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Gómez-Acebo & Pombo

No. 10 | 2018

Life Sciences Newsletter

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Supplementary protection certificates for medicinal products and Brexit

The negotiators in the withdrawal of the United Kingdom (UK) from the European Union (EU) have agreed that supplementary protection certificates (SPCs) for medicinal products and plant protection products applied for in the UK before the end of the transition period on 31 December 2020 may be granted after such date and with the same level of protection as that provided for in the EU regulations governing SPCs (Regulations (EC) Nos 1610/96 and 469/2009).

This agreement is recorded in the "Joint Statement from the negotiators of the European Union and the United Kingdom Government" of 19 June 2018. (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/717697/Joint_Statement_-_19_June_2018.pdf).

Pharmaceutical Industry and Brexit

On 19 June 2018 the European Medicines Agency (EMA) and the European Commission updated their guidance to help pharma companies in the Brexit process ('Questions and Answers related to the United Kingdom's withdrawal from the European Union with regard to the medicinal products for human and veterinary use within the framework of the Centralised Procedure', available at the link http://www.ema.europa.eu/docs/en_GB/document_library/Other/2017/05/WC500228739.pdf).

In parallel, the EMA has published a new version of its document 'Practical guidance for procedures related to Brexit for medicinal products for human and veterinary use within the framework of the centralised procedure' (EMA/478309/2017 Rev. 2.) available at http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2017/11/WC500239369.pdf.

Launch of the IRIS portal

In order to ensure that the pharmaceutical industry invests in the research, development and marketing of medicines for the diagnosis, prevention or treatment of rare diseases, the EU establishes a system of incentives, contained in Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products, as well as in Commission Regulation (EC) No. 847/2000 of 27 April 2000 laying down the provisions for

implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concepts 'similar medicinal product' and 'clinical superiority'. Equally relevant is the Communication from the Commission on Regulation (EC) No 141/2000 of the European Parliament and of the Council on orphan medicinal products (2003/C 178/02), a document issued after the first few years of application of the named regulation in response to a number of requests for interpretation and clarification.

In June, the European Medicines Agency launched a new online portal through which applications for the designation of an orphan medicinal product can be submitted. This is the IRIS portal (https://iris.ema.europa.eu/).

Proposal to amend the regulation on supplementary protection certificates for medicinal products to introduce the manufacturing waiver

Following a public consultation launched in October 2017, on 28 May 2018 the European Commission presented a 'Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products' aimed at exempting from infringement of an SPC all the necessary acts related to manufacturing for export purposes [Document COM(2018) 317 final].

The proposal consists of an amendment of Art. 4 of Regulation (EC) No 469/2009 in order to introduce a provision according to which the certificate shall not confer protection against a particular act against which the basic patent conferred protection, provided that, in addition to meeting other conditions, the act compromises making for the exclusive purpose of export to third countries or any related act that is strictly necessary for that making or for the actua export itself.

For a more detailed examination of this issue, see GARCÍA VIDAL, Á., '*Propuesta de modificación del Reglamento sobre los certificados complementarios de protección de medicamentos para introducir el límite de la fabricación para la exportación (manufacturing waiver)*', https://www.lexology.com/library/detail.aspx?g=0a42f6a2-130e-4abd-be33-db31ccb503d5

The European Commission publishes two studies on supplementary protection certificates

The European Commission has published in the month of May two reports of great interest in their analysis of the legal and economic aspects, respectively, of SPCs:

a) The 'Study on the legal aspects of Supplementary Protection Certificates in the EU', written by the Max Planck Institute for Innovation and Competition. https://ec.europa.eu/docsroom/documents/29524

b) The 'Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe", written by Copenhagen Economics and published on 29 May 2018 (https://www.copenhageneconomics.com/publications/publication /study-on-the-economic-impact-of-supplementary-protection-certificates- pharmaceutical-incentives-and-rewards-in-europe)

Targeted stakeholder consultation on duplicate marketing authorisations for biological medicinal products

As is well known, Art. 82 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency provides that only one authorisation may be granted to an applicant for a specific medicinal product. However, where there are objective verifiable reasons relating to public health regarding the availability of medicinal products to healthcare professionals and/or patients, or for co-marketing reasons, the Commission shall authorise the same applicant to submit more than one application to the Agency for that medicinal product.

And in relation to this issue, the European Commission carried out a public consultation, closed on 10 September 2018, related to the granting of duplicate marketing authorisations for biological medicinal products prior to amending its October 2011 note on the 'Handling of duplicate marketing authorisation applications'. In particular, the objective of the targeted stakeholder consultation is, in the words of the European Commission, "to seek the views of interested parties on the specific issue of the impact of duplicate marketing authorisations of biological medicinal products on the availability of biosimilars to healthcare professionals and patients".

Clinical trials of medicinal products for human use

The European Commission has published a draft Question and Answer document on Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. Available at https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/regulation5362014_qa_en.pdf

Communicable diseases and special health issues

OJ L 170 of 6 July 2018, https://eur-lex.europa.eu/legal-content/EN/TXT PDF/?uri=CELEX:32018D0945&from=EN, has published Commission Implementing Decision (EU) 2018/945 of 22 June 2018 on the communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions.

Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products

1. Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 [OJ L 150 of 14 June 2018, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0848&from=EN] establishes the principles of organic production and lays down the rules concerning organic production, related certification and the use of indications referring to organic production in labelling and advertising, as well as rules on controls additional to those laid down in Regulation (EU) 2017/625.

