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Legislation and legislative proposals

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New documents from the MDCG

The Medical Device Coordination Group (MDCG) has prepared several documents:

(a) A new version, of October 2019, of the "Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR" (https://ec.europa.eu/docsroom/documents/37581?locale=es).

(b) The document, of 4 October, on the "Application of transitional provisions concerning validity of certificates issued in accordance to Directives 90/385/EEC and 93/42/EEC" (https://ec.europa.eu/docsroom/documents/37402).

(c) A new version of the document "Questions and answers: Requirements relating to notified bodies" (https://ec.europa.eu/docsroom/documents/37688).

(d) The document "Designating authority's final assessment form: Key Information" (https://ec.europa.eu/docsroom/documents/37689).

New European Parliament resolution on the patentability of plants and essentially biological processes

The European Parliament has adopted a new resolution, of 19 September 2019, on the patentability of plants and essentially biological processes, in which it reiterates that patents on products derived from essentially biological processes or on genetic material necessary for conventional breeding undermine the European Patent Convention and Directive 98/44/EC. And, thus, calls on the Commission and the Member States "to do everything in their power to obtain legal clarity regarding the prohibition of the patentability of products obtained from essentially biological processes by the EPO".

Additionally, the European Parliament calls on the Commission "to engage actively with third countries when negotiating trade and partnership agreements with a view to ensuring the exclusion of essentially biological processes and the products thereof from patentability" and to —in the context of proceedings carried on at the time in the Enlarged Board of Appeal of the European Patent Office (EPO) — submit "an amicus curiae before 1 October 2019 with the Enlarged Board of Appeal of the EPO, reinforcing the conclusions laid down in its Notice of 2016 that the EU legislator's intention when adopting Directive 98/44/EC was to exclude from patentability products that are

obtained through essentially biological processes, and to attach this resolution to its statement". And, in short, "calls on the Enlarged Board of Appeal of the EPO to restore, without delay, legal certainty by affirmatively answering the questions that have been referred to it by the President of the EPO in the interest of breeders, farmers and the public".

CHED accompanying consignments of animals and goods to their destination

Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, provides that consignments of animals and goods that enter the Union through designated border control posts are to be accompanied by the Common Health Entry Document ('CHED'). Once the official controls have been performed and the CHED has been finalised, the consignments may be split into different parts, according to the commercial needs of the operator.

Now, Commission Delegated Regulation (EU) 2019/1602 of 23 April 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council concerning the Common Health Entry Document accompanying consignments of animals and goods to their destination, has been adopted for the purpose of establishing rules on the conditions and the practical arrangements under which the CHED should accompany consignments intended for placing on the market to their destination (OJ L 250, 30.9.2019, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R1602&from=EN).

Designation of expert panels in the field of medical devices

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, states in Art. 106 that the Commission shall make provision for expert panels to be designated for the assessment of the clinical evaluation in relevant medical fields, to provide views on the performance evaluation of certain in vitro diagnostic medical devices, and, where necessary, for categories or groups of devices, or for specific hazards relating to categories or groups of devices, observing the principles of highest scientific competence, impartiality, independence and transparency. Art. 48 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices also refers to this very panel.

Now, by way of Commission Implementing Decision (EU) 2019/1396 of 10 September 2019 laying down the rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the designation of expert panels in the field of medical devices (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019D1396), one expert panel is designated in each of the following areas: (1) Orthopaedics, traumatology, rehabilitation, rheumatology; (2) Circulatory system; (3) Neurology; (4) Respiratory system, anaesthesiology, intensive care; (5)

Endocrinology and diabetes; (6) General and plastic surgery and dentistry; (7) Obstetrics and gynaecology, including reproductive medicine; (8) Gastroenterology and hepatology; (9) Nephrology and urology; (10) Ophthalmology; and (11) In-vitro diagnostic medical devices (IVD).

Test methods for the determination of toxicity to human health

The Official Journal of the European Union no. 247, of 26 September 2019, published Commission Regulation (EU) 2019/1390 of 31 July 2019 amending, for the purpose of its adaptation to technical progress, the Annex to Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Available at https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R1390&from=EN.

