

Yes, the United States implemented changes to the Plant Variety Patent Act to conform to the 1991 Act of the UPOV Convention. These changes were implemented through the Plant Variety Protection Act Amendments of 1994, Pub. L. No. 103-349, 108 Stat. 3136.

*Concurrent Protection*

*(b) Indicate whether patent protection can be enjoyed in your country with respect to botanical genera and species of plants, if any, that are excluded from protection under your plant variety protection system.*

No botanical genera or species are excluded from eligibility under the Plant Variety Protection Act (i.e., for sexually reproduced plant varieties).

The plant patent act precludes protection for asexually reproduced, tuber propagated varieties. However, any plant, regardless of its method of production and its genera or species, can be the subject of a utility patent, provided it satisfies all the criteria for the grant of such a patent.

*(c) Indicate whether a party can enjoy concurrent patent rights and plant variety protection for the identical plant variety under your law with respect to plant varieties that are eligible to be protected through your plant variety protection system.*

Yes.

*(d) Indicate whether any judicial decision in your country has addressed the issue of whether an entity that holds a plant variety protection certificate has been unable to commercially exploit the plant variety subject to that protection due to action by a second entity that holds and has enforced patent protection covering that plant variety.*

No judicial decision has addressed the fact pattern described above.

*Commercial Sales of Propagating Material by Third Parties / Farmer's Privilege*

*(e) Indicate whether any of the following uses by persons other than the owner of a plant variety protection right and not having his/her consent is permitted under your law :*

For each of the questions, answers are being provided for the three forms of protection that are possible under the U.S. system; namely, utility patents, plant patents and plant variety protection certificates.

*(i) commercial sales of propagating material,*

Type of Protection	Infringement of Protected Plant or Plant Variety?
Utility Patent	Yes, this would infringe a utility patent covering a plant or plant variety. See, 35 U.S.C. 271.
Plant Patent	Yes, the sale of an asexually reproduced plant variety (i.e., the propagating material protected under a plant patent) would give rise to liability for infringement of a plant patent. See, 35 U.S.C. 163. <sup>16</sup>
PVP Certificate	Yes, this would infringe the rights provided through a plant variety protection certificate. See, 7 U.S.C. 2541. <sup>17</sup>

<sup>16</sup> 35 U.S.C. § 163 defines the rights provided through a plant patent. It states: "In the case of a plant patent the grant shall be of the right to exclude others from asexually reproducing the plant or selling or using the plant so reproduced."). See also, *Imazio Nursery, Inc., v. Dania Greenhouses et al.*, 69 F.3d 1560, 36 USPQ2d 1673 (Fed. Cir. 1995).

<sup>17</sup> 7 U.S.C. 2541 provides:

**7 U.S.C. 2541 Infringement of plant variety protection**

(a) Except as otherwise provided in this title [7 U.S.C. §§ 2521 et seq.], it shall be an infringement of the rights of the owner of a protected variety to perform without authority, any of the following acts in the United States, or in commerce which can be regulated by Congress or affecting such commerce, prior to expiration of the right to plant variety protection but after either the issue of the certificate or the distribution of a protected plant variety with the notice under section 127 [7 U.S.C. 2567]:

- (1) sell or market the protected variety, or offer it or expose it for sale, deliver it, ship it, consign it, exchange it, or solicit an offer to buy it, or any other transfer of title or possession of it;
- (2) import the variety into, or export it from, the United States;
- (3) sexually multiply, or propagate by a tuber or a part of a tuber, the variety as a step in marketing (for growing purposes) the variety;
- (4) use the variety in producing (as distinguished from developing) a hybrid or different variety therefrom;
- (5) use seed which had been marked "Unauthorized Propagation Prohibited" or "Unauthorized Seed Multiplication Prohibited" or progeny thereof to propagate the variety;
- (6) dispense the variety to another, in a form which can be propagated, without notice as to being a protected variety under which it was received;
- (7) condition the variety for the purpose of propagation, except to the extent that the conditioning is related to the activities permitted under section 113 [7 U.S.C. 2543];
- (8) stock the variety for any of the purposes referred to in paragraphs (1) through (7);
- (9) perform any of the foregoing acts even in instances in which the variety is multiplied other than sexually, except in pursuance of a valid United States plant patent; or
- (10) instigate or actively induce performance of any of the foregoing acts.

