

PARLIAMENT OF THE REPUBLIC OF MOLDOVA

LAW
on Amending Some Normative Acts
(Improving the Mechanism for Issuing Compulsory Licenses)

The Parliament adopts this organic law.

Article I. – Law No. 50/2008 on the Protection of Inventions (Official Gazette of the Republic of Moldova, 2008, No. 117-119, Art. 455), with subsequent amendments, shall be amended as follows:

1. In Article 3:
 - the notion “Eurasian application” shall be excluded;
 - the notion “Eurasian patent” shall be supplemented with the text “, on the basis of an application filed before April 26, 2012,”;
 - the Article shall be completed with a new notion with the following wording:
 - “*TRIPs Agreement* - Agreement on Trade Aspects of Intellectual Property Rights, concluded in Marrakech on April 15, 1994, as subsequently amended”.
2. In Article 20 paragraph (2) letters a) and c), the text “use, importing” shall be replaced by the text “use, transporting, importing, other way of putting into circulation”.
3. In Article 22, paragraph (1) shall be supplemented with letter b¹) with the following wording:
 - “b¹) acts done for the purpose of obtaining an authorization to place a product on the market that is the subject-matter of the invention;”.
4. Article 28 shall have the following wording:
 - “**Article 28.** Grant of a Compulsory License
 - The courts may grant a compulsory license for a patent to any interested person:
 - a) on the grounds of non-exploitation or insufficient exploitation of the patent;
 - b) in the public interest;
 - c) for the purpose of remedying an anti-competitive practice;
 - d) in the case of inventions in the field of semiconductor technology and for the purpose of exploiting dependent patents and plant variety patents.”.
5. The Law shall be supplemented with Articles 28¹ - 28⁴ with the following wording:
 - “**Article 28¹.** Grant of a Compulsory License on the Grounds of Non-Exploitation or Insufficient Exploitation of the Patent
 - (1) If, according to an application filed upon the expiration of a period of 4 years from the date of filing of the patent application or a period of 3 years from the issuance of the patent, whichever is later, the patent owner has not exploited / has exploited insufficiently the patent in the

territory of the Republic of Moldova or has not undertaken serious and effective preparations for such purpose, the court may grant a compulsory patent license to any interested person requesting such a license (the applicant) without the consent of the patent owner, unless the patent owner justifies the non-exploitation or insufficient exploitation thereof.

(2) A compulsory patent license, in accordance with the provisions of paragraph (1), shall be granted solely where the interested person has made efforts to conclude a license contract with the patent owner on reasonable commercial terms and conditions and that such efforts have not been successful within 6 months from the date of the request to conclude such contract.

(3) No distinction shall be made between the domestic products and imported products for the purposes of establishing the fact of the non-exploitation or insufficient exploitation of the patent.

Article 28². Grant of a Compulsory Patent License in the Public Interest

(1) The court may grant a compulsory license in the public interest, in cases determined by situations of national emergency or other circumstances of extreme urgency in the fields of public health, national defense, agriculture, environmental protection, climate changes and natural resources, and in cases of public non-commercial use.

The grant of a compulsory license in the public interest shall not be conditional on the obligation of the interested person to negotiate a license contract with the patent owner.

(2) An application for the grant of a compulsory patent license in the public interest shall be filed with the Chisinau Court of Appeal and shall be examined within 20 calendar days from filing.

(3) An application for the grant of a compulsory patent license in the public interest shall be filed by the ministry ensuring the implementation of government policy in the field of activity entrusted to it, as follows:

- a) in the case of public health emergency – the Ministry of Health;
- b) in the case of national defense emergency – the Ministry of Defense;
- c) in the case of national emergency concerning the field of agriculture – the Ministry of Agriculture and Food Industry;
- d) in the case of national emergency concerning the field of environmental protection, climate changes and natural resources – the Ministry of Environment;
- e) in the case of public non-commercial use – the Ministry of Economic Development and Digitization.

(4) An application for the grant of a compulsory patent license in the public interest shall contain:

- a) the name of the entity selected by the ministry as capable of ensuring the production of the subject-matter of the patent according to the existing needs;
- b) data/information regarding the existing needs, the period for which the grant of a compulsory license is requested, the volume of production under the compulsory license.

