Amendments of Act XXXIII of 1995 on the protection of inventions by patents

Submitted by Hungary

I. In 2020 **Act XXXIII of 1995 on the protection of inventions by patents** (Hungarian Patent Act) has been amended by **Act CLII of 2020 on amending certain acts in connection with the entry into force of the act on the legal status of the personnel of the National Tax and Customs Administration.**

The amendments entered into force on 1 January 2021 and are indicated below *in italics:*

Article 17

The provisions of Articles 9 to 16 shall apply mutatis mutandis to inventions created by persons employed in a government service, public service or public employee legal relationship, *tax and customs authority service legal relationship*, law enforcement administration service legal relationship, national defence employee legal relationship or service relationship, or by members of a co-operative employed within the framework of a legal relationship of an employment relationship nature.

II. In 2020 the Hungarian Patent Act has also been amended by **Act LVIII of 2020 on the transitional rules and epidemiological preparedness related to the cessation of the state of danger.**

The amendments entered into force on 18 June 2020 and are indicated below *in italics:*

„Compulsory licences falling within the scope of Regulation (EC) No 816/2006

Article 33/A

(1) The Hungarian Intellectual Property Office shall grant a compulsory license for the exploitation of an invention in the cases and on the terms laid down in Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2007 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (hereinafter referred to as "Regulation 816/2006/EC").

(2) The licensee may not grant a license of exploitation on the basis of the compulsory license under paragraph (1). (3) The licensee may relinquish his compulsory license under paragraph (1) at any time. Unless relinquished or cancelled, a compulsory license under paragraph (1) shall have effect until expiration of the term of validity fixed by the Hungarian Intellectual Property Office or until the termination of patent protection. Public health compulsory licences."

„Article 33/B

(1) With a view to satisfying the needs arising in Hungary in connection with the health crisis as defined by section 228(2) of Act CLIV of 1997 on healthcare, and/or with a view to exploitation for export in connection with compulsory licences for the treatment of a public health problem arising in another country (hereinafter "foreign compulsory licence"), the Hungarian Intellectual Property

Office shall grant a public health compulsory licence (hereinafter "public health compulsory licence") for the exploitation of a) a medicinal product, an active substance or an investigational medicinal product under patent or supplementary protection, or a medical device under patent protection (hereinafter jointly "healthcare product"); or b) a process, equipment or tool under patent protection that is required for the production of a healthcare product.

(2) A public health compulsory licence for exploitation for export shall only be granted if a) the applicant has a foreign compulsory licence for exploitation in the country of destination, except if the healthcare product in question or the process, equipment or tool required for the production of the healthcare product is not under patent protection or supplementary protection in the country of destination; b) based on a certificate issued by the pharmaceutical state administration organ the exploitation for export does not jeopardise the management of the health crisis; and c) the exploitation for export does not exceed the extent specified in the foreign compulsory licence.

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

Article 33/C

(1) The HIPO shall determine the duration of a public health compulsory licence a) in the case of exploitation in Hungary, based on a certificate issued by the pharmaceutical state administration organ and having regard to the needs of the management of the health crisis, as a period of at least six months; b) in the case of exploitation for export, the duration of the compulsory licence shall be identical with the temporal scope of the foreign compulsory licence.

(2) The pharmaceutical state administration organ shall issue the certificate regarding the supply need under section 33/B(2)(b) and section 33/C(1)(a) at its own discretion, based on the analysis of information on the quantity of supplies available and the assessment of risks. To obtain additional data necessary for issuing the certificate, the pharmaceutical state administration organ may request data also from the administrator of the National Healthcare Reserve or the Ministry headed by the Minister responsible for healthcare.

(3) For a public health compulsory licence, the patent holder shall be entitled to adequate remuneration. The remuneration shall be determined by the HIPO. The remuneration shall reflect the economic value of the public health compulsory licence and, in particular, it shall be commensurate with the royalty that the public health compulsory licence holder would have to pay under a licensing contract concluded with the patent holder, having regard to the licensing conditions that are common in the technological field of the subject matter of the invention. (4) When determining the remuneration under paragraph (3), the HIPO shall take into account, in particular, a) the typical rate of remuneration for exploitation and net sales in the industrial sector concerned, and

b) to what extent the use of the patent under public health compulsory licence contributes to the economic advantage brought about by the healthcare product, or the process, equipment or tool under patent protection that is required for the production of a healthcare product (patent contribution rate).

(5) The public health compulsory licence holder may surrender the public health compulsory licence at any time, by means of a declaration addressed to the HIPO. If a public health compulsory licence covers both exploitation in Hungary and exploitation for export, the public health compulsory licence holder may declare a partial surrender concerning either exploitation in Hungary or exploitation for

export. The HIPO shall notify the patent holder and the pharmaceutical state administration organ of the surrender.