(b)(1) Subject to paragraph (2), the owner of a protected variety may authorize the use of the variety under this section subject to conditions and limitations specified by the owner.

- (2) In the case of a contract between a seed producer and the owner of a protected variety of lawn, turf, or forage grass seed, or alfalfa or clover seed for the production of seed of the protected variety, the producer shall be deemed to be authorized by the owner to sell such seed and to use the variety if-
  - (A) the producer has fulfilled the terms of the contract;
  - (B) the owner refuses to take delivery of the seed or refuses to pay any amounts due under the contract within 30 days of the payment date specified in the contract; and
  - (C) after the expiration of the period specified in subparagraph (B), the producer notifies

- (ii) *storage by the person that harvests seed from his own holdings in order to use the seed in subsequent plantings on those holdings, or*

Type of Protection	Infringement of Protected Plant or Plant Variety?
Utility Patent	Yes, this would infringe a utility patent covering a plant or plant variety. See, 35 U.S.C. 271.
Plant Patent	No, only the acts of asexual reproduction of the protected variety, or use or sale of the asexually reproduced variety, would give rise to liability for infringement of a plant patent. Since seed is the product of sexual reproduction of the variety, it falls outside the scope of infringing acts defined in 35 U.S.C. 163.
PVP Certificate	No, pursuant to 7 U.S.C. 2543 <sup>18</sup> , a person who engages in the acts described in the question would not be liable as an infringer of a plant variety protection certificate.

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the owner of the producer's intent to sell the seed and unless the owner fails to pay the amounts due under the contract and take delivery of the seed within 30 days of such notification. For the purposes of this paragraph, the term "owner" shall include any licensee of the owner.

- (3) Paragraph (2) shall apply to contracts entered into with respect to plant varieties protected under this Act (7 U.S.C. 2321 et seq.) as in effect on the day before the effective date of this provision as well as plant varieties protected under this Act as amended by the Plant Variety Protection Act Amendments of 1994.
- (4) Nothing in this subsection shall affect any other rights or remedies of producers or owners that may exist under other Federal or State laws.
- (c) This section shall apply equally to-
- (1) any variety that is essentially derived from a protected variety, unless the protected variety is an essentially derived variety;
  - (2) any variety that is not clearly distinguishable from a protected variety;
  - (3) any variety whose production requires the repeated use of a protected variety; and
  - (4) harvested material (including entire plants and parts of plants) obtained through the unauthorized use of propagating material of a protected variety, unless the owner of the variety has had a reasonable opportunity to exercise the rights provided under this Act with respect to the propagating material.

(d) It shall not be an infringement of the rights of the owner of a variety to perform any act concerning propagating material of any kind, or harvested material, including entire plants and parts of plants, of a protected variety that is sold or otherwise marketed with the consent of the owner in the United States, unless the act involves further propagation of the variety or involves an export of material of the variety, that enables the propagation of the variety, into a country that does not protect varieties of the plant genus or species to which the variety belongs, unless the exported material is for final consumption purposes.

(e) It shall not be an infringement of the rights of the owner of a variety to perform any act done privately and for noncommercial purposes.

(f) As used in this section, the term "perform without authority" includes performance without authority by any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in the official capacity of the officer or employee. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this Act in the same manner and to the same extent as any nongovernmental entity.

<sup>18</sup> 7 U.S.C. 2543 provides:

(iii) *other uses of the propagating material (e.g. barter or seed exchange).*

Type of Protection	Infringement of Protected Plant or Plant Variety?
Utility Patent	Yes, this would infringe a utility patent covering a plant or plant variety. See, 35 U.S.C. 271.
Plant Patent	No, only the act of asexual reproduction of the protected variety would give rise to liability for infringement of a plant patent. See, 35 U.S.C. 163.
PVP Certificate	Yes, the acts described fall within the definition of infringing activity under 7 U.S.C. 2541.

*If so, please describe the situations where this is permitted and the conditions that apply to such use.*

See response to each question above.

