

Original: Spanish – English
Translation: non FTAA Secretariat

FTAA – NEGOTIATING GROUP ON INTELLECTUAL PROPERTY RIGHTS

DOCUMENT FROM THE CHAIR

TEXT FOR THE CHAPTER ON INTELLECTUAL PROPERTY RIGHTS
PATENTS, UTILITY MODELS, RIGHTS OF BREEDERS OF PLANT VARIETIES, AND UNDISCLOSED
INFORMATION

PART II. INTELLECTUAL PROPERTY RIGHTS

SECTION 6. PATENTS [FOR INVENTIONS]

Article 1. Patentable Subject Matter

[1.1. [Subject to the provisions of article 3 (Exceptions to Patentability),] each Party shall make patents available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.]

[For purposes of this Article, a Party may treat the terms "inventive step" and "capable of industrial application" as being synonymous with the terms "non-obvious" and "useful", respectively.]

[1.1. Each Party shall apply Article 27 of the TRIPS Agreement *mutatis mutandis*.]

[1.1. Each Party shall apply article 27.1 of the TRIPS Agreement. For these purposes:]

[a) An invention shall be considered new when it does not form part of the prior art.]

[Prior art comprises [everything][the body of technical knowledge] which had been made public before the filing date of the patent application, or where applicable, the priority date claimed by written or oral description, [use, marketing,][by exploitation] or any other means [of dissemination or information anywhere in the world.]

[Solely for the purpose of determining novelty, other pending patent applications with an earlier filing or priority date shall be considered as part of the prior art as long as their content is included in an earlier published application.]

[b) An invention shall be regarded as involving an inventive level if, for a person skilled in the relevant art, such invention is neither obvious nor obviously derived from the prior art.]

[b) There shall be inventive step if, for a person skilled in the relevant art, the creative process or the results thereof cannot be deduced from the prior art.]

[c) An invention shall be regarded as industrially applicable when its subject matter may be produced or used in any type of industry; industry being understood as that involving any productive activity, including services.]

[c) An invention shall be regarded as industrially applicable when its subject matter is conducive to the achievement of a result or a product that may be produced or used in any type of industry.]

[1.2. Each Party shall exclude information contained in public disclosures used to determine if an invention is novel or has an inventive step if the public disclosure was made or authorized by, or derived from, the patent applicant and occurs within 12 months prior of the date of filing of the application in the Party.]

[1.3. Subject to the exceptions in this Chapter, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether the products are imported or locally produced.]

[Each Party may prohibit, regulate, or limit the exploitation of patented inventions, and no provision of this Chapter shall be construed in any other manner.]

[1.4. Microorganisms shall be patentable as long as different measures are adopted as a result of the examination established in subsection b) article 27, No 3 of the TRIPS Agreement. For this purpose, account shall be taken of the commitments assumed by the Parties under the Convention on Biological Diversity.]

[1.5. The following shall not be considered inventions [among others]:]

- [a] Discoveries [that consist of making known or revealing something already existing in nature, although previously unknown to man;]
- [b] [Theoretical or scientific principles;][scientific theories, and mathematical methods;]
- [c] All or part of any living being, as found in nature, natural biological processes, and biological material, as existing in nature or isolated there from, including the genome or germ plasm of any living being;]
- [c] [All [or part of]] biological [and genetic] material existing in nature [or a replica thereof, in the biological processes implicit in animal, plant and human reproduction, including genetic processes involving material of such a nature as to produce a replica of itself under normal and free conditions as in nature];]
- [c] All types of living matter and substances preexisting in nature;]
- [d] literary and artistic works or any other creation protected by copyright;]
- [e] [Schemes,] plans, rules, and methods [for the pursuit of intellectual activities, games, economic and commercial activities;][for performing mental acts, games or businesses];]
- [e] Economic or business plans, principles or methods and those related to purely mental or industrial activities or to games;]
- [f] modes for presenting information.]
- [g] Computer programs *per se*;]
- [h] Diagnostic, therapeutic and surgical methods for the treatment of the human body or animals; and,]
- [i] The juxtaposition of previously known inventions or mixtures of known products, variations in their form, dimensions or materials, except when in reality such combination or fusion does not function separately, or where the qualities or functions characteristic thereof are modified to obtain an industrial result that is non-obvious to a technical specialist in the respective field.]
- [j] Products or processes already patented based on a different use to the one covered by the original patent.]