(6) The public health compulsory licence shall terminate upon surrender, upon expiry of the fixed duration under paragraph (1) or upon the termination of patent or supplementary protection. Regarding exploitation for export, the public health compulsory licence shall cease to have effect upon termination of the foreign compulsory licence. Within eight days from the termination of the foreign compulsory licence the public health compulsory licence holder shall notify the HIPO of the fact of termination.

(7) If the public health compulsory licence is terminated due to surrender or the expiry of the fixed duration under paragraph (1), the pharmaceutical state administration organ shall order, by way of a decision, the destruction of the healthcare product, or the 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, or the discontinuance of the exploitation of the process required for the production of the healthcare product.

(8) Paragraph (7) shall not apply if, before the expiry of the fixed duration under paragraph (1), the public health compulsory licence holder obtains a new public health compulsory licence with the same material scope as that of the public health compulsory licence serving as a basis for the production of the healthcare products.

(9) If placing on the market of a healthcare product produced under a public health compulsory licence is subject, by virtue of an Act, to an authorisation by an authority, the authorising authority – when deciding on an application in the course of its authorisation procedure – shall consider the content of the public health compulsory licence as having been proven.

(10) Healthcare products produced under a public health compulsory licence shall be distinguished by unique marking from the products produced by the patent holder. The fact that a healthcare product has been produced under a public health compulsory licence granted by the HIPO for the sole purpose of placing it on the market in Hungary or for export to be put on the market of the country specified in section 83/J(2)(b) shall be clearly indicated on the packaging and in any related documents.

(11) The pharmaceutical state administration organ shall oblige public health compulsory licence holders who fail to fulfil their obligation under paragraph (10) to repackage the healthcare products in compliance with paragraph (10) and/or section 83/J(2)(d).”

„GENERAL PROVISIONS GOVERNING PATENT PROCEDURES

Competence of the Hungarian Intellectual Property Office

Article 44

(1) [repealed]

(2) The Hungarian Intellectual Property Office shall have authority in the following patent matters: (a) grant of patents; (b) decision on the termination of patent protection and the restoration of patent protection; (c) revocation of patents; (d) decision on lack of infringement; (e) interpretation of patent descriptions; (f) keeping the registers of patent applications and patents, including matters concerning their maintenance; (g) official information on patent matters.

(3) The Hungarian Intellectual Property Office shall also have authority in matters deriving from the application of provisions relating to European patent applications and European patents (Chapter X/A) and to international patent applications (Chapter X/B). (4) The Hungarian Intellectual Property Office shall also proceed in matters relating to supplementary protection certificates provided for in specific legislation.

(5) The Hungarian Intellectual Property Office shall conduct proceedings relating to compulsory licences (sections 83/A to 83/H) falling within the scope of Regulation 816/2006/EC [section 33/A(1)] and also in proceedings relating to public health compulsory licences [section 33/B(1)] (sections 83/I to 83/K)."

„Decisions of the Hungarian Intellectual Property Office

Article 46

(1) [repealed]

(2*) In revocation proceedings, in proceedings for a declaration of non-infringement, as well as – in the absence of a provision of this Act to the contrary – in proceedings relating to compulsory licences (sections 83/A to 83/H) falling within the scope of Regulation 816/2006/EC[section 33/A(1)] and in proceedings relating to public health compulsory licences [section 33/B(1)] (sections 83/I to 83/K), the Hungarian Intellectual Property Office shall proceed and take its decisions in boards consisting of three members. It shall give an expert opinion on the interpretation of a patent description also in three-member boards. The boards shall take their decisions by majority vote.*

(3) Decisions of the Hungarian Intellectual Property Office shall take effect on service unless a review is requested.

(4) Decisions of the Hungarian Intellectual Property Office shall be served by a public notice if (a) the address or place of business (establishment, branch of establishment) of the party is unknown, or (b) the mail is returned with a remark that the whereabouts or the address of the party are unknown.

(5) The public notice shall be published in the official journal and on the website of the Hungarian Intellectual Property Office on the same day. Decisions served by a public notice shall be considered delivered on the fifteenth day after the publication of the notice. In any other matters pertaining to the service of decisions by a public notice the provisions of the Act on the general rules of administrative authority proceedings and services shall apply with the proviso that posting shall mean publication of the public notice.

(6) Where the provisions of Article 51(1) apply, all decisions shall be delivered to the representative.

(7) The provisions of the Code of General Administrative Procedure related to the publication of decisions shall not apply in patent matters."