(5) The ministries referred to in paragraph (3) shall establish the mechanism for selecting the entity capable of ensuring the production of the subject-matter of the patent according to the existing needs.

(6) In the case of grant of a compulsory patent license in the public interest following the occurrence of a public health emergency, the court, at the proposal of the Ministry of Health, shall designate a national entity capable of exercising it. If the national entity is not able to exercise the compulsory license, the court shall grant, in accordance with the provisions of the TRIPs

Agreement, the compulsory license to a foreign entity, proposed by the Ministry of Health, on the basis of which the products will be imported.

(7) The court, examining the request for the grant of a compulsory patent license in the public interest, shall adopt a decision, in which the terms and conditions of the compulsory license, as well as the license holder will be provided.

(8) In accordance with the provisions of the TRIPs Agreement, a compulsory patent license may also be granted to a national entity for the manufacture and export of a pharmaceutical product protected by a patent or supplementary protection certificate to an importing country that has public health problems.

(9) Within 5 days from the pronouncement, an appeal can be lodged against the decision of the Chisinau Court of Appeal. The appeal shall be examined within 10 days from the receipt of the respective file.

Article 28³. Grant of a compulsory License for the Purposes of Remediating an Anti-Competitive Practice

(1) For the purpose of remediating a practice that has been qualified after administrative procedure to be anti-competitive, being determined by the abusive use of the patent, the court may grant a compulsory license, on request, to any interested person, following the decision of the Competition Council.

(2) The grant of a compulsory license in accordance with the provisions of paragraph (1) shall not be conditional on the obligation of the interested person to negotiate a license contract with the patent owner

Article 28⁴. Grant of a Compulsory License in the Case of Semiconductor Technology and for the Purpose of Exploiting Dependent Patents and Plant Variety Patents

(1) In the case of inventions in the field of semiconductor technology, the court may only grant a compulsory patent license for public non-commercial use or to remedy a practice qualified after administrative procedure to be anti-competitive.

(2) In the case of dependent patents or plant variety patents, the court may grant a compulsory patent license, on request, to an owner of a patent for an invention or an owner of a patent for a plant variety who cannot exploit his invention or protected plant variety (the second patent), without infringing another patent (the first patent), provided that the invention or plant variety claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the plant variety and the invention claimed in the first patent. The court shall take all necessary measures to verify 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 exploit the patented invention or the protected plant variety.”

6. Article 29 shall have the following wording:

“Article 29. Conditions Applicable to the Grant of a Compulsory License

(1) At the time of grant of a compulsory patent license, the court shall specify the types of use covered by such license, the terms and conditions to be observed. The following conditions shall apply:

a) the scope and duration of such use shall be limited to the purpose for which it was authorized;

b) such use shall be non-exclusive;

c) such use shall be non-assignable, even in the form of grant of a sublicense, except with the assignment of that part of the enterprise or goodwill which enjoys such use;

d) any such use shall be authorized predominantly for the supply of the domestic market, except where such use is permitted to remedy an anti-competitive practice;

e) the license holder shall pay the patent owner an adequate remuneration, established in relation to the economic value of the authorization and, eventually, the need to remedy an anti-competitive practice, and in the cases stipulated in Article 28² paragraph (3) the remuneration cannot exceed the amount of 4% of the total price to be paid by or on behalf of the importing country.

f) in case of a compulsory license for a dependent patent or a plant variety patent, the use authorized in respect of the first patent shall be non-assignable, except with the assignment of the second patent.

(2) In the case of grant of a compulsory license, the patent owner shall be notified of this on the same day or on the next working day.

(3) The court may, upon motivated request, decide that action of a compulsory patent license granted pursuant to Article 28 shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if the circumstances which led to it cease to exist and are unlikely to recur. The court shall have the authority to refuse termination of the action of a compulsory license if the circumstances which led to its grant are likely to recur.

(4) The legal validity of any act relating to the grant of the compulsory license referred to in paragraph (1) and any other act relating to the remuneration provided for in respect of such use shall be subject to judicial review.

(5) The holder of the license shall communicate to AGEPI the court decision to grant a compulsory license or, where appropriate, to terminate its action, and the mention with reference to such fact shall be entered in the National Register of Patents for Invention and published in BOPI. The compulsory license granted in the situation referred to in Article 28² shall be entered in the National Register of Patents for Invention without payment of fee.