Article 2. Exceptions to Patentability

[2.1. Each Party may exclude inventions from patentability only as defined in paragraphs 27.2 and 27.3 a) of the TRIPS Agreement.]

[2.1. Each Party may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public*, security, morality and mores, including to protect and promote human health and preserve human, animal and plant life, nutrition of the population, or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by its domestic laws.]

[2.1. The following inventions shall not be patentable nor shall they be published:

- a) Inventions the exploitation of which would be contrary to public order or morality.
- b) Inventions that are clearly contrary to human or animal health or life or that may cause serious environmental damage.
- c) Plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and micro-biological processes.]

[2.2. Each Party may provide for exceptions pursuant to article 27.3 of the TRIPS Agreement.]

[2.3. However, each Party shall provide for protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. [For the purposes of the previous paragraph, the system of breeder's rights set forth in the International Convention for the Protection of New Varieties of Plants (UPOV) shall be considered an effective *sui generis* system.]]

Article 3. Rights Conferred

[3.1. Each Party shall apply article 28 of the TRIPS Agreement.]

[3.2. The scope of the protection conferred by a patent shall be determined by the wording of the claims. The description and drawings, or the deposit of biological material, where applicable, shall be used in the interpretation of the claims.]

[3.3. When the patent protects a biological product or process that claims to have specific characteristics, the protection shall also cover any biological material derived through multiplication or propagation of the patented product or the material directly obtained from the process, and having the same characteristics.]

[3.4. When the patent protects a specific genetic sequence or biological material containing that sequence, the protection shall also cover any product that includes that sequence or material expressing that genetic information.]

Article 4. Exceptions to Rights Conferred

[4.1. Each Party may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.]

[4.1. Each Party may provide for exceptions pursuant to article 30 of the TRIPS Agreement.]

[4.2. The patent owner may not exercise the right referred to in article 4 (Rights Conferred) with respect to acts carried out:

- a) in a private circle and for non-commercial purposes;
- b) exclusively to experiment with the subject matter of the patented invention;
- c) exclusively for the purposes of teaching or scientific or academic research;
- d) the acts referred to in Article 5Ter of the Paris Convention on the Protection of Industrial Property;
- e) where the patent protects biological material that is capable of being reproduced, except for plants, using that material as a basis for obtaining a viable new material, except where the patented material must be used repeatedly to obtain the new material.]

[4.3. The rights conferred by a patent may not be enforced against a person who can prove that, prior to the date of application or, if appropriate, the date of priority of the application for the corresponding patent, he or she was already producing the product, or using the procedure that constitutes the invention in the country. That person shall have the right to continue producing the product and using the procedure as he or she had been doing, but this right may only be transferred or assigned together with the establishment or enterprise in which such production or use was being made. This exception shall not apply if the person acquired knowledge of the invention by unfair means.]

[4.4. Each Party may provide in its legislation that the rights conferred to patent holders shall not prevent unauthorized third parties from making, in necessary and sufficient quantity, the patented product or the product produced using the patented procedure and to perform all the other acts necessary for the purposes of approving the marketing of products. Marketing thereof shall be done following the expiry of the patent.]

[4.4. Where a Party permits the use of a patented invention to generate information required by a regulatory authority to obtain approval to market a product, such Party shall limit such use to acts reasonably performed to generate information to demonstrate that a product is scientifically equivalent to a previously approved product, provided, however, that:

- a) where the grant of the patent precedes the approval for marketing of the product subject to the patent, the Party shall extend the term of the patent by a period sufficient to confer a reasonable term of exclusivity;
- b) any product produced under this authority shall not be commercially used, sold or offered for sale in the Party or exported outside the territory of the Party except as reasonably performed for obtaining marketing approval; and
- c) the patent owner shall be provided notice of the identity of any entity that includes data generated under this authority in an application for marketing approval based on the previously approved product that seeks the authority to market the product prior to expiration of the patent.]

