16 and 27 of the Act № 435/2001 Coll. on Patents, Supplementary Protection Certificates and Amendment of Some Acts (Patent Act (as amended up to Act No. 291/2018 Coll.))

Exhaustion of rights

§ 16

(1) The patent owner does not have the right to prohibit third parties from disposals of the product that is the subject matter of patent protection after this product has been placed on the market by the patent owner or with his express consent in a member state of the European Union or a state that is a party to the Agreement on the European Economic Area; this does not apply if there are reasons for extending the rights resulting from the patent to such disposals.

(2) Subsection 1 also applies to biological material obtained by reproduction of protected biological material, provided that such reproduction necessarily results from the use for which the biological material has been placed on the market, if the biological material thus obtained is not subsequently used for its further reproduction.

(3) The acquisition of protected plant reproduction material by a grower within a business relationship with the patent owner or with his consent includes the grower's right to use the product of his work to reproduce this product in his farm. To determine the scope of the grower's right according to the first sentence and the conditions for the exercise of this right, the provisions of a special piece of legislation shall be used mutatis mutandis. 6(a)

(4) The acquisition of protected animal reproduction material by a breeder within the framework of a business relationship with the patent owner or with his consent includes the right of the breeder to use protected livestock for agricultural purposes, including the use of animal reproduction material to carry out the breeder's agricultural activities, with the exception of the sale of animal reproduction material in connection with business or for the purpose of business5) in the form of subsequent reproduction activity.

Compulsory license

§ 27

[…]

(5) Regardless of the prerequisites pursuant to subsection 1 and the conditions pursuant to subsection 2, a court may, upon motion, grant a forced non-exclusive license for the exploitation of a biotechnological invention, if the breeder cannot use or acquire the right to a plant variety without infringing an earlier right to the patent, if the movant proves that

(a) before filing the motion he gave the patent owner a proper offer to conclude the license contract and the patent owner did not accept this offer within three months of its filing, and

(b) the plant variety represents an important technical progress of significant economic importance comparable to the invention that is the subject-matter of the motion for the granting of the compulsory license.

(6) In the case of the granting of a compulsory license according to subsection 5, the patent owner has the right to grant a compulsory cross-license for the use of a plant variety pursuant to a special piece of legislation.

(7) If a patent owner has been granted a compulsory license for the exploitation of a plant variety pursuant to a special piece of legislation, the holder of a cultivator certificate has the right to be granted a compulsory cross-license for the exploitation of the biotechnological invention.

[…]

SLOVENIA

Articles 9, 10 and 11 of the Decree on the Legal Protection of Biotechnological Inventions

Article 9.

The protection referred to in Articles 7 and 8 shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market in the territory of the Republic of Slovenia 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.

Article 10.

(1) By way of derogation from Articles 7 and 8, 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, according to Article 16 of the Protection of New Plant Varieties Act, for propagation or multiplication by him on his own farm.

(2) By way of derogation from Articles 7 and 8, 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.

Article 11.

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

(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 nonexclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty.

(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.

SPAIN

Articles 61.3, 62 and 93 of the Law № 24/2015 of July 24, 2015 on Patents (as amended by Law № 6/2018, of July 3, 2018)

61. *Límites generales y agotamiento del derecho de patente.*

[…]

3. Los derechos conferidos por la patente no se extenderán a los actos relativos a la materia biológica obtenida por reproducción o multiplicación de una materia biológica protegida objeto de la patente, después de que ésta haya sido puesta en el mercado en el Espacio Económico Europeo por el titular de la patente o con su consentimiento, cuando la reproducción o multiplicación sea el resultado necesario de la utilización para la que haya sido comercializada dicha materia biológica, y a condición de que la materia obtenida no se utilice posteriormente para nuevas reproducciones o multiplicaciones.

Esta limitación no se aplicará cuando existan motivos legítimos que justifiquen que el titular de la patente se oponga a la comercialización ulterior de la materia biológica.

