

VII COMPULSORY LICENSE

1. Common Provisions

COMPETENCE AND PROCEDURE FOR THE GRANT OF A COMPULSORY LICENSE

Article 67a

- (1) The Commercial Court in Zagreb shall be competent to grant compulsory licences.
- (2) The procedure for the grant of a compulsory licence shall be instituted by a legal action against the owner of a patent or a holder of a Supplementary Protection Certificate, containing an application for the grant of a compulsory licence. In the notice of legal action, the plaintiff shall indicate all the facts and present all the evidence, on which the application is based. The court shall decide on the grant of a compulsory licence by a judgment.
- (3) The decisions of the court issued in the procedures for the grant of a compulsory licence may be appealed in accordance with the rules laid down in the Act on Civil Proceedings.
- (4) In the absence of proof to the contrary, it shall be considered that, in the procedure for the grant of a compulsory licence, the owner of a patent or the holder of a Supplementary Protection Certificate is the person who is entered as such in the Register of Patents.
- (5) The Act on Civil Proceedings shall apply to particular matters relating to the procedure for the grant of a compulsory licence, not regulated by this Act.

2. Compulsory licences in the cases of insufficient exploitation of a patent, national emergencies, the need for protection from unfair market competition, exploitation of another patent or protected plant variety, and cross-licensing.

GRANT OF A COMPULSORY LICENSE

Article 68

- (1) The competent court in the Republic of Croatia may grant a compulsory license for lack or insufficiency of exploitation of a patent to any person filing a request for the grant of a compulsory license, or to the Government of the Republic of Croatia, if the patent owner has not exploited the invention protected by a patent in the territory of the Republic of Croatia on reasonable terms or has not made effective and serious preparations for its exploitation.
- (2) A request for the grant of a compulsory license based on paragraph (1) of this Article can be filed after the expiration of a period of four years as of the filing date of a patent application, or after the expiration of three years as of the date on which the patent was granted.
- (3) A compulsory license cannot be granted if the patent owner provides legitimate reasons to justify non-exploitation or insufficiency of exploitation of the protected invention.

(4) On a reasoned request, the court may grant a compulsory license in respect of a first patent to the owner of a patent or to the owner of a plant variety right who cannot use his patent (second patent) or his plant variety right without infringing the first patent, provided that the invention claimed in the second patent or a protected plant variety involves an important technical advance of considerable economic significance in relation to the invention claimed in the first patent. The competent court may take any measure it regards as useful to verify the existence of such a situation.

(5) In the case of a compulsory license as provided in paragraph 4 of this Article, the owner of the first patent shall be entitled to a cross license on reasonable terms to use the invention protected by the second patent or protected plant variety.

(6) The court may grant a compulsory license if the exploitation of the patented invention is necessary in situations of extreme urgency (national security, public interest protection in the field of health, food supplying, environmental protection and improvement, specific commercial interest) or when it is necessary to remedy a practice determined after judicial or administrative process to be anticompetitive.

(7) In the case of semi-conductor technology, a compulsory license may be granted only in the cases set out in paragraph 6 of this Article.

(8) A compulsory license may be granted only if a person filing a request has made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions and if such efforts have not been successful within a reasonable period of time. The court may derogate from these conditions in the situations set out in paragraph (6) of this Article. The right holder shall be informed of the granting of a compulsory license as soon as reasonably possible.

CONDITIONS APPLICABLE TO THE GRANT OF A COMPULSORY LICENSE

Article 69

(1) A Compulsory license shall be non-exclusive, and its scope and duration shall be exclusively limited to the purpose for which it was authorized.

(2) A compulsory license shall be transferred only with the production plant or the part thereof respectively, in which the invention it is granted for has been exploited.

(3) A compulsory license shall be granted predominantly for the purposes of supplying the domestic market unless it is necessary to correct a practice determined after judicial or administrative process to be anti-competitive.

(4) The competent authority shall, on a reasoned request of an interested person, cancel a compulsory license, subject to adequate protection of the legitimate interests of the persons so authorized, if and when the circumstances, which led to its authorization, cease to exist and are unlikely to recur.