Article 5. Other Use¹Without Authorization of the Right Holder

[5.1. Article 31 of the TRIPS Agreement shall apply, *mutatis mutandis*, to use without the right holder's authorization.]

[5.1. Each Party shall apply article 31 of the TRIPS Agreement, maintaining the right to determine the grounds or reasons for authorizing use by third parties without the authorization of the right holder, that are different from the limitations and exceptions established in this chapter.]

[5.1. On expiration of a three-year period following a patent grant, or four years following the application for a patent, whichever is longer, each Party may grant a compulsory license mainly for the industrial manufacture of the product covered by the patent, or for full use of the patented process, at the request of any interested party, but only if, at the time of the request, the patent had not been exploited in the Party in which the license is sought, or if the exploitation of the invention had been suspended for more than one year.

- a) Compulsory licenses shall not be granted if patent owners are able to give valid reasons for their failure to act, which may be reasons of *force majeure* or an act of God, in accordance with the domestic provisions in effect in each Party.
- b) A compulsory license shall be granted only if, prior to applying for it, the proposed user has made efforts to obtain a contractual license from the patent holder on reasonable commercial terms and conditions and that such efforts were not successful within a reasonable period of time.
- c) Following the declaration by a Party of the existence of public interest, emergency, or national security considerations, and only for so long as those considerations exist, the patent may be subject to compulsory licensing at any time. In that case, the competent national office shall grant the licenses that are applied for. The owner of the patent so licensed shall be notified as soon as is reasonably possible.
- d) Each Party shall specify the scope or extent of the compulsory license and, in particular, the term for which it is granted, the subject matter of the license, and the amount of remuneration and the conditions for its payment.
- e) The grant of a compulsory license for reasons of public interest shall not reduce the right of the patent owner to continue exploiting it.
- f) Each Party shall refuse termination of a compulsory license if and when the conditions that led to the granting of the license are likely to recur.
- g) Each Party shall grant a license, upon request by the owner of a patent whose exploitation necessarily requires the use of another patent, and that right holder has been unable to secure a contractual license to the other patent on reasonable commercial terms. That license shall subject to the following conditions:
 - i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

¹ [To be determined.]

- ii) the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and,
- iii) the license authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.
- h) The provisions of this article shall be applied to cases covered by Section II-13 (Intellectual Property Rights-Control of Anticompetitive Practices in Contractual Licenses) of the present chapter.]

[5.1. Where a Party permits use of the subject matter of a patent without the authorization of a patent owner by the Government of the Party or by a private entity acting on behalf of the Government of the Party, such authorization shall comply with the following conditions:

- a) The authorization shall be granted only for public non-commercial purposes or in situations of a declared national emergency or other situations of extreme urgency.
- b) The authorization shall be limited to the making, using or importing of the patented invention solely to satisfy the requirements of the Government use, and shall not entitle a private party acting on behalf of the Government to sell products produced pursuant to such authorization to a party other than the Government, or to export the product outside the territory of the Party.
- c) The patent owner shall be provided with reasonable and entire compensation for such use and manufacture.
- d) No Party shall require the patent owner to transfer undisclosed information or technical "know how" related to a patented invention that has been subjected to involuntary use authorization.

No Party shall grant authorizations to third parties to use the subject matter of the patent without the consent of the patent owner, other than in circumstances specified in article 5 (Exceptions), unless to remedy a practice determined after judicial or administrative process to be anti-competitive under the competition law of the Party. Each Party recognizes that an intellectual property right does not necessarily confer market power upon its owner.].

[5.2. Each Party shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which may result from the exercise of the exclusive right to conferred by the patent, for example, failure to work.]

[5.3. A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license.]

[5.4. Each Party has the right to grant other uses without the authorization of the right holder, with said uses understood to be compulsory licenses, as well as the freedom to determine the bases on which said licenses are granted.]

[5.5. Each Party has the right to determine what constitutes a national emergency or other circumstance of extreme urgency, with the understanding that public health crises, including those related to HIV/AIDS, tuberculosis, malaria, and other epidemics, may constitute national emergencies.]

[5.6. For the purpose of determining what is understood to be reasonable commercial terms and conditions, the particular circumstances of each case must be taken into account as well as the average royalty for the sector in question in licensing agreements between independent parties.]

