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Page: 1/9

Council for Trade-Related Aspects of Intellectual Property Rights

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REVIEW OF THE PROVISIONS OF ARTICLE 27.3(b) OF THE TRIPS AGREEMENT

RESPONSES TO THE CHECKLIST OF QUESTIONS[1]

MEXICO

Addendum

The present document contains the responses to the checklist of questions that the Secretariat received from the delegation of Mexico by means of a communication dated 20 May 2019.

Introduction

I. RESPONSES TO THE ILLUSTRATIVE LIST OF QUESTIONS PREPARED BY THE SECRETARIAT (document IP/C/W/122)

A. Patent Protection of Plant and Animal Inventions

1. To what extent are inventions concerning plants or animals, whether products or processes, patentable under your country's law, if they meet the conditions for patentability stipulated in Article 27.1 of the TRIPS Agreement?

Article 15 of the Industrial Property Law (LPI) defines an invention as any human creation that allows matter or energy existing in nature to be transformed for use by man and to satisfy his specific needs. Article 16 of the LPI establishes that new inventions involving an inventive step that are industrially applicable are patentable, excluding protection for: (i) essentially biological processes for obtaining, reproducing and propagating plants and animals; (ii) biological and genetic material as found in nature; (iii) animal varieties; (iv) the human body and the living matter constituting it; and (v) plant varieties. Article 19 of the LPI does not consider as inventions discoveries that simply reveal or disclose something that exists in nature, even if unknown to humans. This means that processes that are not essentially biological or microbiological, as well as animals or plants bred through a technical process entailing human intervention, may be patentable – provided they are novel, involve an inventive step, are industrially applicable and are sufficiently well described.

2. Where any such inventions are not patentable, even if they meet these conditions:

(i) To what extent is this due to per se exclusions from patentability?

Inventions that meet the conditions set out in Articles 15 and 16 of the LPI are not subject to exclusion.

[1] Documents IP/C/W/122 and IP/C/W/126.

(ii) To what extent is this based on other grounds (for example because conditions for patentability other than those stipulated in Article 27.1 are not met or in order to protect ordre public or morality (see Article 27.2 of the Agreement))?

Article 4 of the LPI provides that no patent whatsoever will be granted for inventions contrary to ordre public or morality. Patents can thus be denied based on a case-by-case analysis – even for inventions, as defined in Article 15 of the LPI, that consist of a process or procedure that is not essentially biological or microbiological, or an animal or plant resulting from human intervention using technical means – if granting the patent would be contrary to ordre public or morality.

3. Please describe any specific provisions, guidelines, final judicial decisions and administrative rulings of general application concerning the application of the conditions for patentability stipulated in Article 27.1 to subject-matter addressed by Article 27.3(b).

There are none.

4. Where plant varieties are not as such patentable subject-matter under your country's law, please indicate the extent to which the scope of protection under patents for inventions concerning plants can nevertheless embrace plant varieties or a botanical taxon whose plants express a trait covered by the claims of a patent.

The LPI excludes the taxonomic level of plant variety; however, if the plant results from a genetic modification procedure that solves a technical problem by virtue of technical characteristics, it may be claimed at a taxonomic level other than plant variety.

5. Please provide any definitions used under your country's law with regard to subject-matter specifically excluded from patentability or specifically patentable (e.g. micro-organisms, microbiological processes, non-biological processes, plant varieties).

Not applicable.

6. To what extent is subject-matter that is identical to what occurs in nature patentable under your country's law?

It is possible to obtain a patent for inventions that consist of biological or genetic material isolated from its natural state and obtained through a technical process, even though it might be identical to what occurs in nature.

7. Explain the requirements under your country's law for ensuring adequate disclosure of the patentable inventions referred to above.

Article 47(I) of the LPI provides that patent applications must be accompanied by:

- A description of the invention, which must be sufficiently clear and complete to permit a full understanding and, as appropriate, to guide its application by a person possessing average skills and knowledge in the subject-matter. It should also include the method best known to the applicant for applying the invention in practice when not clear from the description, as well as information illustrating the industrial application of the invention.