2. From amongst its extensive content, Art. 30 should be highlighted here. This article provides, inter alia, that for the purposes of the Regulation a product shall be regarded as bearing terms referring to organic production where, in the labelling, advertising material or commercial documents, such a product, its ingredients or feed materials used for its production are described in terms suggesting to the purchaser that the product, ingredients or feed materials have been produced in accordance with this Regulation.

   In particular, the terms listed in Annex IV and their derivatives and diminutives, such as 'bio' and 'eco', whether alone or in combination, may be used throughout the Union and in any language listed in that Annex for the labelling and advertising of products referred to in this Regulations and which comply with the same.

   Moreover, according to para. 4, these terms shall not be used for a product for which Union law requires the labelling or advertising to state that the product contains GMOs, consists of GMOs or is produced from GMOs.

Amendment as regards the definition of the concept 'similar medicinal product'

Commission Regulation (EC) No 847/2000 of 27 April 2000 laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concepts 'similar medicinal product' and 'clinical superiority' lays down factors to be considered when implementing Art. 3 of Regulation (EC) No 141/2000 on orphan medicinal products and establishes definitions of 'similar medicinal product' and 'clinical superiority' for the purposes of implementing Art. 8 of the abovementioned Regulation. OJ L 132 of 30 May 2018, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0781&from=EN,— published Commission Regulation (EU) 2018/781 of 29 May 2018 amending Regulation (EC) No 847/2000 as regards the definition of the concept of 'similar medicinal product'.

Judgments and decisions

European Union

Supplementary protection certificate for medicinal products and products protected by a basic patent in force

The Court of Justice (Grand Chamber), in its judgment of 25 July 2018 in Case C-121/17, Teva UK Ltd, Accord Healthcare Ltd, Lupin Ltd, Lupin (Europe) Ltd and Generics (UK) Ltd (trading as 'Mylan') v Gilead Sciences, Inc., has stated the following:

"Article 3(a) of Regulation No 469/2009 of the European Parliament and of the Council of 6 May 2009, concerning the supplementary protection certificate for medicinal products, must be interpreted as meaning that a product composed of several active ingredients with a combined effect is 'protected by a basic patent in force' within the meaning of that provision where, even if the combination of active ingredients of which that product is composed is not expressly mentioned in the claims of the basic patent, those claims relate necessarily and specifically to that combination. For that purpose, from the point of view of a person skilled in the art and on the basis of the prior art at the filing date or priority date of the basic patent:

— the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and

— each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent".

The supplementary protection certificates for medicinal products and the Specific Mechanism provided for in certain States' Act of Accession to the European Union

1. In Case C-681/16, Pfizer Ireland Pharmaceuticals and Operations Support Group v Orifarm GmbH, the Court of Justice is asked to interpret the Specific Mechanism provided for in certain countries' Act of Accession to the European Union.

   Thus, the Act of Accession of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia provides that "[w]ith regard to the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia or Slovakia, the holder, or his beneficiary, of a patent or supplementary protection certificate for a pharmaceutical product filed in a Member State at a time when such protection could not be obtained in one of the abovementioned new Member States for that product, may rely on the rights granted by that

patent or supplementary protection certificate in order to prevent the import and marketing of that product in the Member State or States where the product in question enjoys patent protection or supplementary protection, even if the product was put on the market in that new Member State for the first time by him or with his consent".

A similar provision is contained in the Act of Accession of the Republic of Bulgaria and Romania and in the Act of Accession of Croatia.

2. The Court (Second Chamber), in its judgment of 21 June 2018, ruled that "[t]he Specific Mechanisms laid down in Chapter 2 of Annex IV to the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded, in Chapter 1 of Annex V to the Act concerning the conditions of accession of the Republic of Bulgaria and Romania and the adjustments to the Treaties on which the European Union is founded, and in Chapter 1 of Annex IV to the Act concerning the conditions of accession of the Republic of Croatia and the adjustments to the Treaty on European Union, the Treaty on the Functioning of the European Union and the Treaty establishing the European Atomic Energy Community, must be interpreted as authorising the holder of a supplementary protection certificate issued in a Member State other than the new Member States referred to in those Acts of Accession to oppose the parallel importation of a medicinal product from those new Member States in a situation where the legal systems of those States provided for the possibility of obtaining equivalent protection at the time when the application for the basic patent was published and/or the application for a supplementary protection certificate in the importing Member State was filed, but did not yet provide for such a possibility at the time when the application for a basic patent was filed, with the result that it was impossible for the patent holder to obtain an equivalent patent and a supplementary protection certificate in the exporting States".

GMOs, organisms obtained by GMOs and organisms obtained by means of techniques/methods of mutagenesis

Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC defines in Article 2(2) a 'genetically modified organism (GMO)' as 'an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination'.

The Court (Grand Chamber), in its judgment of 25 July 2018 in Case C-528/16, Confédération paysanne, Réseau Semences Paysannes, Les Amis de la Terre France, Collectif Vigilance OGM et Pesticides 16, Vigilance OG2M, CSFV 49, OGM dangers, Vigilance OGM 33 and Fédération Nature

et Progrès v Premier minister and Ministre de l'Agriculture, de l'Agroalimentaire et de la Forêt, ruled that Article 2(2) of Directive 2001/18/EC must be interpreted as meaning that organisms obtained by means of techniques/methods of mutagenesis constitute genetically modified organisms within the meaning of that provision.

Furthermore, according to the Court of Justice, only organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record are excluded from the scope of that directive, even though the Member States are not denied the option of subjecting such organisms, in compliance with EU law, to the obligations laid down in that directive or to other obligations.

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