62. Excepciones del ganadero y del agricultor.

1. No obstante lo dispuesto en el artículo 59, la venta, o cualquier otra forma de comercialización de material de reproducción vegetal realizada por el titular de la patente o con su consentimiento a un agricultor para su explotación agrícola, implicará el derecho de éste último a utilizar el producto de su cosecha para ulterior reproducción o multiplicación realizada por él mismo en su propia explotación. El alcance y las modalidades de esta excepción corresponderán a las previstas en el artículo 14 del Reglamento (CE) n.º 2100/94, del Consejo, de 27 de julio, relativo a la protección comunitaria de las obtenciones vegetales y a la Ley 3/2000, de 7 de enero, de régimen jurídico de la protección de obtenciones vegetales.

2. No obstante lo dispuesto en el artículo 59, la venta o cualquier otra forma de comercialización de animales de cría o de material de reproducción animal realizada por el titular de la patente o con su consentimiento a un agricultor o ganadero, implicará la autorización a estos últimos para utilizar el ganado protegido con fines agrícolas o ganaderos. Ello incluirá la puesta a disposición del ganado o de otro material de reproducción animal para que el agricultor o ganadero pueda proseguir su actividad agrícola o ganadera, pero no la venta en el marco de una actividad de reproducción comercial o con esa finalidad. El alcance y las modalidades de esta excepción corresponderán con las que se fijen reglamentariamente.

93. Licencias obligatorias por dependencia

[…]

1. 1. Cuando no sea posible explotar el invento protegido por una patente sin menoscabo de los derechos conferidos por una patente o por un derecho de obtención vegetal anterior, el titular de la patente posterior podrá solicitar una licencia obligatoria, para la explotación del objeto de la patente o de la variedad objeto del derecho de obtención vegetal anterior, mediante el pago de un canon adecuado.

2. Cuando no sea posible explotar un derecho de obtención vegetal sin menoscabo de los derechos conferidos por una patente anterior, el obtentor podrá solicitar una licencia obligatoria, para la explotación del invento protegido por la patente, mediante el pago de un canon adecuado.

[…]

4. Los solicitantes de las licencias a que se refieren los apartados anteriores deberán demostrar:

a) Que la invención o la variedad representa un progreso técnico significativo de considerable importancia económica con relación a la invención reivindicada en la patente anterior o a la variedad protegida por el derecho de obtención vegetal anterior.

b) Que han intentado, sin conseguirlo en un plazo prudencial, obtener del titular de la patente o del derecho de obtención vegetal anterior, una licencia contractual en los términos previstos en el artículo 97.1.

5. Cuando proceda la concesión de una licencia obligatoria por dependencia, también el titular de la patente o del derecho de obtención vegetal anterior podrá solicitar el otorgamiento, en condiciones razonables, de una licencia para utilizar la invención o la variedad protegida por la patente o por el derecho de obtención vegetal posterior.

6. Las licencias obligatorias por dependencia se otorgarán solamente con el contenido necesario para permitir la explotación de la invención protegida por la patente, o de la variedad protegida por el derecho de obtención vegetal de que se trate, y quedarán sin efecto al declararse la nulidad o la caducidad de alguno de los títulos entre los cuales se dé la dependencia.

7. La tramitación y la resolución de las solicitudes de licencias obligatorias por dependencia para el uso no exclusivo de una invención patentada, se regirá por lo dispuesto en la presente Ley. La tramitación y la resolución de las solicitudes de licencias obligatorias por dependencia para el uso de la variedad protegida por un derecho de obtentor se regirán por su legislación específica.

SWEDEN

Sections 8, 9, 10 and 13, Chapter 3, and Section 7, Chapter 13, of the Patents Act (2024:945)

3 kap. Ensamrätten

[…]

Utnyttjanden för framtagande av nya växtsorter

8 § Från ensamrätten till patent undantas användning av biologiskt material i syfte att odla fram, upptäcka eller utveckla nya växtsorter.

Utnyttjanden i jordbruk

9 § Om en patenthavare eller någon med patenthavarens samtycke överlåter växtförökningsmaterial till en jordbrukare för att utnyttjas i jordbruket, får jordbrukaren trots 1–3 §§ använda skörden för reproduktion eller mångfaldigande i det egna jordbruket i den utsträckning som följer av artikel 14 i rådets förordning (EG) nr 2100/94 av den 27 juli 1994 om gemenskapens växtförädlarrätt.