- In the case of biological material in which the description of the invention cannot be provided in detail, the application must be accompanied by certification that the material has been deposited with an institution recognized by the Institute in accordance with the regulations for this law.

Under Article 37 of the LPI Regulations, certification that the biological material has been so deposited will be required when:

I.- the claim is for a microorganism as such;

II.- the biological material referred to in the application is not available to the public; and

III.- the description of the biological material provided is insufficient to permit reproduction by an expert in the subject-matter.

When a patent application refers to a sequence of nucleotides and amino acids, they must be listed in the description and claims.

8. What rights are conferred upon owners of the patents referred to above? Are product and process patents subject to the same rules as other patents? Do they benefit from the same protection as stipulated in Article 28 of the TRIPS Agreement?

Under Article 25 of the LPI, patent holders have the following exclusive rights in respect of their patented inventions (the same exclusive rights as conferred by Article 28 of the TRIPS Agreement):

I.- in the case of a patent for a product, the right to prevent others from manufacturing, using, selling, offering for sale or importing the patented product without consent, and

II.- in the case of a patent for a process, the right to prevent others from using said process and from using, selling, offering for sale or importing products obtained directly by means of the process without consent.

9. Are there any specific exceptions to these rights (affecting the scope or duration of the patents referred to above)? To what extent are exceptions, available in respect of plant variety rights (e.g. those referred to under question B.4(i) below), available in respect of rights conferred upon patent owners?

There are no exceptions that affect the scope or duration of the patent; there are, however, exceptions with respect to uses that are not considered infringements, as set out in Article 22 of the LPI.

Article 22.- The right conferred by a patent shall produce no effect against:

I.- a third party who in the private or academic sphere and for non-commercial purposes engages in scientific or technological research activities for purely experimental, testing or teaching purposes, and to that end manufactures or uses a product or process equivalent to the one patented;

II.- any person who markets, acquires or uses the patented product, or the product obtained by the patented process, after the said product has been lawfully placed on the market;

III.- any person who, prior to the filing date of the patent application, or where applicable the recognized priority date, uses the patented process, manufactures the patented product or begins the necessary preparations for effecting such use or manufacture;

IV.- the use of the invention concerned in transport vehicles of other countries when it forms part of such vehicles and when the vehicles are in transit on the national territory;

V.- a third party who, in the case of patents relating to live material, makes use of the patented product as an initial source of variation or propagation to obtain other products, except where such use is made recurrently; and

VI.- a third party who, in the case of patents relating to products consisting of live material, puts into circulation or markets the patented products for purposes other than multiplication or propagation, after the said products have been lawfully placed on the market by the patent owner or by the person to whom a license has been granted.

Article 22(IV) and (V) of the LPI regulates exceptions and limitations in the use of patented inventions by farmers and plant breeders.

10. Are there any specific provisions under your country's law for compulsory licensing in respect of the patents referred to above?

No. The LPI contains general provisions regulating compulsory licensing on emergency or national security grounds, without distinction as to the type of invention.

B. Protection of Plant Varieties

1. Does your country's law provide for the protection of plant varieties by plant breeder's rights, plant patents or any other *sui generis* system for the protection of plant varieties?

Mexico has a *sui generis* system for the protection of plant varieties, as regulated in the Federal Law on New Plant Varieties.

2. (a) If your country is a party to the International Convention for the Protection of New Varieties of Plants (UPOV), please indicate which Act or Acts of the UPOV Convention your country has signed; which it has ratified; to which it has acceded; and to the standards of which its law conforms but to which it has not (yet) adhered.

Mexico is a party to the UPOV of 2 December 1961, as revised in Geneva on 10 November 1972 and 23 October 1978.

Mexican law is consistent with the 1978 Act.

(b) If your country is not a party to the UPOV Convention, does the protection offered to plant varieties under your country's law conform to the standards of any of the Acts of the UPOV Convention and, if so, which?

Not applicable.

