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Contents

Legislation and legislative proposals

European Union

Proposed amendments to pharmaceutical legislation in the European Union

On 26 April 2023, the European Commission published two regulatory proposals for the amendment of pharmaceutical legislation in the European Union. On the one hand, it presented the Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 [COM(2023) 193 final][1].

On the other hand, the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC [COM(2023) 192 final][2].

Reform of the regulation of Supplementary Protection Certificates (SPCs)

1. The European Commission has presented four proposals for regulations to reform the European system of supplementary protection certificates for both medicinal products and plant protection products.

2. Firstly, there is the intention to create a unitary supplementary protection certificate, granted on the basis of European patents with unitary effect. The following proposals respond to this aim:

   a) Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013 [COM(2023) 222 final] of 27 April 2023[3].

   b) Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for plant protection products [COM(2023) 221 final] of 27 April 2023[4].

   These proposals allow the unitary certificate to be filed in any language of the European Union with the European Union Intellectual Property Office (EUIPO) in Alicante, which

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023PC0193

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0192

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023PC0222

[4] https://single-market-economy.ec.europa.eu/system/files/2023-04/COM_2023_221_1_EN_ACT_part1_v8.pdf

would thus acquire this important responsibility in a new area for this office.

3. In addition, two other proposals for regulations have been submitted:

   a) Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast) [COM(2023) 231 final] of 27 April 2023[5].

   b) Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for plant protection products (recast) [COM(2023) 223 final] of 27 April 2023[6].

   The aim of these two proposals is to create a centralised procedure for obtaining national supplementary protection certificates. This would require a basic European patent. The granting office would also be the EUIPO and the procedure would be very similar, with combined applications for a unitary protection certificate and national certificates for the other States covered by the European patent which do not participate in the unitary patent (as is the case in Spain) being accepted.

Proposal for a Regulation of the European Parliament and of the Council on compulsory licensing

The European Commission has presented a Proposal for a Regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006 [COM(2023) 224 final] of 27 April 2023[7].

The proposed regulation aims to lay down rules on the procedure and conditions for the granting of a Union compulsory licence of intellectual property rights that are necessary for the supply of crisis-relevant products to the Member States in the context of a Union crisis or emergency mechanism.

The scope of the compulsory licence covers patents, published patent applications, supplementary protection certificates and utility models. Compulsory licences shall be issued by the European Commission.

Proposal for a Regulation of the European Parliament and of the Council on standard essential patents

The European Commission has presented a Proposal for a Regulation of the European Parliament and of the Council on standard essential patents and amending Regulation (EU)2017/1001 [COM(2023) 232 final] of 27 April 2023.

The proposed regulation seeks to establish a series of measures in relation to patents that are essential to a standard that has been published by a standard development organisation, to which the SEP holder has made a commitment to license its SEPs on fair, reasonable and non-discriminatory (FRAND) terms and conditions.

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[5] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0231

[6] https://single-market-economy.ec.europa.eu/system/files/2023-04/COM_2023_223_1_EN_ACT_part1_v9.pdf

[7] https://single-market-economy.ec.europa.eu/system/files/2023-04/COM_2023_224_1_EN_ACT_part1_v11.pdf

On that basis, a register of standard-essential patents - to be kept by the EUIPO - and a procedure for the amicable settlement of disputes related to fair, reasonable and non-discriminatory nature of terms and conditions, among other things, are envisaged.

Implementation of the European patent system with unitary effect begins

1. The regulation of the unitary patent is contained in two European Union regulations published in the *Official Journal of the European Union* L 361 of 31 December 2012: Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December implementing enhanced cooperation in the area of the creation of unitary patent protection and Council Regulation (EU) No 1260/2012 of 17 December implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements. In addition, procedural issues relating, inter alia, to defences to patent infringements and proceedings for revocation of patents are regulated in the Agreement on a Unified Patent Court.

   Well, the system designed by these three texts will apply from 1 June 2023, i.e. more than a decade after their adoption.

