

**CABINET OF MINISTERS OF UKRAINE
RESOLUTION**

№ 877 of 4 December 2013

Kyiv

**On Approval of the Procedure for Granting Permission by the Cabinet of Ministers of
Ukraine to Use the Patented Invention (Utility Model) concerning Medicines**

According to Paragraph 3 of Article 30 of the Law of Ukraine “On Protection of Rights to Inventions and Utility Models”, Paragraph 11 of Article 9 of the Law of Ukraine “On Medicines” the Cabinet of Ministers of Ukraine decides:

1. To approve the Procedure for Granting Permission by the Cabinet of Ministers of Ukraine to Use the Patented Invention (Utility Model) concerning Medicines (attached).

2. To add an additional paragraph to Paragraph 1 of the Procedure for Granting Permission by the Cabinet of Ministers of Ukraine to Use the Patented Invention (Utility Model) or Registered Topography of Integrated Circuit, approved by the Resolution of the Cabinet of Ministers of Ukraine of 14 January 2004 № 8 (the Official Bulletin of Ukraine, 2004, № 2, p. 38; 2011, № 71, p. 2673), with the following content:

“This Procedure does not apply to the Procedure for Granting Permission by the Cabinet of Ministers of Ukraine to Use the Patented Invention (Utility Model) concerning Medicines.”.

Prime Minister of Ukraine

APPROVED
by the Resolution of the Cabinet of
Ministers of Ukraine
of 4 December 2013 № 877

PROCEDURE

**for Granting Permission by the Cabinet of Ministers of Ukraine to Use the Patented
Invention (Utility Model) concerning Medicines**

1. This Procedure determines the process of granting permission by the Cabinet of Ministers of Ukraine to use the patented invention (utility model) concerning medicines (hereinafter - permission), without the consent of the patent owner, but with payment of an adequate compensation to the patent owner.

2. With the purpose to protect public health, including in cases of HIV/AIDS and other socially dangerous diseases, the Cabinet of Ministers of Ukraine may give the permission to the person, authorized by it, if there is documentary confirmation of the following circumstances together:

the patent owner can not meet the needs in appropriate medicines due to its own abilities and capacities, which are commonly used for production of such medicines;

the patent owner has groundlessly rejected granting a license for the use of the invention (utility model) to the applicant.

3. The permission shall be granted in compliance with such requirements:

the scope and the duration of the use of the patented invention (utility model) shall be determined by the purpose of the granted permission;

the permission to use the patented invention (utility model) shall not deprive the patent owner of the right to grant licenses for the use of an invention (utility model);

the right to use the patented invention (utility model) shall not transferred to third parties, excluding the case, when it is transferred together with the part of the enterprise, in which this use is carried out;

the use of the patented invention (utility model) is permitted to meet the domestic pharmaceutical market needs;

an adequate compensation in accordance with an economic value of the invention (utility model) shall be paid to the patent owner at the expense of the authorized person on the basis of the the decision of the Cabinet of Ministers of Ukraine concerning granting the permission to use the patented invention (utility model).

4. The permission may be granted to business entity, which produces medicines in full-scale circle or at the final stages of production of medicines with the use of active pharmaceutical ingredient of other manufacturer on production sites, located in Ukraine, under the license for

production of medicines, or to business entity, which imports medicines to Ukraine under the licenses for import of medicines and for wholesale and retail trade in medicines.

The business entity concerned (hereinafter - the applicant) shall submit a request to the Ministry of Health of Ukraine concerning granting permission by the Cabinet of Ministers of Ukraine, with indication of the following information:

International Nonproprietary Name (INN) of medicine;
the name of the invention (utility model);
the patent number, information concerning its owner (s), its (their) address or location;
the applicant's name, its location, signature of the authorized person with documentary confirmation of such authority.

The request shall be added with the following:

justification of necessity to use the patented invention (utility model) with indication of specific circumstances and required duration of the permission for the use of the patent;

technical and economic justification of possibility, conditions and procedure of the use of the patented invention (utility model);

documentary confirmation of unreasonable refusal of the patent owner to grant license for the use of the patented invention (utility model) on appropriate applicant`s request;

calculation of the amount of compensation, which shall be offered to the patent owner by the applicant (such calculation should be made in accordance with Paragraph 13 of this Procedure).

The request should be signed by the applicant or by its authorized person (the document, confirming authority of such person to act on behalf of the applicant, shall be attached). The request and its annexes shall be made in Ukrainian and submitted to the Ministry of Health of Ukraine in three copies, one of which shall remain at the Ministry, the second one shall be given back to the applicant together with a mark on acceptance for consideration, and the third one shall be sent to the patent owner within 10 working days. If there are several patent owners, the applicant shall additionally submit appropriate quantity of copies of requests and annexes.

The patent owner may submit appropriate information relating to the request within 30 working days of the date of its receiving. That should be confirmed by the mark in the notice on delivery of postal item.

5. If the requirements of Paragraphs 3 and 4 of of this Procedure are violated, the Ministry of Health of Ukraine shall return submitted materials together with explanation of reasons of returning within 5 working days of the date of receiving the request. The applicant may re-submit the request once again after redressing all insufficiencies within the term, set by the Ministry of Health of Ukraine. The Ministry of Health of Ukraine shall consider appropriate information, submitted by the patent owner.

