Government Decree 212/2020 (16 May)
on public health compulsory licences for exploitation within Hungary

The Government,

acting within its original legislative power laid down in Article 53 (2) of the Fundamental Law, having regard to the provisions of Act XII of 2020 on the containment of coronavirus,

acting, with respect to section 7, within its original legislative power laid down in Article 53 (3) of the Fundamental Law, on the basis of authorisation by the National Assembly under section 3 (1) of Act XII of 2020 on the containment of coronavirus,

acting within its function laid down in Article 15 (1) of the Fundamental Law,

decrees as follows:

Section 1 (1) With a view to satisfying the needs arising within Hungary in connection with the health crisis as defined by section 228 (2) of Act CLIV of 1997 on healthcare, the Hungarian Intellectual Property Office (hereinafter "HIPO") shall issue a public health compulsory licence (hereinafter "public health compulsory licence") for the exploitation of

a) a medicinal product or an active substance under patent or supplementary protection, or a medical device or an investigational medicinal product under patent protection (hereinafter jointly "healthcare product"), or

b) a procedure, equipment or tool under patent protection that is required for the production of a healthcare product.

(2) On the basis of a public health compulsory licence, the compulsory licence holder shall be entitled to exploit the healthcare product, procedure, equipment or tool solely for satisfying the needs arising within Hungary as set out under paragraph (1).

(3) The public health compulsory licence shall not confer exclusive right of exploitation; on the basis of the public health compulsory licence, the public health compulsory licence holder may not grant any licence for exploitation.

(4) The HIPO shall determine the period of a public health compulsory licence based on information provided by the pharmaceutical state administration organ and having regard to the needs suitable for the management of the health crisis, with the proviso that the period for which a public health compulsory licence is granted shall not last longer than until 31 March 2021.

(5) The pharmaceutical state administration organ shall issue the certificate regarding the supply need under paragraph (4) at its own discretion, based on the analysis of information on the amount of supplies available and the assessment of risks. To acquire further data required for issuing the certificate, the pharmaceutical state administration organ may contact also the administrator of the National Healthcare Reserve or the Ministry led by the Minister responsible for healthcare for data provision.

(6) For a public health compulsory licence, the patent holder shall be entitled to an appropriate fee. The fee shall be determined by the HIPO. The fee shall reflect the economic value of the public health compulsory licence and, in particular, it shall be proportionate to the fee that the public health compulsory licence holder should pay on the basis of a licensing contract concluded with the patent holder, having regard to the conditions of licence trade established in the technological sector of the invention.

(7) When determining the fee under paragraph (6), the HIPO shall take into account, in particular,

a) the typical rate of exploitation fees and net sales in the industrial sector concerned and

b) the rate of the contribution of the use of the patent under public health compulsory licence to the economic advantage manifest in the healthcare product, or in the procedure, equipment

or tool under patent protection that is required for the production of a healthcare product (patent contribution rate).

(8) The public health compulsory licence holder may renounce the public health compulsory licence at any time, by means of a declaration addressed to the HIPO. The HIPO shall notify the patent holder and the pharmaceutical state administration organ of the renunciation.

(9) The public health compulsory licence shall terminate upon renunciation, the expiry of the fixed period under paragraph (4) or the termination of the supplementary protection.

(10) In case the public health compulsory licence is terminated due to renunciation or the expiry of the fixed period under paragraph (4), the pharmaceutical stated administration organ shall order, by way of a decision, the destruction of the healthcare product, or the procedure, equipment or tool required for the production of a healthcare product, that has not been lawfully placed on the market by the public health compulsory licence holder.

(11) Paragraph (10) shall not apply if, before the expiry of the fixed period under paragraph (4), the public health compulsory licence holder acquires a new public health compulsory licence with the same material scope as the public health compulsory licence serving as basis for the production of the healthcare products.

(12) If placing on the market of a healthcare product produced on the basis of a public health compulsory licence is conditional, by virtue of an Act, upon a permit issued by an authority, in the course of its permission procedure, when deciding on an application, the authority of permission shall regard the content of the public health compulsory licence as having been proven.

Section 2 (1) Healthcare products produced on the basis of a public health compulsory licence shall be distinguished from products produced by the patent holder by a unique marking. The fact that a healthcare product was produced on the basis of a public health compulsory licence granted by the HIPO for the sole purpose of placing it into market in Hungary shall be clearly indicated on the packaging and any related documents.

