

Former Yugoslav Republic of Macedonia¹

Legal basis

Arts. 97 to 115 of the Law on Industrial Property No. 21/09 of 2009 (hereinafter PL).

Grounds for applying for a licence

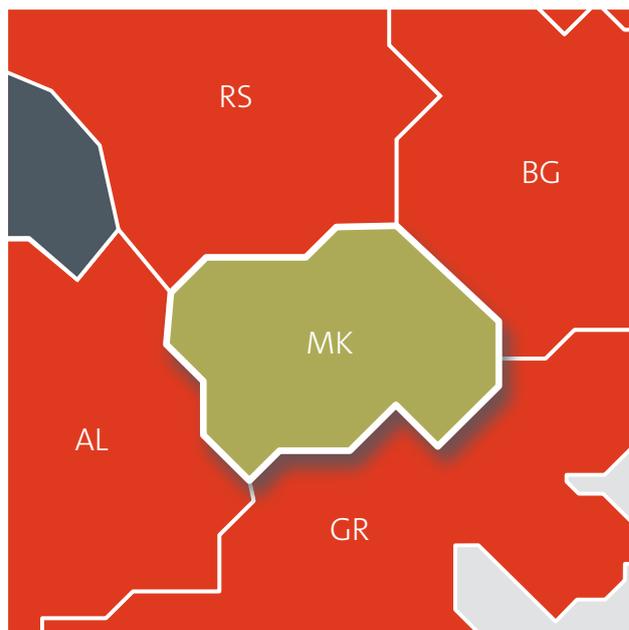
- (1) non-working of a patent, insufficient exploitation (importation of a patented product also qualifies as exploitation of the invention);
- (2) public interest in the area of public health (pharmaceutical industry), food, protection and promotion of the environment;
- (3) national emergency;
- (4) necessary to implement judicial and administrative procedure related to protection of competition.

General procedure

The primary court (court of first instance) is responsible for disputes concerning industrial property rights, and also decides on the granting of compulsory licences.

In the course of making a decision upon the request for issuance of a compulsory licence, the court shall verify whether:

- (1) each importing country listed in the request that is a WTO member has sent a notification to the WTO pursuant to the decision, and each importing country listed in the request that is not a WTO member has made a notification to the Ministry of Economy in accordance with the provisions of this Article, in respect of each of the products listed in the request and irrespective of the possibilities that the least developed countries have under the decision;
- (2) the quantity of the product listed in the request does not exceed the one for which the importing country as a WTO member has notified the WTO or the Ministry of Economy; and



- (3) the total quantity of products approved to be produced in view of any importing country does not significantly exceed the quantity regarding which the respective country notified the WTO or the Ministry of Economy, taking into consideration the other compulsory licences issued.

The activities for the production of which the requesting entity is authorised, and which are necessary for the production, export, and distribution to the country, that is, countries listed in the request, shall be listed in the court's decision.

The court decision shall order the products to be clearly marked with specific labels or marks that are produced under a compulsory licence, so that they can be distinguished from those made by the holder of the right through special packaging and/or special colouring and shaping, provided that such distinction is possible and does not have a significant impact on the price.

In the decision, the court shall order the licensee, prior to the delivery to the importing country, to publish data on the web page regarding the quantity of the products which it supplies to the importing countries, obtained under the compulsory licence, as well as regarding the manner and type of marking those products, and to inform the Ministry of Economy and the Ministry of Health about the web page address.

¹ At the time of writing, the Parliament initiated the constitutional changes needed to implement the Prespa Agreement with Greece. However, the Agreement is also subject to the Greek Parliament's ratification in Athens.

The court may, based on the proposal for provision of evidence submitted by the holder of the right, impose a measure for conducting an inspection of the work books and the other documents for licence receipt, for the sole purpose of checking whether all obligations deriving from the decision on issuance of a compulsory licence are met, and in particular for the purpose of checking the final destination of the product, and the work books and the documents must include evidence of the export of the product, in the form of an export declaration certified by customs, as well as evidence of the import.

The court has discretion in determining the term of duration and scope of a compulsory licence.

The duration and the scope of the compulsory licence that are listed in the issuance decision of the court shall depend only on the duration of the reason due to which it has been issued. The court responsible for making a decision on disputes over the industrial property rights is competent to decide on this.

The lawsuit containing a request for issuance of a compulsory licence for the needs of public health shall be filed with the court pursuant to Art. 101 PL, provided that there is a patent or a supplementary protection certificate on the territory of the Republic of Macedonia covering export-related production and sale activities.

The plaintiff shall be obliged to attach the following to the lawsuit for issuance of a compulsory licence:

- (1) the requests for issuance of compulsory licences in other states for the same product, also containing data on the quantities for the importing countries;
- (2) the requesting entity for issuance of a compulsory licence, and if a representative has been appointed, data on its representative;
- (3) the name of the pharmaceutical product that is not subject to protection and that the requesting entity intends to produce under a compulsory licence;
- (4) the amount of the pharmaceutical product that the requesting entity intends to produce under the compulsory licence;
- (5) the data on the importing country;
- (6) evidence of prior negotiations with the holder of the right; and

- (7) the evidence of the request containing the quantity of the required product by the authorised representative of the importing country or the non-governmental organisation which operates with an authorisation from one or several importing countries or UN bodies or another international health organisation operating with an authorisation from one or several importing countries.

Appeal/review

The decision of the first court can be appealed to the court of second instance, i.e. a court of appeal.

Statistics and jurisprudence

None available.