10 § Om en patenthavare eller någon med patenthavarens samtycke överlåter avelsdjur eller annat animaliskt reproduktionsmaterial till en jordbrukare, får jordbrukaren trots 1–3 §§ använda djuret eller reproduktionsmaterialet inom den egna jordbruksverksamheten. Jordbrukaren får dock inte sälja djuret eller materialet inom ramen för yrkesmässig reproduktionsverksamhet eller i syfte att bedriva sådan verksamhet. Rätten enligt första stycket får inte utövas i vidare omfattning än vad som är skäligt med hänsyn till jordbrukarens behov och patenthavarens intressen.

[…]

Utnyttjanden av biologiskt material

13 § Från ensamrätten till patent undantas i fråga om biologiskt material utnyttjanden i form av reproduktion eller mångfaldigande av produkter när reproduktionen eller mångfaldigandet är ett nödvändigt led i den användning för vilken det biologiska materialet har förts ut på marknaden inom Europeiska ekonomiska samarbetsområdet av patenthavaren eller med hans eller hennes samtycke, under förutsättning att den erhållna produkten inte senare används för ytterligare reproduktion eller mångfaldigande.

13 kap. Licens

[…]

Korsvisa tvångslicenser för växtförädlare och patenthavare

7 § En växtförädlare som inte kan få eller utnyttja en växtförädlarrätt eller en gemenskapens växtförädlarrätt kan få en tvångslicens att utnyttja en tidigare meddelad patentskyddad uppfinning, om

1. en sådan licens är nödvändig för att växtsorten ska kunna utnyttjas, och

2. växtförädlaren visar att växtsorten utgör ett viktigt tekniskt framsteg av betydande ekonomiskt intresse i förhållande till uppfinningen.

Om en patenthavare får en tvångslicens i en växtförädlarrätt eller en gemenskapens växtförädlarrätt, har innehavaren av växtförädlarrätten rätt att på skäliga villkor få en tvångslicens (motlicens) att utnyttja patenthavarens uppfinning. […]

SWITZERLAND

Article 9, para. 1, lets. E and f, Article 9a, para. 3, Articles 35a and 36a of the Patent Act of 25 June, 1954 (status as of 1 July, 2023)

9. The effects of the patent do not extend to:

[…]

e. the use of biological material for the purpose of the production or the discovery and development of a plant variety;

f. biological material that is obtained in the field of agriculture due to chance or is technically unavoidable;

[…]

9a.

[…]

[3] If the proprietor of the patent has placed patent-protected biological material on the market in Switzerland or within the European Economic Area, or consented to its placing on the market in Switzerland or within the European Economic Area, this material may be imported and propagated in Switzerland, provided this is necessary for its intended use. The material so obtained may not be used for further propagation. Article 35*a* remains reserved.

[…]

35a.

[1] Farmers who have acquired plant reproduction material placed on the market by the proprietor of the patent or with his consent may reproduce, on their own farm, the product from this material cultivated on their own farm.

[2] Farmers who have acquired animal reproductive material or animals placed on the market by the proprietor of the patent or with his consent may reproduce, on their own farm, the animals obtained through reproduction of this material or these animals on their own farm.

[3] Farmers are required to obtain the consent of the proprietor of the patent when they wish to give the product of their harvest or the animal or animal reproductive material obtained to third parties for reproduction purposes.

[4] Contractual agreements which limit or revoke the farmers' privilege in the area of food and feed production are null and void.

36a.

[1] When a plant variety right may not be claimed or used without infringing an earlier-granted patent, the plant breeder or the owner of the plant variety has the right to a non-exclusive licence to the extent required to obtain and use his plant variety right, provided that the plant variety represents an important advance of considerable economic significance in comparison to the patent-protected invention. For varieties for agriculture and food, the criteria under the Seed Ordinance of 7 December 1998 serve as a reference point.

[2] The proprietor of the patent may make the grant of a licence conditional on the owner of the plant variety granting him a licence to use his plant variety right in return.

