

## REPUBLIC OF MOLDOVA

I hereby inform you that in the Republic of Moldova according to the Law on the Protection of Inventions No. 50-XVI, applicable from 04.10.2008, the following exceptions to patentability and limitations of the effects of patents are provided:

### Answer to point (a)

#### ***Article 7. Exceptions to Patentability***

(1) Patents shall not be granted within the meaning of this Law in respect of:

a) inventions the publication or exploitation of which would be contrary to “ordre public” or morality, including those harmful for human, animal or plant life or health, and which are likely to cause serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by a clause;

b) plant or animal varieties;

c) essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;

d) inventions concerning the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene;

(2) Patents shall not be granted within the meaning of paragraph 1(a) in respect of biotechnological inventions which, in particular, concern the following:

a) processes for cloning human beings;

b) processes for modifying the germ line genetic identity of human beings;

c) uses of human embryos for industrial or commercial purposes;

d) processes for modifying the genetic 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.

(i) Exceptions to patentability are clearly and comprehensively described in Art. 7 mentioned above;

(ii) The purpose of these provisions is to protect people and animals from inventions that can cause serious suffering when patenting them and can cause a negative impact on society, while plant varieties in the Republic of Moldova are protected by Law on the Protection of Plant Varieties No. 39-XVI, applicable from September 6, 2008;

(iii) The legal provisions on exceptions to patentability are implemented by Law on the Protection of Inventions No. 50-XVI, applicable from 04.10.2008;

(iv) From the moment of introduction of these legal provisions, the Republic of Moldova does not face any problem of understanding and application of the provisions on exceptions to patentability;

(v) In the period of 04.10.2008, 3 patent applications were rejected by invoking Art. 7 of the Law on the Protection of Inventions No. 50-XVI.

***Article 22. Limitation of Effects of a Patent***

**(1)** The rights conferred by a patent shall not extend to:

- a) acts done privately on a non-commercial scale;
- b) acts done for experimental purposes relating to the subject-matter of the patented invention;
- c) extemporaneous preparation for individual cases, in a pharmacy, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared;
- d) use of the subject-matter of a patented invention on board of any foreign vessel of a State party to the international conventions in the field of inventions to which the Republic of Moldova is also party which temporarily or accidentally enters the waters of the Republic of Moldova, provided that the invention is used exclusively for the needs of the vessel;
- e) use of the subject-matter of the patented invention in the construction or operation of foreign aircraft or land vehicle or other means of transport of a State party to the international conventions in the field of inventions to which the Republic of Moldova is also party, or in the manufacture of spare parts for such vehicles when such means of transport temporarily or accidentally enter the territory of the Republic of Moldova;
- f) acts done for the purpose of ensuring state security.

**(2)** The use referred to in paragraph (1) above shall be allowed, provided that it does not unreasonably conflict with a normal use of the patented invention and does not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. In the contrary case, the patent owner is entitled to an adequate compensation for the injury suffered because of the unauthorized exploitation of the invention.

Answer to point (b)

As far as flexible possibilities are concerned, we can mention that the Republic of Moldova perceives the flexible possibilities as some possibilities by means of which the TRIPS provisions can be transposed into the national legislation in order to ensure the national interests and at the same time not to contravene the TRIPS provisions. Republic of Moldova through the Law on the Protection of Inventions No. 50-XVI, applicable from 04.10.2008, provided for flexible possibilities such as:

- grant of compulsory license;
- exhaustion of rights;

- limitations in research;
- possibilities upon expiry of the legal protection term of the patent;
- short-term patents for invention.

## **Grant of compulsory license**

### ***Article 28. Compulsory License***

(1) If after the expiration of a period of 4 years from the day of filing of the patent application or 3 years from the grant of the patent, whichever is later, the patent owner has not exploited the patent in the territory of the Republic of Moldova or if he has not undertaken serious and effective preparations for such purpose, the courts may grant a compulsory license, on request, to any interested person, unless the patent owner justifies the lack or insufficiency of exploitation. No distinction shall be made between the domestic products or imported products for the purposes of establishing the fact of the lack of exploitation or insufficient exploitation of the patent.

(2) A compulsory license shall be granted solely where the proposed user has made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived in the cases referred to in paragraph (3) below. In such cases, the patent owner shall be notified as soon as reasonable practicable.

(3) A compulsory license may be granted in the case of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.

(4) In the case of semiconductor technology, a compulsory license may only be granted for public non-commercial use or to remedy a practice, determined after judicial or administrative process to be anti-competitive.

(5) A compulsory license may be granted to a patent owner or an owner of a plant variety patent who cannot exploit his invention or protected plant variety (the second patent) without infringing another patent (the first patent), provided the invention or plant variety 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. The court shall have the authority to review the existence of these circumstances. In the case of a compulsory license in respect of a patent for an invention or a patent for a plant variety, the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the patented invention or the protected plant variety.

