

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

Information Communicated by Members

Addendum

ROMANIA<sup>1</sup>

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?**

The legislation in force does not contain any express provisions concerning the protection of plants and animals. However, Patent Law No. 64/1991 (IP/N/1/ROM/P/1) stipulates that any invention relating to a product, process or method is patentable if the invention is new, involves an inventive step and is susceptible of industrial application.

Rule 11(1) of Government Decision No. 152/1992 concerning the implementation of Law No. 64/1991 (IP/N/1/ROM/P/2) specifies that “the subject-matter of a patentable invention ... may be from any field of activity”.

At the same time, the Romanian legislation in force includes regulations on the protection of breeds of animals and new plant varieties. Thus, Law No. 64/1991 and Government Decision No. 152/1992 provide for the patentability of inventions relating to “animal breeds” and Law No. 255 of 30 December 1998, published in “*Monitorul Oficial*” (Official Journal of Romania – OJR) No. 525 of 31 December 1998, which will shortly be notified to the WTO, regulates the protection of new plant varieties.

**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?**

(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))?**

(i) Article 13 of Patent Law No. 64/1991 lists the categories of inventions not considered patentable, but does not expressly refer to those mentioned in Article 27.3(b) of the TRIPS Agreement.

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<sup>1</sup>An illustrative list of questions prepared by the Secretariat in response to a request from the Council is available in document IP/C/W/122.

- (ii) Article 12 of Law No. 64/1991 states that “inventions contrary to morality or public policy shall not be patentable”.

**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).**

“An invention shall be considered new if it does not form part of the state of the art. The state of the art includes all knowledge that has been made available to the public up to the date on which the patent application was registered or up to the date of recognized priority” (Article 8.1 of Law No. 64/1991).

“An invention shall be regarded as involving an inventive step if, to a person skilled in the relevant field, it does not obviously derive from prior art” (Article 9 of Law No. 64/1991).

“An invention shall be susceptible of industrial application if its subject-matter may be used in at least one field of industrial activity, agriculture or any other activity, and may be reproduced with the same characteristics whenever necessary” (Article 10 of Law No. 64/1991).

**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.**

In Romania, new plant varieties are protected by a special law, Law No. 255 of 30 December 1998.

**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).**

Government Decision No. 152/1992 makes express reference to certain categories of patentable inventions:

“Micro-organisms, newly created” which, according to Rule 11(2)(d), are defined by their morphological, taxonomic, biochemical or physiological characteristics and culture effects or other effects specific to the use thereof.

“biological or genetic processes” which, according to the fourth paragraph of Rule 11(3), are defined by their specific characteristics, namely:

- For biological processes: the individuals with which the process starts, the way of acting on them and the environment in which they develop;
- for genetic processes: separation of RNA and DNA, DNA sequences, modification of DNA sequences, cloning, and RNA and DNA syntheses, possibly accompanied by chemical or biological processes.

Law No. 255/1998 defines plant 'variety' as follows: plant grouping within a single botanical taxon of the lowest known rank which can be:

1. Defined by the expression of the features characterizing a given genotype or a certain combination of genotypes;

2. distinguished from any other plant grouping by the expression of at least one of the specified characteristics;
3. considered as a unit with respect to its suitability for being propagated unchanged.

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

Such subject-matter is patentable to the extent that the invention involves a creative effort.

Example:

Under Rule 11(2)(b) of Government Decision No. 152/1992, chemical and biological substances existing in nature are patentable provided that a creative effort is involved.

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

The State Office for Inventions and Trademarks (OSIM) does not take into consideration a disclosure made during the 12 months preceding the date of registration of the patent application or the recognized priority date if that disclosure:

- (a) Is made by the inventor or his successor in title,
- (b) is made by a third party and the inventor or his successor in title send the OSIM written confirmation, stating that the corresponding information was obtained directly or indirectly from him.

(See Law No. 4/1991, Article 8.2 and Article 44.1; Government Decision No. 152/1992, Rule 30(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?**

- (1) The patent confers on its owner the right to prohibit third parties from performing the following acts without his consent:
  - (a) in relation to products: making, marketing, offering for sale, using, importing or storing for the purposes of marketing, selling, offering for sale or use;
  - (b) in relation to processes or methods: use (Law No. 64/1991, first paragraph of Article 34).
- (2) Yes. Under the legislation in force the rules are the same for all patents.
- (3) Yes. Under the first paragraph of Article 34 of Law No. 64/1991, product and process patents confer on the owner the same protection as stipulated in Article 28 of the TRIPS Agreement.