3. Please indicate whether concurrent protection under your country's plant variety protection law and its patent law is available (see also question A.4 above).

No concurrent protection is available, in that plant varieties are not patentable under patent law.

4. Please provide the following details of your country's *sui generis* system for the protection of plant varieties:

(a) the relevant laws and regulations and, if they have been notified to the Council for TRIPS, a reference to the relevant WTO documents;

Federal Law on New Plant Varieties (LFVV) and its Regulations.

(b) the definition of "plant variety";

For "plant variety", the LFVV uses the Spanish term *"variedad vegetal"*, which it defines as "a subdivision of a species that includes a group of individuals with similar characteristics that is considered stable and homogeneous".

(c) the conditions required for protection;

The plant variety must be novel, distinct, stable and homogeneous, and must have a denomination.

(d) the extent to which subject-matter that is already known to the public or identical to what occurs in nature is protectable under your country's *sui generis* system for the protection of plant varieties;

No.

(e) the extent to which protection can be based on characteristics of germplasm, as opposed to characteristics of plant varieties derived from such germplasm;

Protection is based on the expressed morphological features of a group of plants that is characterized overall by distinction, homogeneity and stability.

(f) who is entitled to the rights;

A natural or legal person that has used an improvement process to obtain and develop a plant variety of any genus and species.

(g) the procedure for the acquisition of rights, including the authority in charge of administering the rights;

An application for issuance of a breeder's title must be submitted to the Ministry of Agriculture and Rural Development.

(h) the rights conferred;

I.- the right to be recognized as the breeder of a plant variety, a right that is inalienable and imprescriptible, and

II.- the right to utilize and exploit, exclusively and temporarily (for the duration indicated in (j) below), directly or through a third party with his consent, a plant variety and its propagation material, for its production, reproduction, distribution or sale, as well as for the production of other plant varieties and hybrids for commercial purposes.

(i) exceptions to the rights conferred, such as:

- **acts performed for research or experimental purposes;**
- **acts performed to develop new varieties of plants;**
- **acts performed to commercialize such newly developed varieties;**
- **any "farmer's privilege" (e.g. acts performed by a farmer on his own land in respect of seed saved from the previous harvest);**
- **acts done privately and for non-commercial purposes;**
- **compulsory licensing.**

The consent of the breeder of a plant variety is not required for it to be used as follows:

I.- as a source or an input for research into the genetic improvement of other plant varieties;

II.- for the multiplication of propagation material, provided it is for personal use as grain for consumption or sowing, in accordance with the regulations for this law and Official Mexican Standards established by the Ministry of Agriculture and Rural Development; or

III.- for human or animal consumption, benefitting only the person who harvests it.

The Ministry of Agriculture and Rural Development can issue emergency licences.

(j) the duration of protection;

I.- eighteen years in the case of perennials (forest, fruit and ornamental species and vines), including their rootstocks; and

II.- fifteen years for all other species.

These periods will run from the date of issuance of the breeder's title. After they elapse, the plant variety, its use and exploitation will enter the public domain.

(k) transfer of rights;

The rights conveyed by the breeder's title, with the exception of the right to be recognized as the breeder of a plant variety, may be taxed and transmitted wholly or partially by means of any legal title before a notary public.

(l) enforcement of the rights;

Whosoever utilizes or exploits a plant variety, or propagation material thereof, during the time between the date on which the submission of the application is recorded and the issuance of the

relevant breeder's title, without the consent of the legitimate breeder at that time, will be responsible for any damages caused to the latter, who may claim such damages as from the effective starting date of the title.

In administrative proceedings for the imposition of penalties for infringements under the LFVV the Ministry of Agriculture and Rural Development may also take the following provisional measures:

I.- order the withdrawal from circulation or prevent the distribution of plant varieties or propagation material that infringe rights protected by this law;

II.- order the withdrawal from circulation of articles, packaging, packing, containers, stationery, advertising material and the like that infringe any of the rights protected by this law;

III.- seize goods that infringe rights protected by this law; and

IV.- order the alleged infringer to suspend or discontinue activities that constitute an infringement of the provisions of this law.