[Article 6. Exhaustion of Rights]

[6.1. A patent shall not confer on its owner the right to proceed against a third party making commercial use of a product protected by the patent once that product has been introduced into the commerce of any country by the owner or another person authorized by, or with economic ties to the owner of the patent.

For the purposes of the preceding paragraph, two persons shall be deemed to have economic ties when one of the persons is able to exercise a decisive influence on the other, either directly or indirectly, with respect to the exploitation of the patent, or when a third party is able to exert such influence over both persons.

Where the patent protects biological material capable of reproduction, the patent coverage shall not extend to the biological material that is obtained by means of the reproduction, multiplication, or propagation of material that was introduced into commerce, as described in the first paragraph, provided that it was necessary to reproduce, multiply, or propagate the material in order to fulfill the purposes for which it was introduced into commerce, and that the material so obtained is not used for multiplication or propagation purposes.]

[6.1. This Chapter shall not affect the right of each Party to determine the conditions under which exhaustion of rights shall operate with regard to any products placed legitimately on the market by the patent holder or by an authorized third party.

However, each Party undertakes to review its domestic laws within a maximum period of 5 years from entry into force of this Agreement with a view to adopting at least the principle of regional exhaustion *vis a vis* all countries signatories to this Agreement.]

[6.1. Each Party shall be free to establish the Exhaustion of Rights regime it deems appropriate and those provisions shall not be subject to challenge by the other parties, except for the provisions on National Treatment and Most Favored Nation Treatment.]

[6.2. These rights shall be limited to the provisions of TRIPS Article 6 with regard to the international exhaustion of the rights conferred.]

Article 7. Revocation/Forfeiture

[7.1. Each Party shall apply article 32 of the TRIPS Agreement.]

[7.2. Each Party may revoke or forfeit a patent only when grounds exist that would have justified a refusal to grant the patent.]

[Administrative proceedings provided by a Party that permit a third party to challenge a finding that a patent complies with requirements of the patent law of the Party shall be limited to grounds that would have justified a refusal of the grant of the patent. Where such proceedings include opposition proceedings, opposition proceedings shall not be made available prior to the grant of the patent.]

Article 8. Term of Protection.

[8.1. The term of protection available shall not end before the expiration of a nonrenewable period of twenty years, counted from the filing date.]

[8.1. Each Party shall apply article 33 of the TRIPS Agreement.]

[8.2. Each Party, at the request of the patent owner, shall extend the term of a patent to compensate for unreasonable delays that occur in granting the patent. For the purposes of this paragraph, an unreasonable delay shall at least include a delay in the issuance of the patent of more than four years from the date of filing of the application in the Party, or two years after a request for examination of the application has been made, whichever is later, provided that periods of time attributable to actions of the patent applicant need not be included in the determination of such delays.]

[8.3. Where a Party provides for the grant of a patent on the basis of an examination of the invention conducted in another country, that Party, at the request of the patent owner, shall extend the term of a patent granted under such procedure by a period equal to the period of the extension, if any, provided in respect of the patent granted by such other country.]

[Article 9. Process Patents: Burden of Proof]

[9.1. Each Party shall apply article 34 of the TRIPS Agreement.]

Article 10. Procedural Issues

[10.1. Each Party shall respect the principle of first to file, especially in the case of the right of priority stipulated in Article 4 of the Paris Convention (1967). Once the requirements for patentability have been met, the patent shall be granted to the first applicant whose filing has produced effects under the Paris Convention (1967).]

[10.2. Each Party shall ensure that procedures for the granting of patents are sufficiently clear, and respect the principles of due process.]

[10.3. Each Party shall establish a system for patenting inventions, which shall include at least:

- a) measures to ensure that applications in process and annexes thereto are treated confidentially until they are published;
- b) publication of the patent application;
- c) submission of observations or opposition on behalf of third parties;
- d) the option to request that patents granted in breach of the rules in force be declared null and void or be cancelled.]

Article 11. Conditions on Patent Applicants

[11.1. Each Party shall apply article 29 of the TRIPS Agreement.]

