

REVIEW OF THE PROVISION OF TRIPS ARTICLE 27.3(b)

Responses to Checklist of Questions

Addendum

MOLDOVA

The following communication, dated 20 November 2003, is being circulated at the request of the Delegation of Moldova.¹

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?*

According to Article 4(1) of the Law on Patents for Inventions (No.461/1995), an invention in any field of technology may be patented if it is new, if it involves an inventive step and if it is susceptible of industrial application. An invention may concern a product or a process, including micro-organisms, or the use of a known product or process for new purposes. Patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

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?*

Discoveries are not considered patentable inventions. But, if a discovery is practically applied, it could be the subject of a patentable invention. The following shall not be deemed patentable inventions: the human body at every stage of its formation and development, or *per se* elements of that (Article 4(2), Law on Patents for Inventions).

¹ The questions to which answers are provided are those which can be found in document IP/C/W/273.

- (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))?*

There are excluded from patentability the inventions, the prevention of commercial exploitation of which is necessary to protect *ordre public* or morality, including the necessity to protect human, animal or plant life or health or to avoid serious prejudice to the environment, in particular the processes for cloning a human being; the processes for modifying the germinal genetic identity of human beings; the utilization of the human embryo in non-medical industrial and commercial purposes; the processes for modifying the identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes (Article 4 (3), Law on Patents for Inventions).

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).*

Subject matter of Article 27.1 of the TRIPS Agreement, patentable inventions are also considered those, that refer to a product, which consist of or contain biological material, or refer to a method for reproduction, processing or utilization of a biological material.

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.*

Plants can be protected under patents for inventions only in case the claims do not limit to a certain plant variety because plant varieties are protected in the Republic of Moldova by the Law on the Protection of Plant Varieties (Article 4(2)h, Law on Patents for Inventions).

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).*

According to Article 4(2)h of the Law on Patents for Inventions, plant varieties are not considered patentable inventions as subject-matter under this law.

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

Products that are identical with those which already exist in nature are not patentable because they are discoveries, which are not considered patentable inventions (Law on Patents for Inventions, Article 4(2)). If such a product was isolated from its natural environment or produced by means of a creative technical process, it may be the subject of an invention.

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

According to the Law on Patents for Inventions, Article 10(2)b, an invention shall be disclosed in a manner sufficiently clear and complete to be carried out by a person skilled in the art. If the invention refers to a reproducible biological material that cannot be disclosed in such a manner as to enable a person skilled in the art to reproduce it or if such material is not freely accessible, an

attestation concerning the deposit of the material with the depositary institute designated by the Government or with a body having the status of international depositary authority shall be attached to the application. The deposit must have been made prior to the filing date of the patent application (Law on Patents for Inventions, Article 10(4)).

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?*

In accordance with the provisions of Article 23 of the Law on Patents for Inventions, that implements the provisions of Article 28 of the TRIPS Agreement, the owner of a patent shall enjoy the exclusive right to exploit the invention, to dispose of the patent and to prohibit others who act without his consent to carry out the following activities:

- a) the manufacture, use, import, offering for sale, sale and any other form of placing on the market, or holding for such purpose, of a product obtained by means of the invention protected by the patent;
- b) where the subject matter of a patent is a process, to prevent third parties not having owner's consent from the act of using the process, and from the acts of using, offering for sale, selling, or importing for these purposes the product obtained by that process.

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 14(i) below), available in respect of rights conferred upon patent owners?*

The use of an invention protected by a patent shall not constitute an infringement of the patent owner's exclusive right for the performance of research work or scientific experimentation for assessing the application of the subject matter of the invention or for non-commercial purposes; in relation to exceptional circumstances, such as natural disasters, catastrophes and epidemics, and the like; for the occasional preparation of medicines on a medical prescription; for private purposes without gain (Law on Patents for Inventions, Article 24(1)). The exceptions concerning the patent owner's right for the performance of research work or scientific experimentation for non-commercial purposes or for private purposes without gain are similar with the exceptions, available in respect of owner's right in case of utilization of a protected plant variety.

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

N.B. Please ensure that your responses to the questions above cover each category of subject-matter specified in Article 27.3(b), namely micro-organisms, essentially biological processes for the production of plants or animals, microbiological processes, non-biological processes; plant varieties and other inventions concerning plants or animals.

Every invention protected under a patent can be subject matter of a non-exclusive compulsory licence granted by the judicial authorities, in accordance with the conditions stipulated by the Law on Patents for Inventions, Article 33.

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?*

The Law No. 915/1996 on the Protection of Plant Varieties protects plant varieties. Rights in a variety are recognized and protected on the territory of the Republic of Moldova and are certified by the grant of a variety patent.

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.*

(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?*

The Republic of Moldova has been a member of UPOV since 18 November 1998, and has ratified the 1991 Act, harmonizing the national legislation in compliance with the standards of the above-mentioned Act.

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).*

Plant varieties are protected only under the Law on the Protection of Plant Varieties; their protection under the Law on Patents for Inventions is not available.

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;*

The Law No. 915/1996 on the Protection of Plant Varieties and The Regulations on Application of the Law No. 915/1996 on the Protection of Plant Varieties were notified to the TRIPS Council.