(2) The pharmaceutical state administration organ shall oblige public health compulsory licence holders who fail to fulfil their obligation under paragraph (1) to repackage the healthcare products in compliance with paragraph (1) and section 3 (2) *c)*.

(3) In accordance with section 35 (3) of Act XXXIII of 1995 on the protection of inventions by patents (hereinafter "Szt."), a patent holder may claim damages for the unauthorised use of a healthcare product, or a procedure, equipment or tool that is required for the production of a healthcare product, under patent protection. This provision shall apply to supplementary protection accordingly.

Section 3 (1) To the procedure relating to public health compulsory licences, the provision of the Szt. shall apply subject to the following derogations:

a) the HIPO shall proceed in a panel of three,

b) for the remedy of deficiency or the making of statements, a time limit not shorter than fifteen days, but not longer than thirty days, shall be set, and extensions of time limits may be granted only in particularly justified cases,

c) the HIPO shall proceed as a matter of priority.

(2) In addition to the requirements specified in section 45 (5) and (6) of the Szt., an application for a public health compulsory licence shall contain the following:

a) the registration number of the patent or supplementary protection certificate granted for the invention to be exploited on the basis of the public health compulsory licence,

b) the name of the healthcare product, or the non-proprietary name of a medicinal product, the applicant wishes to produce on the basis of the compulsory licence,

c) the markings distinguishing the healthcare product to be produced on the basis of the public health compulsory licence from the products of the patent holder, in accordance with section 2 (1),

d) a certificate by the pharmaceutical state administration organ certifying that the applicant applies for a public health compulsory licence for a healthcare product suitable for satisfying the needs arising within Hungary in connection with the health crisis in a necessary amount, as set out in the certificate,

e) a certificate that the applicant for a public health compulsory licence has the capacity required for the production of the amount to be produced on the basis of the public health compulsory licence as specified in the certificate under point *d)*,

f) if the requirements set out in point *e)* are not met, a certificate that the applicant made substantive preparations to secure the capacity required for the production of the amount specified in the certificate under point *d)*.

(3) The submission of an application for public health compulsory licence shall be subject to a fee as set out in the law on administrative service fees in industrial property procedures. In the case of a failure to pay such fee, the application shall be deemed withdrawn.

(4) After the receipt of an application, the HIPO shall examine whether

a) the application meets the conditions set out in paragraphs (2) and (3),

b) the conditions set out in section 1 (1) are met.

(5) Within eight days following the receipt of an application, the HIPO shall notify the patent holder concerned of the fact that an application for compulsory licence was submitted regarding his invention.

(6) Any infringement proceedings against the applicant for a public health compulsory licence related to the patent, or supplementary protection certificate, specified in the application, or any provisional measures connected thereto, shall be suspended until the decision by the HIPO.

(7) If an application for a public health compulsory licence does not meet the conditions set out in paragraph (4), the applicant shall be called upon to remedy the deficiencies or to make a statement. The application shall be rejected if it fails to meet the examined requirements, even after the remedy of deficiencies or the making of a statement. If the applicant fails to respond to a notice to remedy deficiencies within the time limit set, the application shall be deemed withdrawn.

Section 4 (1) The HIPO shall decide on granting a public health compulsory licence or rejecting an application without conducting a hearing. The decision shall be put in writing and communicated to the applicant. The HIPO shall notify the patent holder of the decision within eight days following the making of the decision.

(2) A decision granting a public health compulsory licence shall include the following:

a) the period of the public health compulsory licence,

b) the characteristics distinguishing the healthcare product to be produced on the basis of the public health compulsory licence from the product of the patent holder,

c) the fee payable to the patent holder,

d) the registration number of the patent or the supplementary protection certificate, and

e) the name of the healthcare product or the non-proprietary name of a medicinal product.

(3) A public health compulsory licence shall be registered in the register of patents or supplementary protection certificates and an official notice thereon shall be published in the official journal of the HIPO about it.

(4) The HIPO shall notify the pharmaceutical state administration organ of granting a public health compulsory licence without delay.

Section 5 (1) To legal remedies against a decision of the HIPO under section 4 (1), the provisions of the Szt. shall apply, with the proviso that an application for modification shall have no suspensory effect regarding a public health compulsory licence granted.

(2) During the period of the compulsory licence, an interim relief shall not be allowed in an action brought against a decision concerning a medicinal product produced on the basis of the compulsory licence.

Section 6 (1) With the exception specified in paragraph (2), this Decree shall enter into force on the day following its promulgation.

(2) Section 7 shall enter into force on the fifteenth day following the promulgation of this Decree.

Section 7