[SECTION 8. UTILITY MODELS]

[Article 1. Utility Models]

[1.1. A utility model shall be defined as any new shape, configuration or arrangement of components of any device, tool, implement, mechanism or other object, or any part thereof, [that permits improved or different operation, use, or manufacture of the object incorporating it, or that endows it with any utility, advantage, or technical effect that it did not previously have][insofar as they effect a functional improvement to its use or manufacture and industrially applicable].]

[1.2. Utility models shall be protected by patents or utility model certificates.]

[1.3. The provisions on patents for inventions included in this Chapter shall be applicable to utility models when relevant.]

[Article 2. Term of Protection]

[2.1. Each Party shall protect utility models, for a [non-renewable] period of at least ten years, counted from the filing date.]

[Article 3. Exceptions]

[3.1. The following may not be granted a utility model patent or certificate:]

- [a) Procedures;]
- [b) Chemical, metallurgical or any other type of substance or composition; and,]
- [c) Matters excluded from patent protection.]

[3.2. Each Party may establish limitations and exceptions to the rights of utility model owners provided that such exceptions do not unreasonably conflict with a normal exploitation of the protected models and do not unreasonably prejudice the legitimate interests of the owner of the protected model, taking account of the legitimate interests of third parties.]

[SECTION 10. RIGHTS OF BREEDERS OF PLANT VARIETIES]

[Article 1. General Obligations]

[1.1. Each Party shall recognize and guarantee protection of the rights of breeders of new plant varieties through the issuance of a breeder's certificate or registration.]

[Each Party shall encourage research activities and technology transfer related to the breed of new plant varieties.]

[1.1. Each Party shall grant protection to plant varieties, through patents [or certificates], through an effective *sui generis* [registration] system, such as the system of the International Union for the Protection of New Varieties of Plants – UPOV, or through a combination thereof.]

[1.1. Each Party shall grant protection to plant varieties through breeders' rights established in the system of the International Union for the Protection of New Varieties of Plants (UPOV), in accordance with its national legislation.]

[1.2. For purposes of the previous paragraph, protection shall be granted pursuant to the International Convention for the Protection of New Varieties of Plants (UPOV), 1978 or 1991 Acts, in accordance with the national legislation of each Party.]

[Article 2. Genera and Species to be Protected]

[2.1. The scope of application of this Chapter shall cover all botanical genera and species [, provided that their cultivation, possession or use are not prohibited for reasons of human, animal or plant health][and shall apply, in general, to entire plants, including any type of flower, fruit or seed, and any other part of plants that can be used as material for reproduction or multiplication].

[Article 3. Conditions of Protection]

[3.1. Each Party shall grant breeder's certificates or registration to the creator of a plant variety, provided it is new, uniform, distinct and stable, and that it has been given a denomination which will be its generic designation.]

[3.2. A variety shall be deemed to be new, or novel, if the propagating or multiplication material, or harvested product, has not been sold or otherwise disposed of to third parties, by or with the consent of the breeder or his assignee, for purposes of commercially exploiting the variety.]

[3.3. Novelty shall be deemed to have been lost when:

- a) Exploitation has begun at least one year before the date of filing the application for a breeder's certificate, or claimed priority date, if sale or disposal took place within the territory of any Party;
- b) Exploitation has begun at least four years before, or in the case of trees or vines, earlier than six years before the date of filing the application for a breeder's certificate, or claimed priority date, if sale or disposal took place in the territory other than that of Party.]

[3.4. Novelty shall not be deemed to have been lost by the sale or disposal to third parties, among other things, when those acts:

- a) are the result of an abuse that affects the interest of the breeder or his successor in title;
- b) are part of an agreement to transfer the right in the variety, provided that the variety has not been physically disposed of to a third party;
- c) are part of an agreement under which a third party, on behalf of the breeder, increased supplies of the material of reproduction or multiplication;

- d) are part of an agreement under which a third party undertakes field or laboratory testing, or small-scale processing tests in order to evaluate the variety;
- e) involve harvested material obtained as a byproduct or surplus product of the variety or from the activities mentioned in subparagraphs c) and d) of this paragraph; or,
- f) are performed in any other unlawful manner.]

[3.5. The variety shall be deemed to be distinct if it is clearly distinguishable from any other variety whose existence is a matter of common knowledge at the time of the filing of the application, or any priority claimed.