2. This is because the requirements for its application had not been met so far. Indeed, according to Regulation (EU) No. 1257/2012, it will apply from 1 January 2014, or from the date of entry into force of the Agreement on a Unified Patent Court, whichever is later. In turn, the said agreement enters into force at the later of the following points in time: *(a)* 1 January 2014; *(b)* the first day of the fourth month after the deposit of the thirteenth instrument of ratification or accession "including the three Member States in which the highest number of European patents had effect in the year preceding the signature of the Agreement takes place"; (c) the first day of the fourth month after the date of entry into force of the amendments to Regulation (EU) No 1215/2012 concerning its relationship with this Agreement.

   Of these three requirements, the one that has been delayed is the ratification of the Agreement establishing the Unified Patent Court. In February 2023 Germany deposited its instrument of ratification and, as France and Italy (the other two States with the most European patents) had already done so and the minimum number of ratifying States had been reached, the system will start applying on 1 June 2023.

Agreement to fix the seat of the Central Division of the Unified Patent Court with jurisdiction over chemical patents in Milan

As just recalled in the previous entry in this newsletter, the Agreement on a Unified Patent Court is an international treaty that forms an essential part of the so-called *unitary patent package* together with Regulation (EU) No. 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection and Council Regulation (EU) No. 1260/2012 of 17 December implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements.

The object of the agreement is the establishment of a Unified Patent Court, which, as stated in Article 1 of the agreement, is "a court common to the Contracting Member States and thus subject to

the same obligations under Union law as any national court of the Contracting Member States" and will have jurisdiction not only for litigation relating to European patents with unitary effect, but also for litigation relating to any type of European patent.

The Unified Patent Court comprises a Court of First Instance, a Court of Appeal and a Registry. The Court of First Instance comprises a central division, national divisions and regional divisions.

The Central Division has its seat in Paris, with sections originally planned to be located in London and Munich. The Paris branch, in addition to housing the President's Office, will deal with patent matters relating to various performing operations, transporting, textiles, paper, fixed constructions, physics and electricity. The section initially planned for London will deal with cases relating to the human necessities, chemistry and metallurgy, while the Munich section will handle patent litigation relating to mechanical engineering, lighting, heating, weapons and blasting.

However, following the United Kingdom's exit from the European Union, it had yet to be decided where the London section will now be located (and in the meantime its responsibilities are distributed between Paris and Munich).

The Italian government has now announced that it has reached an agreement with France and Germany to locate the remaining sectionin Milan[8]. This section of the Central Division of the Unified Patent Court is very important in the field of life sciences, given its responsibilities over chemical patents.

Good practices for industry for the prevention of human medicinal product shortages

The European Medicines Agency has published a document on good practices for industry for the prevention of human medicinal product shortages (Doc. EMA/760980/2022)[9]. The document makes a number of recommendations to industry to implement preventive strategies.

Transparency rules for publication of clinical trial information

The European Medicines Agency has opened a public consultation period for the revision of the transparency rules for the publication of clinical trial information submitted through the Clinical Trials Information System in the European Union (EU)[10]. The proposed revision aims to reduce administrative burdens while improving the balance between trial transparency and respect for confidentiality.

[8] https://www.esteri.it/it/sala_stampa/archivionotizie/comunicati/2023/05/tribunale-unico-dei-brevetti-italia-otterra-sezione-distaccata-per-milano

[9] https://www.ema.europa.eu/en/news/guidance-industry-prevent-mitigate-medicine-shortages

[10] https://www.ema.europa.eu/en/news/review-transparency-rules-eu-clinical-trials-information-system-ctis

Judgments, rulings and decisions

European Union

Revocation or suspension of authorisation to operate as a wholesaler of medicinal products

1. As is known, Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use provides in Article 77(1) that medicinal products covered by a previously granted marketing authorisation may be distributed wholesale only where Member States grant an authorisation for this activity.