„Legal remedies

Article 53/A

(1) Appeals, administrative court actions, supervisory procedures, or interventions or actions by the prosecutor under the Act on the prosecution service shall not be admissible with regard to the decisions of the Hungarian Intellectual Property Office.

(2) The decisions of the Hungarian Intellectual Property Office in patent matters shall be reviewed by the court in non-contentious civil procedure laid down in Chapter XI.

(3) In the absence of a provision of this Act to the contrary, the Hungarian Intellectual Property Office may withdraw or modify its decisions – terminating the procedure – taken in the following matters only if a request for review is made and only until such request is transmitted to the court:
(a) grant of patents;

(b) decision on the termination of patent protection and the restoration of patent protection;

(c) revocation of patents;

(d) decision on lack of infringement;

(e) grant, modification and review of compulsory licenses to which Regulation 816/2006/EC [Article 33/A(1)] applies, as well as access to books and records kept by the licensee (Articles 83/A to 83/G);

(f) grant of public health compulsory licences;

(g) publication of the translation of the claims of the published European patent application, filing of the translation of the text beyond the claims of a European patent and correction of the translation.

(4) In the absence of a provision of this Act to the contrary, the Hungarian Intellectual Property Office may withdraw or modify its decision – terminating the procedure – taken in the matters referred to in paragraph

(3)(c) to (e) on the basis of a request for review only if it establishes that its decision infringes the law or if the parties request unanimously the modification or withdrawal of the decision.

(5) In cases where no opposing parties are involved, the Hungarian Intellectual Property Office may – according to the request for review – withdraw or modify the decisions defined in Article 85(1)(b) to (e) if the decision does not infringe the law, however the Hungarian Intellectual Property Office agrees with the content of the request for review.

(6) Decision based on a request for review shall be communicated to the requester and to whom the decision concerned by the request for review was communicated.

(7) The same legal remedy shall apply against the modifying decision as against the modified decision."

„Proceedings relating to public health compulsory licences

Article 83/I

(1) In proceedings relating to public health compulsory licences the provisions of this Act shall apply subject to the following derogations: a) to remedy deficiencies or make 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; b) the HIPO shall proceed as a matter of priority.

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

a) information on whether the application concerns exploitation in Hungary, exploitation for export, or exploitation both in Hungary and for export;

b) in the case of exploitation for export, the designation of the countries for which exploitation is applied for;

c) the registration number of the patent or supplementary protection certificate granted for the invention to be exploited under the public health compulsory licence;

d) the name of the healthcare product, or the non-proprietary name of the medicinal product, that the applicant wishes to produce under the compulsory licence;

e) the markings distinguishing the healthcare products to be produced under the public health compulsory licence from the products of the patent holder, in accordance with section 33/C(10);

f) a certificate of the pharmaceutical state administration organ certifying that the applicant applies for a public health compulsory licence for a healthcare product which is suitable for satisfying the needs arising in Hungary in connection with the health crisis and which is of the necessary quantity specified in the certificate;

g) a certificate that the applicant for a public health compulsory licence has the capacity required for the production of the quantity to be produced under the public health compulsory licence as specified in the certificate under point f), or in the case of exploitation for export – if the foreign compulsory licence provides for it – the capacity required for the production of the quantity to be produced under the foreign compulsory licence;

h) if the requirements set out in point g) are not met, a certificate that the applicant has made substantial preparations to ensure the capacity required for the production of the quantity specified in the certificate under point f), or in the case of exploitation for export – if the foreign compulsory licence provides for it – the capacity required for the production of the quantity to be produced under the foreign compulsory licence; and

i) in the case of exploitation for export, the foreign compulsory licence and its certified translation into English or Hungarian.

(3) The submission of an application for public health compulsory licence shall be subject to a fee, to be paid simultaneously with the submission, laid down in the law on administrative service fees in industrial property procedures. In the event of failure to do so, the application shall be deemed withdrawn.

(4) After receipt of the application, the HIPO shall examine whether a) the application meets the conditions set out in paragraphs (2) and (3); and b) the conditions set out in section 33/B are met.

(5) Within eight days from receipt of the application, the HIPO shall notify the patent holder concerned of the fact that an application for compulsory licence has been 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 pending the decision of the HIPO.

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

Article 83/J

(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 from the taking of the decision.

(2) A decision granting a public health compulsory licence shall include the following: a) information on whether the application concerns exploitation in Hungary, exploitation for export, or exploitation both in Hungary and for export; b) in the case of exploitation for export, the country or countries covered by the public health compulsory licence; c) the duration of the public health compulsory licence; d) the markings distinguishing the healthcare products to be produced under the public health compulsory licence from the products of the patent holder; e) the remuneration payable to the patent holder; f) the registration number of the patent or the supplementary protection certificate; and g) the name of the healthcare product or the non-proprietary name of the medicinal product.