The filing of an application for the granting of a breeder's certificate or for the entering of another variety in an official register of varieties, in any country, shall be deemed to render that other variety a matter of common knowledge from the date of the application, provided that the application leads to the granting of a breeder's right or to the entering of the said other variety in the official register of varieties, as the case may be.]

[3.6. A variety shall be deemed to be uniform if, subject to the variation that may be expected from the particular features of its reproduction, multiplication or propagation, it is sufficiently uniform in its relevant characteristics.]

[3.7. The variety shall be deemed to be stable if its essential characteristics remain unchanged from generation to generation, and at the end of each particular cycle of reproduction, multiplication or propagation.]

[Article 4. Rights Conferred]

[4.1. The grant of a breeder's certificate shall confer on the owner thereof the right to prevent third parties, without his consent, from carrying out the following acts with respect to the material of reproduction, propagation or multiplication of the protected variety:

- a) production, reproduction, multiplication or propagation;
- b) conditioning for the purposes of reproduction, multiplication or propagation;
- c) offering for sale;
- d) selling or any other act that implies introduction into the market for commercial purposes, of the material of reproduction, propagation or multiplication;
- e) exporting;
- f) importing;
- g) stocking for any of the purposes mentioned in the preceding paragraphs;
- h) commercial use of ornamental plants, or parts of plants, as multiplication material for the purpose of producing ornamental and fruit plants or parts of plants, or cut flowers;
- i) the performance of the acts referred to in the previous paragraphs in respect of harvested material, including entire plants and parts of plants, obtained through the unauthorized use of material of reproduction or multiplication of the protected variety, shall require authorization from the breeder, unless the owner has had reasonable opportunity to exercise his right in relation to the said material of reproduction or multiplication.

The breeder's certificate shall also confer on its owner the rights established in the preceding paragraphs with respect to varieties that are not clearly distinguishable from the protected variety, within the meaning of Paragraph 3.5 (Distinctness) of this Section, and in respect of varieties whose production requires the repeated use of the protected variety.

The competent national authority may confer on the owner, the right to prevent third parties from performing, without his consent, the acts specified in the previous paragraphs, with respect to varieties essentially derived from the protected variety, except where the latter variety is itself an essentially derived variety.]

[Article 5. Exceptions]

[5.1. A breeder's right shall not confer on its owner the right to prevent third parties from using the protected variety when such use is made:

- a) privately, for non-commercial purposes;
- b) for experimental purposes; and
- c) for the purpose of breeding and exploiting a new variety, except in the case of a variety essentially derived from a protected variety. Any such new variety may be registered in the name of its breeder.]

[5.2. Authorization by the breeder shall not be required for the utilization of the variety as an initial source of variation for the purpose of creating other varieties. The authorization to market such plant varieties shall be subject to the laws of each Party. Likewise, such authorization shall be required when the repeated use of the variety is necessary for the commercial production of another variety.]

[5.3. A breeder's right shall not be infringed by a person who stocks and sows for its own use, or for sale as raw material or food, the product of his cultivation of the protected variety. Commercial use of the material of multiplication, reproduction or propagation, including entire plants and parts of plants of fruit, ornamental and forest species, is excluded from this article.]

[5.3. Parties may restrict the breeder's right in order to permit farmers to use for propagating or multiplication purposes, on their own holdings, the product of the harvest of the protected variety.]

[Article 6. Exhaustion of Breeder's Rights]

[6.1. A breeder's right may not be invoked in respect of acts indicated in Article 4 (Rights Conferred) of this Section, when the material of the protected variety has been sold or otherwise marketed by the owner or with his consent unless such acts:

- a) involve further reproduction, multiplication or propagation of the protected variety, subject to the restriction established in Article 9 (Restrictions/National Security-Public Interest) of this Section;
- b) involve an export of the material of the protected variety, which enables its reproduction, to a country which does not protect varieties of the plant species to which the variety belongs, except where the exported material is destined for human, animal or industrial consumption.]