(6) The respective methods and procedures for the implementation of principles contained in this article are laid down in the Regulations.

## **Exhaustion of Rights**

### ***Article 23. Exhaustion of Rights***

(1) The rights conferred by a patent shall not extend to acts concerning the patented product insofar as such acts are performed on the territory of the Republic of Moldova, after that product has been so put on the market in the Republic of Moldova by the patent owner or with his express consent.

(2) The protection referred to in Article 24 paragraphs (5) - (7) shall not extend to biological material obtained by propagation or multiplication of a biological material put on the market or offered for sale on the territory of the Republic of Moldova by the patent owner or with his consent, when the multiplication or propagation necessarily results from the use for which the biological material has been so put on the market, provided that the material obtained is not subsequently used for other propagation or multiplication.

(3) By way of derogation from Article 24 paragraphs (5) – (7), the sale or other form of commercialization of the plant propagating material to a farmer by the owner of the patent or with his consent for agricultural use implies authorization for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm.

(4) By way of derogation from Article 24 paragraphs (5) – (7), the sale or other form of commercialization of breeding stock or other animal reproductive material to a farmer by the owner of the patent or with his consent implies authorization for the farmer to use the protected livestock for an agricultural purpose, with the exception of breeding holdings; this includes making the animal or other animal reproductive material available for the purposes of pursuing his agricultural activity.

### ***Article 24. Extent of Protection***

(1) The extent of the protection conferred by a patent or a patent application shall be determined by the terms of the claims. The description and drawings shall be used to interpret the claims.

(2) For the period up to grant of the patent for invention, the extent of the protection conferred by a patent application shall be determined by the claims contained in the application as published under Article 49.

(3) The patent as granted or as amended in opposition, limitation or revocation proceedings shall determine retroactively the protection conferred by the patent application, in so far as such protection is not thereby extended.

(4) The protection conferred by a patent on a process which is the subject-matter of the patent shall extend to any product directly obtained by the patented process.

(5) The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

(6) The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to the biological material directly obtained by that process and to any other biological material derived from the biological material obtained directly through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

(7) The protection conferred by a patent on a product containing or consisting of genetic information shall extend to any other material in which the product is incorporated and in which the genetic information is contained and performs its function, except for the human body, in different formation and development stages, and to the elements thereof.

### **Limitations in research**

#### Article 22. Limitation of Effects of a Patent

(1) The rights conferred by a patent shall not extend to:

- a) acts done privately on a non-commercial scale;
- b) acts done for experimental purposes relating to the subject-matter of the patented invention;
- c) extemporaneous preparation for individual cases, in a pharmacy, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared;
- d) use of the subject-matter of a patented invention on board of any foreign vessel of a State party to the international conventions in the field of inventions to which the Republic of Moldova is also party which temporarily or accidentally enters the waters of the Republic of Moldova, provided that the invention is used exclusively for the needs of the vessel;
- e) use of the subject-matter of the patented invention in the construction or operation of foreign aircraft or land vehicle or other means of transport of a State party to the international conventions in the field of inventions to which the Republic of Moldova is also party, or in the manufacture of spare parts for such vehicles when such means of transport temporarily or accidentally enter the territory of the Republic of Moldova;
- f) acts done for the purpose of ensuring state security.

(2) The use referred to in paragraph (1) above shall be allowed, provided that it does not unreasonably conflict with a normal use of the patented invention and does not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of

third parties. In the contrary case, the patent owner is entitled to an adequate compensation for the injury suffered because of the unauthorized exploitation of the invention.

### **Possibilities upon expiry of the legal protection term of the patent**

(1) The owner of a patent with effects in the Republic of Moldova, the subject-matter of which is a medicinal product or a phytopharmaceutical product (basic patent) for which an authorization for marketing the product has been granted, shall avail himself, in accordance with the requirements of this law and the Regulations, of a supplementary protection certificate, hereinafter certificate, for those parts of the primary patent which correspond to the authorization.

(2) The certificate shall take effect upon expiry of the legal protection term of the basic patent, for a period equal to the period covered between the date of filing of the patent application and the date of issuance of the first authorization under paragraph (1), minus 5 years.

(3) Without prejudice to the provisions of paragraph (2), the duration of the certificate may not exceed 5 years from the expiration date of the legal protection term in respect of the basic patent, subject to payment of the prescribed fee for maintenance of the certificate.

(3<sup>1</sup>) In the case of a patent whose subject-matter is a medicinal product for which pediatric studies have been conducted, and the results of those studies are reflected in the information on the product for which an authorization for marketing has been issued, the periods specified in paragraphs (2) and (3) shall be extended by 6 months, while the period referred to in paragraph (2) may be extended once.