TÜRKIYE

Articles 85 and 129 of the Industrial Property Law, Law № 6769 of December 22, 2016 (as amended up to Law No. 7251 dated 22/7/2020)

Scope of a patent right and its limits

85. […]

(4) A small farmer whose definition is made in the Law on Protection of Breeder's Rights for New Plant Varieties dated 01.08.2004 and numbered 5042 has the right, in his own land which they operate, to use the reproduction material that derived from the product in the result of the production made by a patented product provided from the patentee; or sold by his permission; or obtained by another commercial way, in order to do new productions in their own land which they operate. This tenancy shall be subject to the provisions of the Law number 5042.

(5) The farmer has a right to use the patented breeding or other animal reproduction material provided from the patentee; or sold by his permission; or obtained by another commercial way for agricultural purposes. This tenancy covers the use of animals or other animal reproduction material in order to maintain their own agricultural strength. The procedure and rules regarding the use of this right shall be determined by regulations.

[…]

129. (1) Compulsory license may be given in the presence of at least one of the conditions specified below.

[…]

d) If the breeder fails to develop a new plant variety without infringing on a previous patent,

[…]

(7) If a license is granted pursuant to subparagraph (d) of first paragraph, then patent owner may demand the giving of the license to himself to use the protected plant variety and if a license is granted pursuant to sixth paragraph, then holder of breeder right may demand mutually the giving of license to himself to use protected plant variety under reasonable terms.

(8) For licenses specified in subparagraph (d) of first paragraph and in the sixth paragraph, demandant may request the court to issue a compulsory license by means of proving that;

a) it applies to patentee or holder of breeder right belonging to a new plant variety to obtain a contractual license but cannot get any results,

b) compared to protected plant variety or invention protected by the patent, next invention or plant variety show a significant technical advance that largely provides economic benefits.

[…]

UNITED KINGDOM

Section 60 of the Patents Act 1977 (Chapter 37, updated on August 21, 2022)

60. Meaning of infringement

[…]

(5) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if –

[…]

(g) it consists of the use by a farmer of the product of his harvest for propagation or multiplication by him on his own holding, where there has been a sale of plant propagating material to the farmer by the proprietor of the patent with his consent for agricultural use;

(h) it consists of the use of an animal or animal reproductive material by a farmer for an agricultural purpose following a sale to the farmer, by the proprietor of the patent or with his consent, of breeding stock or other animal reproductive material which constitutes or contains the patented invention

[…]

(6A) Schedule A1[1] contains—

[1] To read Schedule A1, please refer to: https://www.gov.uk/guidance/the-patent-act-1977/schedule-a1-section-60-5-g-derogation-from-patent-protections-in-respect-of-biotechnological-inventions-interpretation.

(a) provisions restricting the circumstances in which subsection (5)(g) applies; and

(b) provisions which apply where an act would constitute an infringement of a patent but for subsection (5)(g).

(6B) For the purposes of subsection (5)(h), use for an agricultural purpose—

(a) includes making an animal or animal reproductive material available for the purposes of pursuing the farmer's agricultural activity; but

(b) does not include sale within the framework, or for the purposes, of a commercial reproduction activity.

(6C) In paragraphs (g) and (h) of subsection (5) "sale" includes any other form of commercialisation.

[…]

Regulations 3 and 7 of the Patents and Plant Variety Rights (Compulsory Licensing) Regulations 2002 (updated on September 13, 2024)

3.—(1) Where a person cannot acquire or exploit plant breeders' rights in a new variety without infringing a prior patent, he may apply in accordance with rules to the Comptroller General of Patents for a licence under the patent and on such application shall pay the prescribed fee.

(2) An application under paragraph (1) shall be accompanied by particulars which seek to demonstrate that—

(a) the applicant cannot acquire or exploit plant breeders' rights without infringing a prior patent,

(b) the applicant has applied unsuccessfully to the proprietor of the prior patent concerned for a licence to use that patent to acquire or exploit plant breeders' rights, and

(c) the new plant variety, in which the applicant wishes to acquire or exploit the plant breeders' rights, constitutes significant technical progress of considerable economic interest in relation to the invention protected by the patent.

(3) If and so far as any agreement purports to bind any person not to apply for a licence under paragraph (1), it shall be void.

[…]

7.—(1) A compulsory patent licence shall—

[…]

(c) entitle the proprietor of the patent concerned to a cross licence on reasonable terms to use the new plant variety.