[Article 7. Measures Regulating Commerce]

[7.1. Where necessary, each Party may adopt measures for the regulation or control, in the territory, of the production or marketing, importation or exportation of the material of reproduction or multiplication of the variety, provided that such measures do not imply disregard for the breeder's rights recognized by this Chapter, nor hinder the exercise thereof.]

[Article 8. Licensing and Assignment]

[8.1. The holder of breeder's rights may assign or grant licenses for the exploitation of the variety.]

[8.1. The breeder's right shall be marketable, transferable and inheritable. The owner of the right may grant licenses to third parties for the exploitation of the protected varieties.]

[Article 9. Restrictions/National Security-Public Interest]

[9.1. In order to ensure adequate exploitation of the protected variety, in exceptional cases of national security or public interest, each Party may declare the said variety freely available, subject to equitable remuneration to the breeder.

Each Party shall determine the amount of any such remuneration after hearing arguments from the interested parties and expert opinion, based on the extent of the exploitation of the licensed variety.]

[Article 10. Term of Protection]

[10.1. The right conferred on the breeder shall be for a period of no less than [15][20] years from the date of issue of the title of protection. For vines, forest trees, fruit trees, [and ornamental trees,] including, in each case, their root stocks, the period of protection shall be no less than [18][25] years from the date of issue of the title of protection.]

[Article 11. Variety Denomination]

[11.1. Each Party shall ensure that no rights in the designation registered as the denomination of the variety shall hamper the free use of the denomination in connection with the variety, even after expiration of the breeder's certificate.]

[Article 12. Maintenance of Rights]

[12.1. The owner of a registered variety shall be obliged to maintain it and replace it, as appropriate, throughout the period for which the breeder's certificate is valid.]

SECTION 11. UNDISCLOSED INFORMATION

Article 1. Protection of undisclosed information

[1.1. In the course of ensuring effective protection against unfair competition, as provided in Article 10*bis* of the Paris Convention (1967), each Party shall protect:

- a) undisclosed information in accordance with article 39.2 of the TRIPS Agreement;
- b) data submitted to governments or governmental agencies in accordance with article 39.3 of the TRIPS Agreement.]

[1.2. If a Party requires the submission of information concerning the safety and efficacy of a pharmaceutical or agricultural chemical product prior to permitting the marketing of such product, such Party shall not permit third parties not having the consent of the party providing the information to market the same or a similar product on the basis of the approval granted to the party submitting such information for a period of at least five years from the date of approval.²]

[1.3. To grant such protection, each Party may require that to qualify for protection an industrial or commercial secret must be evidenced in documents, electronic or magnetic means, optical disks, microfilm, films or other similar instruments.]

[1.4. If a Party provides a means of granting approval to market products specified in paragraph 1.2 on the basis of the grant of an approval for marketing of the same or similar product in another Party, the Party shall defer the date of any such approval to third parties not having the consent of the party providing the information in the other Party for a period of at least five years from the date of approval in the Party or the date of approval in the other Party, whichever is later.]

[1.5. Where a product is subject to a system of marketing approval pursuant to paragraphs 1.2 or 1.4 and is also subject to a patent in the Party:

- a) the Party shall not approve an application to market a product on the basis of information in an earlier marketing approval for the same product where that application has been filed by a party other than the recipient of the original marketing approval or with his consent, and shall not otherwise authorize a third party to market the same product, prior to the expiration of the patent; and
- b) the Party shall not alter the term of protection specified in paragraphs 1.2 and 1.4 in the event that the patent expires on a date earlier than the end of the term of such protection.
- c) In addition, if the product is subject to a patent in one Party as well as in another Party, the second Party shall extend the term of the patent within its territory to expire no earlier than the date of expiration of the patent in the first Party.]

[Article 2. Rights Conferred]

[2.1. Each Party shall provide, in its legislation, that any natural or legal person that considers itself to be affected by an act of unfair competition may bring legal action, enabling the competent tribunal to determine the legality or illegality of the act and obtain relief for any damages that the act might have caused.]

² [Where a Party, on the date of its implementation of the TRIPS Agreement, had in place a system for protecting pharmaceutical or agricultural products not involving new chemical entities from unfair commercial use which conferred a period of protection shorter than that specified in paragraph 1.2 that Party may retain such system notwithstanding the obligations of said paragraph.]