(4) Within the limits of the protection conferred by the basic patent, the protection conferred by the certificate shall only extend to the product which forms the subject-matter of the authorization mentioned in paragraph (1) and any use of such product as a medicinal or phytopharmaceutical product, which was authorized prior to the expiration of the certificate. (5) The provisions of this law relating to patents shall apply *mutatis mutandis* to supplementary protection certificates in the absence of any provisions to the contrary and with the exception of the opposition proceedings.

### **Short-term patents for invention**

#### **Article 12. Subject-Matter Protected by a Short-Term Patent for Invention**

(1) A short-term patent for invention shall be granted for any invention which is new, involves an inventive step and is susceptible of industrial application.

(2) An invention shall be considered as involving an inventive step within the meaning of paragraph (1) if it does not directly result from the state of the art and gives a technical or practical advantage.

(3) Additionally to Article 7 (mentioned above at the beginning of the answer), short-term patents for invention shall not be granted in respect of inventions concerning:

a) biological material;

b) chemical or pharmaceutical substances and processes for their preparation.

The invention patent is granted for a period of 6 years, with the right to be extended for a period of 4 years, provided that a search is carried out for the state of the art regarding the novelty and a search report with written opinion is drawn up.

### **Regarding the updating of information on normative acts related to the patenting of inventions**

(a) As regards some aspects of patent law indicated at:

[http://www.wipo.int/scp/en/annex\\_ii.html](http://www.wipo.int/scp/en/annex_ii.html), which refers to the state of the art, novelty, inventive step, grace period, the sufficiently clear description of the invention, exclusions from patentability, exceptions to patentability and limitation of the effects of patents, we inform you that no amendments have been made.

(b) A post-grant opposition procedure before the State Agency on Intellectual Property (AGEPI) is provided in the Republic of Moldova. According to Article 57 of the National Law on the Protection of Inventions, (No. 50-XVI of 07.03.2008, in force from October 4, 2008) within six months from the publication of the mention of the grant of the patent, any person may give a notice of opposition to the AGEPI to the patent in question, specifying, inter alia, the grounds on which the opposition is based, as well as an indication of the evidence and arguments presented in support of those grounds. Within 10 days, the Appeals Board examines the admissibility of the opposition. If the opposition does not meet the requirements, a 2-month deadline is provided to remedy the shortcomings.

An opposition shall only be filed in writing and on the following grounds:

(i) the subject matter of the patent is not patentable within the meaning of Articles 6 to 11; (Article 6 - patentable inventions, Article 7- exceptions to patentability, Article 8 – novelty, Article 9- non-prejudicial disclosure, Article 10- inventive step, Article 11- industrial application)

(ii) the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art;

(iii) the subject matter of the patent extends beyond the content of the application as filed, or, if the patent was granted on a divisional application or on a new application filed by non-entitled persons, beyond the content of the earlier application as filed.

The opposition filed shall have suspensive effect. It shall not be deemed to have been filed until the opposition fee has been paid.

If it is found that the opposition is admissible, the Appeals Board of AGEPI which issued the decision shall examine, in accordance with the provisions of Article 57 of the Law, whether at least one ground for opposition under Article 57, paragraph (2), of the Law, prejudices the grant of the patent. If the opposition is admissible, the patent applicant shall be notified of the opposition filed and shall be invited to file his observations and to amend, where appropriate, the description, claims and drawings within a period of two months. Any observation and amendments filed by the applicant shall be communicated to the opponent who shall reply within a period of two months. (Rule 332 of the Regulations on the Procedure of Filing and Examination of a Patent Application and of Grant of a Patent, approved by Government Decision of the Republic of Moldova No. 528 of 01.09.2009)

Where appropriate, during the opposition procedure, AGEPI shall carry out an additional documentary search and shall draw up a search report on a form approved by AGEPI. A reexamination report shall be drawn up on the basis of the opposition examination results which shall be sent to all parties.

Where it is revealed that the maintenance of the decision to grant the patent is possible by way of amendments, the patent applicant shall be invited to make any amendments or to submit his own amended version of the description and claims, without extending beyond the content of the original application.

If the AGEPI division which took the decision to grant the patent is of the opinion that at least one of the grounds for opposition referred to above prejudices the maintenance of the patent, it shall revoke the respective decision. Otherwise, it shall reject the opposition. If AGEPI is of the opinion that, taking into consideration the amendments made by the applicant during the opposition proceedings, the patent and the invention to which it relates meet the requirements of the law, it shall decide to maintain the decision to grant the patent as amended. (Article 57 of the National Law on the Protection of Inventions)

If a patent is amended, the AGEPI shall, after the payment of the prescribed fee, publish a new specification of the patent containing the description, the claims and, as the case may be, any drawings, in the amended form.

Any person adversely affected by a decision taken by the division of the AGEPI may appeal with the Appeals Board of the AGEPI within 2 months after the date of notification of the decision and shall contain the grounds for appeal.

Since the national Law No. 50-XVI of 07.03.2008 on the Protection of Inventions entered into force till 01.09.2017 only one opposition has been filed.