If any of these measures is taken, the affected party and interested parties will be notified and the circumstance will be noted in the act issued to this effect.

If the plant variety or propagation material is being commercialized, merchants will be required to refrain from disposing of it as from the date on which they are notified of the measure taken.

The same requirement will apply to producers, nursery operators, manufacturers, importers and their distributors, who will be responsible for immediately recovering the plant varieties or propagation material already on the market.

The provisional measures indicated above may be ordered at the request of an interested party.

II. RESPONSES TO REPRESENTATIVE QUESTIONS FOR TRIPS 27.3(B) REVIEW SUBMITTED BY THE DELEGATIONS OF CANADA, THE EUROPEAN UNION (FORMERLY EUROPEAN COMMUNITIES), JAPAN AND THE UNITED STATES (DOCUMENT IP/C/W/126)

A. Patent System Questions

1. In your territory, is there any basis for denying a patent on an invention consisting of an entire plant or animal that is novel and involves an inventive step?

Yes. Article 16(III) and (V) of the LPI provides that plant and animal varieties are not patentable. That exclusion, however, does not apply to microorganisms or inventions resulting from processes that are non-biological or microbiological.

2. If the answer to question 1 is yes, please respond to the following questions:

(a) Does your patent system exclude entire plants or animals as inventions? If it does, please cite the legal basis for this.

No. The LPI refers only to animal and plant varieties as such. Related inventions must consist of a human creation that allows matter or energy existing in nature to be transformed for human use and to satisfy specific human needs. They must also be novel, involve an inventive step and be suitable for industrial application, in accordance with Articles 15 and 16 of the LPI.

(b) If your patent system does recognize entire plants and animals as inventions, does it exclude all such inventions from being patentable subject-matter, or does it only exclude certain types of plants or animals? If it excludes all, please cite the legal basis for their exclusion (e.g. lack of industrial applicability). If it excludes only certain types, please identify the categories or characteristics of inventions that are excluded and cite the legal basis for their exclusion.

The LPI refers only to plant and animal varieties and to human beings as such and excludes them from patentability. However, microorganisms and the results of processes that are non-biological or microbiological are not excluded.

(c) Is there any other basis in your law that precludes the grant of a patent on any categories of plant or animal inventions that otherwise are novel, involve an inventive step and are capable of industrial application? If so, please cite the legal basis for that exclusion from patent eligibility.

Yes. Article 4 of the LPI prohibits the grant of patents whose content is contrary to ordre public and morality.

3. Other than with respect to subject-matter you defined as being ineligible to be patented under question (2), is it possible in your territory to obtain a patent claim defined in any of the following ways?

(a) A patent claim that is not limited to a specific plant or animal variety.

No. Plant and animal varieties cannot be patented.

(b) A patent claim that is expressly limited to a plant or animal variety.

No. Plant and animal varieties cannot be patented.

(c) A patent claim that is expressly limited to a group of plants or animals, where the group is defined through reference to a shared characteristic such as incorporation of a particular gene.

There are two different responses to the question as formulated, based on two different scenarios:

(I) If the shared technical characteristic is intrinsic to the individual (plant or animal), the individual would be considered "wild", so the purpose of the claim would be interpreted as protection of a discovery, animal variety or plant variety. In that case, under Article 16(III) and (V) of the LPI – or perhaps under Article 16(IV), which excludes the human body and live parts thereof from patentability – the claim would pertain to unpatentable subject-matter.

(II) If the shared technical characteristic results from human intervention by means of a technical process to meet a specific need (Article 15 of the LPI), then the individual plant or animal would be considered patentable, and a patent could be granted in response to the claim.

(d) If the answers you provide to question (3)(a) to (c) vary, please provide the definitions of a "plant variety" and an "animal variety" that are used by your examining authority.

Not applicable.

4. Is it possible to obtain a patent in your territory on a microorganism that is novel, involves an inventive step and is capable of industrial application? If not, please identify the legal basis under which these inventions are deemed ineligible to be patented.