(2) Where the controllers order the grant of a compulsory patent licence to a person who has been granted plant breeders' rights in the new plant variety, the proprietor of the patent concerned may request, a cross licence on reasonable terms of the plant breeders' rights to use the new plant variety in

respect of which the compulsory patent licence has been granted and, on such request, the controllers shall order the grant of such a cross licence to that proprietor (or, where the proprietor of the patent is a government department, to any person specified in the request).

(3) Where the controllers order the grant of a compulsory patent licence to a person who has yet to acquire plant breeders' rights in the new plant variety, the proprietor of the patent concerned may request a cross licence on reasonable terms of the plant breeders' rights to use the new plant variety in respect of which the compulsory patent licence has been granted and, on such request, the controllers shall order the grant of such a cross licence to that proprietor (or, where the proprietor of the patent is a government department, to any person specified in the request), and the cross licence shall come into effect on the grant to the holder of the compulsory patent licence of plant breeders' rights in the new plant variety.

ANDEAN COMMUNITY

Article 53(e) and 54 of the *Decision № 486 of September 14, 2000 of the Commission of the Andean Community, Establishing the Common Industrial Property Regime*

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.

EUROPE

Articles 10, 11 and 12 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions

Article 10

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.

Article 11

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

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.

3. The extent and the conditions of the derogation provided for in paragraph 2 shall be determined by national laws, regulations and practices.

Article 12

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

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.

4. Each Member State shall designate the authority or authorities responsible for granting the licence. Where a licence for a plant variety can be granted only by the Community Plant Variety Office, Article 29 of Regulation (EC) No 2100/94 shall apply.

Article 14 of the Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights

Article 14

Derogation from Community plant variety right

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.

2. The provisions of paragraph 1 shall only apply to agricultural plant species of:

(a) Fodder plants:

Cicer arietinum L. - Chickpea milkvetch

Lupinus luteus L. - Yellow lupin

Medicago sativa L. - Lucerne

Pisum sativum L. (partim) - Field pea

Trifolium alexandrinum L. - Berseem/Egyptian clover

Trifolium resupinatum L. - Persian clover

Vicia faba - Field bean

Vicia sativa L. - Common vetch

and, in the case of Portugal, Lolium multiflorum lam - Italian rye-grass

(b) Cereals:

Avena sativa - Oats

Hordeum vulgare L. - Barley

Oryza sativa L. - Rice

Phalaris canariensis L. - Canary grass

Secale cereale L. - Rye

X Triticosecale Wittm. - Triticale

Triticium aestivum L. emend. Fiori et Paol. - Wheat

Triticum durum Desf. - Durum wheat

Triticum spelta L. - Spelt wheat

(c) Potatoes:

Solanum tuberosum - Potatoes

(d) Oil and fibre plants:

Brassica napus L. (partim) - Swede rape

Brassica rapa L. (partim) - Turnip rape

Linum usitatissimum - linseed with the exclusion of flax.

3. Conditions to give effect to the derogation provided for in paragraph 1 and to safeguard the legitimate interests of the breeder and of the farmer, shall be established, before the entry into force of this Regulation, in implementing rules pursuant to Article 114, on the basis of the following criteria:

- there shall be no quantitative restriction of the level of the farmer's holding to the extent necessary for the requirements of the holding,

- 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,

- small farmers shall not be required to pay any remuneration to the holder; 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 (4) 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,

- 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; 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,

- monitoring compliance with the provisions of this Article or the provisions adopted pursuant to this Article shall be a matter of exclusive responsibility of holders; in organizing that monitoring, they may not provide for assistance from official bodies,

- relevant information shall be provided to the holders on their request, by farmers and by suppliers of processing services; relevant information may equally be provided by official bodies involved in the monitoring of agricultural production, if such information has been obtained through ordinary

performance of their tasks, without additional burden or costs. These provisions are without prejudice, in respect of personal data, to Community and national legislation on the protection of individuals with regard to the processing and free movement of personal data.

Article 27 of the Agreement on a Unified Patent Court of June 1, 2023

27. Limitations of the effects of a patent

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

[…]

(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.[2]

[End of the Appendix and of document]

[2] Article 10:
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.