If during the process of consideration of the request the Ministry of Health of Ukraine receives the request concerning granting the permission from other applicant, the Ministry of Health of Ukraine should also prepare proposals on defining the person, to which the permission may be granted, considering technical and economic justification of possibility, conditions and procedure of the use of the patented invention (utility model).

6. If the request is accepted for consideration, the Ministry of Health of Ukraine shall send it to:
the State Intellectual Property Service, asking to give information regarding the patented invention (utility model);

the authorized body, asking to give information concerning conformity of the amount of compensation, offered by the applicant, with the requirements of Paragraph 13 of this Procedure.

7. The State Intellectual Property Service shall submit information to the Ministry of Health of Ukraine concerning conformity of the data, specified in the request, with data, included in the State Register of Patents of Ukraine for Inventions or in the State Register of Patents of Ukraine for Utility Models, within 10 working days of the date of receiving the request.

The authorized body shall submit information to the Ministry of Health of Ukraine concerning conformity of the amount of compensation, offered by the applicant, with the requirements of Paragraph 13 of this Procedure, within 10 working days of the date of receiving the request, specified in Paragraph 6 of this Procedure.

8. The Ministry of Health of Ukraine shall develop a draft decision of the Cabinet of Ministers of Ukraine concerning granting the permission, within 10 working days of the date of receiving of appropriate proposals.

The following documents shall be submitted to the Cabinet of Ministers of Ukraine together with the draft decision:

copies of request and its annexes, submitted by the applicant;

information, received from the State Intellectual Property Service, in respect of the patented invention (utility model) concerning medicines, together with an extract from the State Register of Patents of Ukraine for Inventions or from the State Register of Patents of Ukraine for Utility Models;

information, received from the authorized body concerning the amount of compensation, which should be paid to the medicine patent owner.

materials concerning consideration of the information, submitted by the patent owner.

9. Development, submission and consideration of the draft decision of the Cabinet of Ministers of Ukraine is carried out under the established procedure.

The decision of the Cabinet of Ministers of Ukraine concerning granting the permission shall include:

the name of business entity, to which the permission is granted, its location and the name of the invention (utility model), the patent number;

the duration of granted permission;

conditions of granting the permission (circumstances, under which the permission has been granted, the scope of the use of the patented invention (utility model));

the amount and procedure of payment of compensation to the patent owner by the applicant.

If it is necessary, the Cabinet of Ministers of Ukraine shall entrust the Ministry of Health of Ukraine to carry out additional consideration of the issue concerning the advisability of granting such permission.

10. The Ministry of Health of Ukraine shall inform the applicant and the patent owner within 3 working days of the date of the entry into force of the decision of the Cabinet of Ministers of Ukraine concerning granting the permission.

11. The State Intellectual Property Service shall publish the decision concerning granting the permission, adopted by the Cabinet of Ministers of Ukraine, in the official bulletin on intellectual property.

12. During the process of state registration of the medicine business entity may refer to the information, specified in the registration dossier of appropriate medicine, authorized for the use, on the basis of the decision concerning granting the permission, adopted by the Cabinet of Ministers of Ukraine.

13. The Cabinet of Ministers of Ukraine shall establish the amount of compensation for the use of the patented invention (utility model) in the decision concerning granting the permission, taking into consideration the accessibility of medicines for people at the lowest possible price. The amount of compensation should not exceed the maximum rate of compensation, which is calculated under the Tiered Royalty Method, described in Remuneration Guidelines for Non-voluntary Use of a Patent on Medical Technologies of the World Health Organization, in accordance with the following formula:

$$(PM \times 0,04 \times (PM: PMU) \times (IU: I) = MRC,$$

where PM – the price per unit of the original medicine on the market of the country of origin. The price of the original medicine on the market of the country of origin may be determined under the data from official sources of information;

PMU - the price per unit of the original medicine in Ukraine (the lowest of the following prices: officially declared or according to the latest procurements, carried out by the Ministry of Health of Ukraine, or the weighted average price*);

* The weighted average price of the medicine, supplied by the company-supplier of original medicines in Ukraine, should be considered in the formula.

IU - income per capita in Ukraine according to the data of the International Monetary Fund;

I - income per capita in the country of origin of the original medicine according to the data of the International Monetary Fund;

MRC - the maximum rate of compensation.

14. The permission shall be revoked before the expiry of its validity period by the decision of the Cabinet of Ministers of Ukraine on the proposal of the Ministry of Health of Ukraine in the case of:

submission of the reasonable request concerning revocation of the granted permission by the business entity, authorized to use the patented invention (utility model);

discontinuance of circumstances under which the permission has been granted;

non-fulfilment (unfair fulfilment) of the permission grant conditions by the authorized business entity;

termination of the legal entity (merger, connection, division, transformation or liquidation);

establishing the fact of submission of false information in the request and its annexes.

15. Development and submission of the draft decision of the Cabinet of Ministers of Ukraine concerning revocation of the permission shall be carried out in accordance to Paragraphs 8 and 9 of this Procedure.

16. The decisions of the Cabinet of Ministers of Ukraine concerning granting the permission and its revocation may be appealed in court procedure.