Yes. Microorganisms can be patented.

5. Is it possible to obtain a patent in your territory on an essentially biological process for the production of a plant or animal (i.e. a process limited to those acts that are necessary for sexual or asexual reproduction of a plant or animal)? If not, please identify the legal basis under which a patent on such a process would be denied.

No. Article 16(I) of the LPI provides that essentially biological processes cannot be patented.

6. Is it possible to obtain a patent in your territory covering subject-matter that is identical to that found in nature (e.g. a plant or animal in its natural state)?

No. Article 15 of the LPI defines an invention as any human creation that allows matter or energy existing in nature to be transformed for human use and to satisfy specific needs. Article 16(II) of the LPI excludes from patent protection biological and genetic material as found in nature, and Article 19(II) of the LPI does not consider as inventions discoveries that simply reveal or disclose what already exists in nature, even if previously unknown to humans.

There is no exclusion, however, for inventions consisting of biological or genetic material isolated from its natural state and obtained by a technical process, even if identical to what is found in nature.

B. Plant Variety Protection Systems

7. Do the laws applicable to your territory provide for a *sui generis* form of protection for a new plant variety?

Yes. The applicable legislation in Mexico is the Federal Law on New Plant Varieties and its implementing regulations. The Law entered into force in 1996, and its implementing regulations were promulgated in 1998.

8. If the answer to question 7 is "yes", does that protection conform to the standards defined in one of the Acts of the International Convention for the Protection of New Varieties of Plants (UPOV)?

Yes.

9. If the answer to question 8 is "yes", please specify the Act of the UPOV Convention upon which your legislation is based (i.e. the 1991 Act, the 1978 Act or the 1961/1972 Act).

Mexico acceded to the UPOV (the 1978 Act) in 1997.

10. If *sui generis* protection for plant varieties is provided in your territory, would any of the following acts require the prior authorization of the right holder?

(a) acts performed for research or experimental purposes, or to develop new varieties of plants;

No. Article 5 of the LFVV provides that the consent of the breeder of a plant variety is not required to use that variety as a source or input for research into the genetic improvement of other plant varieties.

(b) acts performed to commercially exploit a variety distinct from the protected variety but sharing its essential characteristics;

No, provided that at least one of the plant variety's relevant characteristics is technically and clearly distinct.

(c) acts performed by a farmer of harvesting seed from his planting of a protected variety legitimately obtained, storage of that seed, and replanting of that seed on the farmers' land.

Authorization is not required provided that the seed is for personal use as grain for consumption or sowing, in accordance with the regulations to the LFVV and the Official Mexican Standards established by the Ministry of Agriculture and Rural Development, or is for human or animal consumption, benefitting only the person who harvests it.

If prior authorization is not required for any of the above examples of activities, is there any requirement that the party undertaking the specified actions provide the right holder with remuneration in any form?

Any person wishing to commercialize a protected variety must obtain authorization from the holder of the breeder's right. Such authorization is generally granted in the form of a licensing agreement between the right holder and the persons interested in exploiting the variety.

11. Can protection be obtained for a plant variety that was known to the public, or was publicly available, prior to the application for *sui generis* protection for that plant variety, and, if so, under what conditions (i.e. what are the time-limits during which public disclosure or availability will not preclude the grant of protection)?

Yes, it is possible, provided that the plant variety:

(a) has not been disposed of in national territory or was disposed of during the year prior to the date on which the application for the breeder's title was submitted, and

(b) has not been disposed of abroad or was disposed of during:

(i) the six years prior to submission of the application in the case of perennials (forest, fruit and ornamental species and vines), including their rootstocks, or

(ii) the four years prior to submission of the application for all other species.

12. Can protection be predicated on identification of an unexpressed gene, on an unexpressed set of genes present in the genome of the plant variety, or on the characteristics of germplasm, rather than the expressed characteristics of plant varieties derived from such genes or germplasm?

No. Protection under the UPOV system is based on the expressed morphological features of a group of plants characterized overall by distinctness, homogeneity and stability.

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