(b) *the definition of "plant variety";*

According to Article 1 of the Law 915/1996, "variety" means a plant grouping created by selection, which grouping:

- conforms to the criteria of patentability;
- presents the characteristics of a given genotype or combination of genotypes; can be distinguished from any other plant grouping of the same botanical taxon by the expression of at least one of the said characteristics;
- may be represented by a single plant or plants, or by a single part or parts thereof provided that such part or parts may be used for the reproduction of entire plants of the variety.

(c) *the conditions required for protection;*

According to the Law 915/1996 (Article 5), a plant variety shall be patentable only where it is new, distinct, uniform and stable. The plant variety shall have a denomination in compliance with the provisions of the Law.

(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;*

A plant variety that is identical to a plant that already exists and was not created as a result of selection (Law on the Protection of Plant Varieties, Article 1), or became known to the public in the Republic of Moldova territory earlier than one year before the date of filing an application for the grant of a patent, and in the territory of any other State, earlier than four years, or in case of varieties of trees, fruit trees and grapevines, earlier than six years before the said date, is not patentable (Law on the Protection of Plant Varieties, Article 6).

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

A plant variety can be protected if it is clearly distinguishable by one or more characteristics from any other variety whose existence is a matter of common knowledge. These characteristics could have morphological, physiological and/or biochemical nature, provided that they could be distinguished and described (Law on the Protection of Plant Varieties, Article 2).

(f) *who is entitled to the rights;*

The right to obtain a patent belongs to the breeder or his successor in title. Where several breeders have bred the variety, the right to obtain a patent shall belong to all breeders jointly. If a variety has been bred in the line of duty, the right to obtain a patent belongs to the employer unless otherwise provided in the employment contract (Law on the Protection of Plant Varieties, Article 11).

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

The procedure for the acquisition of rights includes: filing an application and presenting the necessary documents with the State Agency on Industrial Property Protection which carries out the preliminary and as to form examination and published the particulars of application; testing as to distinctness, uniformity and stability by the State Commission of the Republic of Moldova for Variety Testing; publication of the decision to grant a patent or to reject the application; granting of the patent (Law on the Protection of Plant Varieties, Articles 16, 20, 21, 22, 26).

(h) *the rights conferred;*

The patent owner holds the exclusive right on the protected patent and on the new variety of plant, authorizing him to exploit, under the condition that in the course of exploitation it does not infringe the rights of other patent owners, to use it and prohibit the third parties to perform the following acts with respect to the material of the variety: production or reproduction (multiplication), conditioning for the purpose of propagation,

offering for sale, selling or other marketing, exporting, importing, stocking for any of the purposes mentioned above (Law on the Protection of Plant Varieties, Article 13).

(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 right of the patent owner shall not extend to the use of the material of the protected variety: for private use; for scientific research and experiments or for non-commercial purposes; as initial material for the purpose of breeding other varieties and acts in respect of such other varieties (Law on the Protection of Plant Varieties, Article 14). A protected variety can be subject matter of a non-exclusive compulsory license granted by the judicial authorities without consent of the owner of the patent, in accordance with the conditions stipulated by the Law on the Protection of Plant Varieties, Article 31.

(j) *the duration of protection;*

The term of the patent shall be 25 years from the date of the decision to grant the patent for varieties of trees, fruit trees and grapevine; 20 years from the date of the decision to grant the patent for varieties of other species. At the request of the patent owner the term of the patent may be extended for a period of 10 years (Law on the Protection of Plant Varieties, Article 2).

(k) *transfer of rights;*

The right to own a patent, the rights arising out of the registration of a patent application and the rights afforded by a patent may be assigned to any natural person or legal entity. Transfer of rights may be performed either through an assignment contract, exclusive or nonexclusive license, or through succession, legal or testamentary inheritance. Rights transferred through an assignment contract shall also have effect for third parties and shall determine the alteration of the legal status of the patent immediately as the contract is registered with the Agency (Law on the Protection of Plant Varieties, Article 15).

(l) *enforcement of the rights.*

Any act in respect of the protected variety for which the authorization of the patent owner is required and which is done without such authorization shall be deemed to constitute an infringement of the exclusive right of the patent owner (Law on the Protection of Plant Varieties, Article 33). The patent owner or the owner of an exclusive license may bring an action for infringement of their right. The action for infringement of the exclusive right of the patent owner may include: an action for establishment of the act of infringement, an action for compensation for damages sustained, an action for identification of the

infringer. At the request of the patent owner, the infringer shall cease the infringement and compensate the owner for the damages sustained, including lost profits as well as expenses which may include appropriate attorney's fees (Law on the Protection of Plant Varieties, Article 34). In the course of court proceedings concerning the infringement of the rights of a patent owner, the court or the Specialized Arbitration Centre may, at the request of any party or on its own initiative, decide to apply the following measures in support of the suit: to order the seizure of the infringing seeds or any other plant material, or of the property of the infringer; to prohibit the use, production or sale of material of the protected variety (Law on the Protection of Plant Varieties, Article 35).