(6) If the holder of the compulsory license has not undertaken any effective and serious preparation for exploiting the invention within one year following the date of grant of the license, the compulsory license may be cancelled by a court decision. The validity of a compulsory license shall terminate if the license holder has not begun exploitation of the invention within 2 years following the date on which the license was granted to him.”

7. In Article 31 paragraph (2), the words “made in the Republic of Moldova” shall be replaced by the words “originating in the Republic of Moldova”.

8. In Article 39, paragraph (2) shall have the following wording:

“(2) Every filing under the national law of the State where it was made or under bilateral or multilateral agreements in the field shall be recognized as giving rise to a right of priority.”.

9. The name of Article 44 shall have the following wording:

“**Article 44.** Eurasian Patent”.

10. Article 44² shall be supplemented with paragraph (12) with the following wording:

“(12) The same invention disclosed in a European patent and respectively, in a national patent, originating from the same applicant, having the same filing date or, where priority is claimed, the same priority date, cannot be protected simultaneously by a validated European patent and a national patent. A European patent shall be validated in the Republic of Moldova if the rights conferred by a national patent have expired according to Article 68. A national patent shall be

granted if the rights conferred by a European patent validated in the Republic of Moldova have expired according to Article 68.”

11. In Article 45 paragraph (2), the words “made in the Republic of Moldova” shall be replaced by the words “originating in the Republic of Moldova”.

12. In Article 46, paragraph (2) shall be supplemented with the following sentence: “If the applicant fails to file a request for re-establishment within the omitted term under the terms of the Regulations, the patent application shall be deemed to be withdrawn.”.

13. In Article 49 paragraph (7), the text “paragraph (1)” shall be excluded.

14. In Article 51, paragraph (2), after the words “following the date of entry into the national phase”, shall be introduced the text “, and in the case of a divisional application - within 6 months following its filing, being applied the term that expires later.”

15. In Article 52:

in paragraph (2), after the text “on or after that date,”, shall be introduced the text “patent documents relating to author’s certificates,”;

in paragraphs (3) and (4), the words “meets the requirements of” shall be replaced by the text “complies with the provisions of paragraph (1) and”.

16. In Article 59, paragraph (4) shall have the following wording:

“(4) The decision of the Appeals Board of AGEPI shall be notified to the parties and may be appealed according to the legislation.”.

17. In Article 71 paragraph (1), letter b) shall be supplemented with the words “and is within the limits of the claims in the patent”.

18. In Article 90 paragraph (3), after the text “Article 43 paragraphs (1) and (2)” shall be introduced the text “Article 44² paragraphs (6), (7) and (10),”.

19. Article 92:

in the title of the Article, the words “Re-establishment of Rights” shall be replaced by the words “Reinstatement of Rights”;

in paragraph (2), the words “The request for re-establishment of rights” shall be replaced by the words “The request for reinstatement of rights”, and the text “the period of 12 months shall start from the date” – by the text “the running of the period of 12 months shall start from the date”;

in paragraph (3), the words “The request for re-establishment of rights” shall be replaced by the words “The request for reinstatement of rights”, and the words “re-establishment of rights” – by the words “reinstatement of rights”;

the Article shall be supplemented with paragraph (3¹) with the following wording:

“(3¹) In case of reinstatement of rights, the decision of the subdivision shall be revoked.”;

in paragraph (4), the text “, Article 51 paragraph (2), Article 57 paragraph (1) and Article 58 paragraph (3)” shall be replaced by the text “and Article 57 paragraph (1)”;

in paragraph (5), the words “re-establishment of that right” shall be replaced by the words “reinstatement of that right”.

20. In Article 94 paragraph (1), letter f) shall have the following wording:

“f) reinstatement of rights”.

Article II. – In Article 11⁵ paragraph 12 of Law No. 1456/1993 on the Pharmaceutical Activity (republished in the Official Gazette of the Republic of Moldova, 2005, No. 59-61, Art. 200), with subsequent amendments, the text “Article 28 paragraph (3)” shall be replaced by the text “Article 28 letter b) and Article 28²”.

Article III. – The Government, within 12 months from the date of entry into force of this Law, shall bring its normative acts in line with it.

**CHAIRMAN OF THE
PARLIAMENT**

Igor GROSU

No. 98. Chisinau, April 27, 2023