(3) The 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.

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

Article 83/K

For the duration of the public health compulsory licence, no interim relief shall be allowed in an action brought against a decision of the pharmaceutical state administration organ concerning a medicinal product produced under the public health compulsory licence."

„Review of decisions of the Hungarian Intellectual Property Office

Request for review

Article 85

(1) Upon request, the court may review the Hungarian Intellectual Property Office's

(a) decisions referred to in Article 53/A;

(b) decisions suspending procedure or furnishing a basis for entries in the Patent Register;

(c) orders excluding or limiting the inspection of files, against which independent legal remedy is admissible under the provisions of the Code of General Administrative Procedure;

(d) orders denying persons the legal status as a party to the procedure apart from those who have submitted request for the commencement of a procedure;

(e) decisions imposing procedural fines or ruling on the amount and on the apportionment of procedural costs and their payment.

(2) A request for review brought against an decision imposing procedural fine or ruling on the amount and on the apportionment of procedural costs shall have no delaying force with respect to any other provisions of the decision not contested in the request for review, and shall not prevent them from becoming final.

(2a) A request for review brought against a decision granting a public health compulsory licence shall have no suspensory effect in respect of the public health compulsory licence granted.

(3) Any order of the Hungarian Intellectual Property Office not referred to in paragraph (1) may only be contested in a request for the review of the decisions referred to in paragraph (1).

(4) Review of a decision may be requested by (a) any party to the procedures before the Hungarian Intellectual Property Office; (b) any person excluded from, or limited in, the inspection of files; (c) any person whose legal status as a party to the procedure has been denied.

(5) Review of a ruling on the grant and revocation of a patent may be requested by the public prosecutor under Article 6(2). Any other participant to the procedures before the Hungarian Intellectual Property Office may submit, in his own right, an independent request for review of the decision or a provision of the decision relating to him.

(6) The request for review must be filed or posted by registered mail, with the exceptions laid down in paragraphs (7) and (8), within thirty days from the date of communication of the decision to the party concerned or to any other party to the procedure.

(7) The time limit of thirty days for the filing of a request for review shall be reckoned from the communication of the order refusing, or considering not to have been filed, the request for continuation of the procedure or the request for restitutio in integrum, if (a) that date is later than the date of communication of the decision under paragraph (6), and (b) the request for continuation of the procedure or the request for restitutio in integrum was filed to avert the consequences of an omission which served directly as a basis for the decision under paragraph (6).

(8) [repealed]

(9) The request for review shall be filed with the Hungarian Intellectual Property Office, which shall forward it, together with the documents of the patent file, to the court within fifteen days, except for the case provided for in paragraph (10). Where an opposing party took part in the procedure, the Hungarian Intellectual Property Office shall simultaneously notify the opposing party of the forwarding of the request.

(10) If the request for review raises legal questions of fundamental importance, the Hungarian Intellectual Property Office may make a written statement about that question and shall forward it, together with the request for review and the documents of the patent file, to the court within thirty days.

(11) The following data shall be indicated in the introductory part of the request for review: (a) the name of the court seized, (b) the identification details of the requesting party specified in Article 45(5) to (6), and, if there is a party with opposing interests, the known identification details of that party, and (c) the identification details of the legal representative of the requesting party specified in Article 45(5) to (6) and his secure delivery service address.

(11a) The following data shall be indicated in the substantive part of the request for review: (a) the number of the decision whose review is sought, and, where necessary and available, the registration number, as well as the provision or part of the decision whose review is sought, (b) the explicit request that the court review the decision, and (c) the grounds demonstrating the necessity of reviewing the decision, together with the supporting evidence and a reference to the legal basis.

(11b) The following shall be indicated in the closing part of the request for review: (a) the facts and a reference to the legal provisions establishing the material and territorial jurisdiction of the

court, (b) the amount paid as a procedural fee and the method of payment, or, if a partial procedural fee was paid, the request for legal aid, or, if the law provides for an exemption from paying procedural fees, the facts and a reference to the legal provisions serving as a basis for the exemption, (c) the facts and a reference to the legal provisions establishing the power of representation of the agent,(d) the supporting evidence for the facts referred to in the closing part.

(12) If a request for review is filed late, the court shall decide on the request for restitutio in integrum."

„Article 116/A

The rules of this Act applicable to public health compulsory licences shall be applied to public health compulsory licences granted pursuant to Government Decree 212/2020 (16 May) on public health compulsory licences for exploitation in Hungary."

***