   On that basis, Article 79 of the Directive provides that, in order to obtain a distribution authorisation, applicants must meet at least the following requirements:

   a) they must have suitable and adequate premises, installations and equipment, so as to ensure proper conservation and distribution of the medicinal products;

   b) they must have staff, and in particular, a qualified person designated as responsible, meeting the conditions provided for by the legislation of the Member State concerned;

   c) they must undertake to fulfil the obligations incumbent on them under the terms of Article 80 (an article which sets out a list of obligations which holders of a distribution authorisation are required to fulfil: they must make the premises, installations and equipment accessible at all times to the persons responsible for inspecting them; they must obtain their supplies of medicinal products only from persons who are themselves in possession of the distribution authorization or who are exempt from obtaining such authorization; they must supply medicinal products only to persons who are themselves in possession of the distribution authorization or who are authorized or entitled to supply medicinal products to the public in the Member State concerned; they must have an emergency plan which ensures effective implementation of any recall from the market ordered by the competent authorities or carried out in cooperation with the manufacturer or marketing authorization holder for the medicinal product concerned; etc.).

   All these requirements are not exhaustive and may be extended by the Member States. In any case, according to Article 77(6) of Directive 2001/837/EC, when they are no longer fulfilled, Member States are obliged to suspend or revoke such authorisation and to inform the other Member States and the Commission immediately.

2. Against that background, the Court of Justice was asked in Case C-47/22 *Apotheke B. v Bundesamt für Sicherheit im Gesundheitswesen (BASG)* whether or not it is necessary to revoke an authorisation to operate as a wholesaler of medicinal products if one of the conditions laid down in Article 80 of that directive,

which was originally no longer satisfied, is again satisfied.

3. In that regard, the Advocate General, in his Opinion of 16 March 2023 (ECLI:EU:C:2023:225), considers that, "although the Member States are obliged to adopt measures including at the very least revocation or suspension measures applicable in the event of infringement of Articles 79 and 80 of Directive 2001/83, that directive leaves it to the national legislature to determine the parameters for the application of each of those measures. In such a situation, it is for the national authorities to determine in concreto the most appropriate measure on the basis of the criteria laid down by national law and in the light of the factual circumstances of each case".

   Consequently, the Advocate General takes the view that the question referred for a preliminary ruling concerns only the interpretation of the national provisions which make it possible to determine which of the penalties - suspension or revocation of the authorisation to engage in the activity of wholesaler of medicinal products - is the most appropriate. The Court of Justice has no jurisdiction to rule on the interpretation of national legislation.

International

The Enlarged Board of Appeal of the European Patent Office rules on plausibility and inventive step requirement

1. As set out at length in another paper - "La plausibilidad de la invención y el requisito de la actividad inventiva en materia de patentes", *GA_P Análsis*, December 2021[11], in case G 2/21 the Enlarged Board of Appeal of the European Patent Office was asked to resolve the divergent interpretations of the Technical Boards of Appeal on plausibility in relation to the requirement of inventive step.

   The first question asked was, in essence, whether or not it is appropriate to demand the requirement of plausibility when assessing inventive step. To this end, it was asked whether data provided subsequent to the application should be disregarded when the proof of the achievement of the technical effect rests solely on this evidence. If it is understood that subsequent evidence must be disregarded (and, therefore, that it is considered necessary for the invention to be plausible in the light of the application and the common general knowledge of the skilled person), it is asked whether such subsequent evidence can be considered if the skilled person considers the invention plausible at the time of the application (applying the doctrine of *ab initio* plausibility) or whether, on the contrary, they can be taken into account provided that the invention is not, at the date of application and in view of the application and common general knowledge, clearly lacking in plausibility for a skilled person (according to the doctrine of *ab initio* implausibility).

2. Well, on 23 March 2023, the Enlarged Board of Appeal issued its decision, answering as follows:

   1. Evidence submitted by a patent applicant or proprietor to prove a technical

[11] https://www.ga-p.com/publicaciones/la-plausibilidad-de-la-invencion-y-el-requisito-de-la-actividad-inventiva-en-materia-de-patentes

effect relied upon for acknowledgement of inventive step of the claimed subject-matter may not be disregarded solely on the ground that such evidence, on which the effect rests, had not been public before the filing date of the patent in suit and was filed after that date.

2. A patent applicant or proprietor may rely upon a technical effect for inventive step if the skilled person, having the common general knowledge in mind, and based on the application as originally filed, would derive said effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention.

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