(5) The patent owner has the right to remuneration, taking into account the economic value of the authorization and need to correct anti-competitive practice.

(6) A compulsory license according to Article 68 paragraph (4) of this Act shall be non-transferable except with a transfer of the second patent or the protected plant variety.

3. Compulsory licences for patents relating to the manufacture of pharmaceutical products intended for export to countries having public health problems

GRANTING OF A COMPULSORY LICENCE

Article 69a

(1) The court referred to in Article 67a paragraph 1 of this Act may grant, to any person instituting a legal action claiming the grant of a compulsory license in accordance with the provisions of the Regulation (EC) No. 816/2006, a compulsory license for a patent or a Supplementary Protection Certificate, required for the manufacture and sale of a pharmaceutical product, where such a product is intended for export to importing countries with public health problems.

(2) In relation to compulsory licenses relating to the manufacture of pharmaceutical products for export to countries with public health problems, the terms within the meaning of this Act shall have the same meaning as those used in the Regulation (EC) No. 816/2006.

(3) With an application for the grant of a compulsory license referred to in paragraph (1) of this Article, the applicant shall communicate the number of the granted patent or the Supplementary Protection Certificate for the invention which is the subject matter of the compulsory license, and the website address referred to in Article 10.6 of the Regulation (EC) No. 816/2006.

(4) The provisions of this Act relating to compulsory licenses and the provisions of the Act on Civil Proceedings shall apply *mutatis mutandis* to particular matters relating to the procedure for the grant of a compulsory license, not regulated by the Regulation (EC) No. 816/2006.

ADOPTION OF AN APPLICATION FOR THE GRANT OF A COMPULSORY LICENCE

Article 69b

(1) If in the examination procedure concerning an application for the grant of a compulsory license it has been established that the application complies with all the requirements prescribed by the Regulation (EC) No. 816/2006, and the requirements prescribed by this Act and the Act on Civil Proceedings, the court shall issue a decision on the adoption of the application.

(2) In its decision, the court shall indicate in detail specific conditions set out in Article 10 paragraphs 2 to 9 of the Regulation (EC) No. 818/2006, to be fulfilled by the licensee.

(3) Indication of the grant of a compulsory license shall be entered in the Register of Patents or the Register of Supplementary Protection Certificates and published in the official gazette of the Office.

(4) The court shall notify the Council for TRIPS through the intermediary of the Office of its final decisions relating to the grant of a compulsory license, the conditions under which it was granted, as well as of its termination and review, indicating the data prescribed by Article 12 of the Regulation (EC) No. 816/2006. A copy of this notification shall be communicated by the Office to customs authorities and to the authority competent for medicines and medicinal products in the Republic of Croatia.

REFUSAL OF AN APPLICATION FOR THE GRANT OF A COMPULSORY LICENCE

Article 69c

The court referred to in Article 67a paragraph (1) of this Act shall refuse an application for the grant of a compulsory license by a decision, if it fails to comply with the requirements set out in the Regulation (EC) No. 816/2006, and the requirements prescribed by this Act.

TERMINATION OR MODIFICATION OF A COMPULSORY LICENCE

Article 69d

(1) The right holder or the licensee may institute a legal action claiming from the court to terminate a compulsory licence, if it has established that the counter party has failed to respect a decision on the grant of a compulsory license. In its decision to terminate the compulsory license, the court shall specify the time period within which the licensee shall arrange for any product in his possession, custody, power or control to be redirected at his expense to the countries in need referred to in Article 69a of this Act, or otherwise disposed of, in consultation with the right holder.

(2) When notified by the importing country that the amount of pharmaceutical product has become insufficient to meet its needs, the licensee may institute a legal action, claiming the modification of the licence conditions, for the purpose of permitting the manufacture and export of additional quantities of the product to the extent necessary to meet the needs of the importing country concerned. In such cases the court shall apply expeditious proceedings. If the additional quantity of the product requested does not exceed 25%, the provisions of Article 69a paragraph (8) of this Act shall not apply.