**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?**

- (a) There are no specific exceptions affecting the scope or duration of the patents.
- (b) Under Law No. 64/1991, the following do not constitute infringements of the rights provided for in the first paragraph of Article 34:
  - The production or use of the invention exclusively for experimental purposes;
  - the marketing or offering for sale within the territory of Romania, with or without the express consent of the patent owner, of specimens of the product constituting the subject-matter of the invention that have previously been sold by the patent owner.

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

Article 49 of Law No. 64/1991 provides for a compulsory licence to be granted by the court under the following cumulative conditions:

- Four years have elapsed from the date of registration of the patent application or three years from the date of grant of the patent, whichever period expires the later;
- the invention has not been exploited or has been insufficiently exploited on the territory of Romania during the above-mentioned period;
- the patent owner cannot justify his inaction and it has not been possible to reach an agreement with him regarding the transfer of rights.

**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?**

Law No. 255 of 30 December 1998 provides for the protection of plant varieties by 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?**

Romania is not yet a party to the International Convention for the Protection of New Varieties of Plants (UPOV). Preparations are being made to accede to the Convention – 1991 Act – and it is considered that the legislation in force conforms with that 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).**

The protection for new plant varieties afforded by Law No. 255/1998 (which will enter into force on 1 April 1999 and will simultaneously repeal the provisions on new plant varieties and hybrids of Patent Law No. 64/1991) is based on the granting of a variety patent.

**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;**
  - (b) the definition of "plant variety";**
  - (c) the conditions required for protection;**
  - (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;**
  - (e) the extent to which protection can be based on characteristics of germplasm, as opposed to characteristics of plant varieties derived from such germplasm;**
  - (f) who is entitled to the rights;**
  - (g) the procedure for the acquisition of rights, including the authority in charge of administering the rights;**
  - (h) the rights conferred;**
  - (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.
  - (j) the duration of protection;**
  - (k) transfer of rights;**
  - (l) enforcement of the rights.**
- (a) Law No. 255 of 30 December 1998, published in OJR No. 525 of 31 December 1998, will be notified to the WTO shortly.
- (b) Article 2(a) of the Law No. 255 of 30 December 1998 on the protection of new plant varieties defines "variety" as a plant grouping within a single botanical taxon of the lowest known rank which can be:
1. Defined by the expression of features characterizing a given genotype or a certain combination of genotypes;

2. distinguished from any other plant grouping by the expression of at least one of the specified characteristics;
  3. considered as a unit with respect to its suitability for being propagated unchanged.
- (c) Under Article 5 of Law No. 255/1998, OSIM gives protection to a new plant variety and grants a variety patent if the variety is new, distinct, uniform and stable and has a name that conforms with the provisions of Article 15 of the same Law.
- (d) Under Article 6 of Law No. 255/1998, the variety is deemed to be new if on the date of filing of the variety patent application the propagating or harvested material has not been sold or otherwise disposed of to third parties, by the breeder or with his consent, for the purpose of commercially exploiting the new variety.

The Law also provides for other situations and conditions in which the variety does not lose its novelty, for example, varieties which form the subject-matter of a transfer of rights agreement, of an agreement between the breeder and another authorizing the production of the propagating material under the breeder's control, or of an agreement between the breeder and a third party concerning the carrying out of research or experiments, or have been displayed at officially recognized exhibitions, etc.

- (e) The owner of a variety patent has the exclusive right to exploit the new variety, as well as a variety which:
- is essentially derived from the protected variety, where the protected variety is not itself derived (Article 27(2) of Law No. 255/1998).
- (f) The breeder is entitled to the rights in a variety patent.
- (g) Law No. 255/1998 lays down procedures relating to:
- The filing of the application;
  - the formal examination of the variety patent application (competence of OSIM);
  - the substantive examination of the variety patent application (competence of OSIM);
  - the technical examination of the new variety (responsibility of the competent national authority or another internationally recognized authority);
  - the testing of the new variety (responsibility of the competent national authority and OSIM).

Under Article 5 of Law No. 255/1998, OSIM issues the variety patent.