#### *Plant Protection for Variety Containing Patented Gene*

(f) *Assuming that a new plant variety containing a patented gene has been bred*

- (i) *by the patent holder;*
- (ii) *by a third person not having the consent of the patent holder*

*indicate whether that person is eligible for plant variety protection in respect of this new variety in your country.*

Any person who has produced a new plant variety can protect it under the relevant legal authority in the United States provided it satisfies the criteria for protection. There are no implications as to the eligibility for protection of a new plant variety that stem from the fact that the new variety was produced through use of an existing protected variety. The ability of a third party to sell or use a new variety produced through use of a patented or otherwise protected variety is a separate question that will depend on the type of activity involved and the type of protection for the original protected variety.

#### **7 U.S.C. 2543 Right to save seed; crop exemption**

Except to the extent that such action may constitute an infringement under subsections (3) and (4) of section 111 [7 U.S.C. 2541(3), (4)], it shall not infringe any right hereunder for a person to save seed produced by the person from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seeding purposes and use such saved seed in the production of a crop for use on the farm of the person, or for sale as provided in this section. A bona fide sale for other than reproductive purposes, made in channels usual for such other purposes, of seed produced on a farm either from seed obtained by authority of the owner for seeding purposes or from seed produced by descent on such farm from seed obtained by authority of the owner for seeding purposes shall not constitute an infringement. A purchaser who diverts seed from such channels to seeding purposes shall be deemed to have notice under section 127 [7 U.S.C. 2567] that the actions of the purchaser constitute an infringement.

## Annex A.

### Statistical Reporting related to Patents and Plant Variety Protection

*Member countries should respond to questions contained in this Annex to the extent they have readily available relevant information. For the purpose of the Annex, biotechnology will cover items corresponding to the following International Patent Classification marks:*

[omitted]

*(a) From the date that your examining authority began issuing patents for products specified in the above list of IPC codes, please indicate, on a year-by-year basis :*

- (i) the number of patents filed and granted, per IPC category;*
- (ii) number of patents filed and granted to nationals of foreign countries;*
- (iii) the percentage of such grants that derive from the national stage processing of an application filed under the Patent Cooperation Treaty (PCT); and*
- (iv) the percentage of such grants that make a claim for priority to a filing in a foreign country, broken down by the country of origin of the priority claim.*

*What was the total number of applications (i.e. in any technology) filed and granted in the same time periods ?*

See Attachment D for answers to question (a).

*(b) Indicate the year in which the first patent with claims to the following organisms was granted:*

- (i) a unicellular organism;*

1873, patent number 141,072.

- (ii) a plant*

The first plant patent was granted in 1931 (Plant Patent No. 1). The first utility patent covering a plant was granted in 1983 (patent number 4,378,655 issued Apr. 5, 1983).

- (iii) any multicellular organism;*

The first plant patent was granted in 1931 (Plant Patent No. 1).

- (iv) a mammal.*

The first patent covering a mammal was granted in 1988 (patent number 4,736,866).

(c) *Indicate the number of examiners that are presently employed by your examining authority to handle biotechnology applications, and the approximate total number of applications assigned to such examiners that are currently pending. Indicate the total number of examiners (in all technologies) and the approximate total number of applications pending.*

The total number of examiners in the Biotechnology Group (Group 1800) is 179, and for the entire office in all technical areas, 2,212.

Pending application data responsive to the questions:

	Biotechnology	All Technologies
New Applications	2,106	67,091
Amended Applications	3,523	28,909
Rejected Applications	12,332	111,199
Total Pending	17,961	207,199

(d) *Indicate the date of the oldest biotechnology patent application which has not been examined but is still pending.*

The oldest biotechnology application that had not been examined as of 10/31/97 was filed on 3/31/94.

(e) *Indicate the number of judicial decisions issued on biotechnology patents or patent applications during the past five years.*

The total number of judicial decisions rendered on biotechnology patents or patent applications, regardless of the issue involved, was 30.

(f) *Indicate the median time that is required for examination of a biotechnology patent application and grant of the patent by your examining authority. Indicate the median time required for applications in general (in all technologies) to be examined from the time of filing.*

Average Pendency to Issue or Abandonment (withdrawal of application) for biotechnology applications was 27.0 months.

Average Pendency to Issue or Abandonment (withdrawal of application) for all technology areas was 21.6 months.

(g) *Indicate the number of plant variety protection certificates/rights filed and granted in your country over the past 10 years.*

Number of plant variety protection applications filed (USDA) over the past 10 years: 3,136.

Number of plant variety protection certificates issued (USDA) over the past 10 years: 2,045.