- (h) The owner of a variety patent enjoys the exclusive right to exploit the new variety and the right to prevent anyone from performing, without his authorization, any of the following acts relating to the propagating material and the harvested material of the protected variety:

- (a) Production or reproduction;
  - (b) putting up with a view to propagation;
  - (c) offering for sale;
  - (d) selling or any other form of marketing;
  - (e) importing;
  - (f) exporting;
  - (g) stocking for one of the purposes mentioned under letters (a) to (f).
- (i) The exclusive right of the variety patent owner does not extend to the following acts:
- (a) Use of the variety for private or non-commercial purposes;
  - (b) use of the variety for experimental purposes or for breeding other varieties.

Similarly, the right of the variety patent owner does not extend to acts relating to any propagating material or harvested material of the protected or derived variety nor to acts relating to any part of a plant of the protected variety or to any material derived from that variety which has been sold or marketed by the owner or with his consent, unless such acts involve:

- (a) The propagation of the protected variety;
- (b) the exportation of material of the protected variety to a third country which does not protect plant varieties of the genera or species to which the protected variety belongs, except where the exported material is intended for consumption as food (first paragraph of Article 28 and Article 29 of Law No. 255/1998).

The granting of a compulsory licence does not prevent the variety patent owner from exploiting the variety or granting licences to third parties (Article 37(4) of Law No. 255/1998).

- (j) The duration of protection is 25 years from the date of granting of the variety patent. For new fruit tree, vine and ornamental tree varieties the duration of protection is 30 years from the date of granting of the variety patent.
- (k) The right to the granting of a variety patent, the right in the variety patent and the rights deriving from the filing of a variety patent application with the State Office for Inventions and Trademarks, together with the rights deriving from the variety patent are transferable to other natural or legal persons.

Rights may be transferred by assignment, under a licensing agreement or by legal or testamentary succession.

The rights in a new variety may also be transferred in the event of the enforcement of a judgement against the variety patent owner, in accordance with the law.

- (i) Law No. 255/1998 provides for administrative, civil and criminal remedies.

1. Any interested party may request the State Office for Inventions and Trademarks to review a decision within three months of notification thereof.

The request for review or, as the case may be, the application for revocation or annulment of a variety patent must be examined by the Board of Appeal within three months of the date on which it was lodged.

The decision of the Board of Appeal must be notified to the parties within fifteen days of its being rendered and may be appealed against before the Court of Bucharest within 30 days of such notification.

The decision of the Court of Bucharest may be appealed against before the Court of Appeal of Bucharest within 15 days of notification thereof.

2. Any litigation concerning the standing of a breeder or variety patent owner or other rights arising out of a variety patent, including the economic rights of the breeder under an assignment or licensing agreement, shall fall within the jurisdiction of the courts.

The variety patent owner may request the courts:

- (a) To order provisional measures where there is a risk of violation of rights arising out of a variety patent and if such violation is likely to cause irreparable injury and there is a risk of evidence being destroyed;
- (b) to order, immediately after the proceedings, measures to end acts in violation of rights arising out of a variety patent performed by a third party in connection with the introduction into commercial distribution of imported goods involving an infringement of those rights;
- (c) to order the confiscation or destruction of the propagating material.

The court may require the infringer of rights arising out of a variety patent to inform the owner of the identity of third parties who have participated in the production and distribution of propagating material.

When the court orders provisional measures, it may require the plaintiff to lodge security in the amount it shall determine.

The court may ask the plaintiff to submit any evidence at his disposal showing that he is the holder of the right which has been or inevitably will be infringed.

Where evidence needed to support the claims of the plaintiff is under the control of the defendant, the court may order the evidence to be produced by the defendant, on condition that the confidentiality of the information be guaranteed, in accordance with the law.

The court may order the plaintiff to pay the defendant damages for injury suffered as a result of the wrongful exercise of procedural rights relating to a new variety.

3. The law establishes criminal penalties for the offences of infringement and disclosure.

Criminal proceedings are initiated following the filing of a complaint by the aggrieved party.

The owner of a variety patent is entitled to claim damages for injury suffered, as provided for in ordinary law, and the infringing products may be confiscated, as provided for in the criminal law.

The owner may not bring an action for infringement until the variety patent application has been published.

When a licence has been granted and the agreement does not otherwise provide, the licensee may not bring an action for infringement without the consent of the owner of the variety patent.

An exclusive licensee may bring an infringement action if he has informed the owner of the variety patent and the latter has not taken legal proceedings within the period requested by the licensee.

When an action for infringement has been brought by the owner of a variety patent, any licensee may apply to be joined to the proceedings in order to request compensation for injury suffered as a consequence of the infringement.

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