Rules for the establishment, the management and the functioning of the network of national authorities responsible for eHealth

Art. 14 of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare provides that the Union shall support and facilitate cooperation and the exchange of information among Member States working within a voluntary network connecting national authorities responsible for eHealth designated by the Member States.

This provision led in its day to Commission Implementing Decision of 22 December 2011 providing the rules for the establishment, the management and the functioning of the network of national responsible authorities on eHealth.

Now, the above decision has been replaced by Commission Implementing Decision 2019/1765 of 22 October 2019 providing the rules for the establishment, the management and the functioning of the network of national authorities responsible for eHealth, and repealing Implementing Decision 2011/890/EU (notified under document C(2019) 7460). Available in the Official Journal of the European Union no. 270, of 24 October 2019, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D1765&from=EN.

Guidance on detection and notification of shortages of medicinal products

The European Medicines Agency (EMA) and the Heads of Medicines Agency (HMA) have published Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (EEA) [EMA/674304/2018].

This guidance does not cover any other availability issue such as withdrawals of marketing authorisations. It is available at the following link: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-detection-notification-shortages-medicinal-products-marketing-authorisation-holders-mahs_en.pdf.

Exemption from batch controls carried out on advanced therapy medicinal products (ATMP)

At the end of August, the EMA published Questions and answers on the exemption from batch controls carried out on ATMPs imported into the European Union from a third country [EMA/354272/2019]. It is available at the following link: https://www.ema.europa.eu/en/documents/other/questions-answers-exemption-batch-controls-carried-out-atmps-imported-european-union-third-country_en.pdf.

EU-U.S. Mutual Recognition Agreement

As of July 2019, the Agreement on Mutual recognition between the European Community and the United States of America is fully operational for inspections of manufacturing sites for certain human medicines carried out in their respective territories.

Judgments and decisions

European Union

Restriction on the dispensing by a pharmacy of prescription-only medicinal products

The Judgment of the Court (Fifth Chamber) of 18 September 2019, *VIPA*, C 222/18, EU:C:2019:751, concluded that Article 3(k) and Article 11(1) of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare must be interpreted as not precluding national legislation that does not authorise the dispensing of prescription-only medicinal products on the basis of order forms drawn up by healthcare professionals qualified to draw up prescriptions who practise in a different Member State, whilst said dispensing is permitted if the healthcare professionals are authorised to practise in the Member State where the medicinal products are dispensed, noting that in accordance with the above-mentioned legislation, these order forms do not contain the patient's name.

Articles 35 and 36 of the Treaty on the Functioning of the European Union must be interpreted as not precluding national legislation such as that referred to, provided such legislation is justified by an objective of protecting public health and is appropriate for the purpose of achieving that objective, all of which must be ascertained by the referring court.

Access to documents held by the EMA in the context of an MA authorisation

As reported in a previous issue of this newsletter, on 5 February 2018, the General Court delivered three judgments examining the issue of third-party access to documents incorporated in the marketing authorisation application for medicinal products submitted to the European Medicines Agency.

These judgments were handed down in the following cases: *a*) case T 718/15, regarding an application for access to a clinical study report in the MA application dossier for a medicinal product; *b*) case T 235/15, regarding an application for access to an assessment report Committee for Medicinal Products for Human Use (CHMP) on the clinical superiority of an orphan medicinal product to another previously authorised, as well as on the similarity of both medicinal products; and *c*) case T-729/15, regarding access to toxicology test reports belonging to a file relating to a veterinary medicinal product.

In these, the General Court notes that the prevailing principle is that of public access to information and that the exceptions to that principle relate to those referred to in Article 4(2) of Regulation No 1049/2001, including the exception relating to commercially confidential information. However, the General Court finds that in the cases in question the confidentiality of the documents to which the European Medicines Agency has given access to the public has not been proved. It also states that the fact that the period of data exclusivity is in force does not preclude the disclosure of the documents in which such data are contained.

The judgments of the General Court in case T-718/15 and case T-729/15 were appealed (respectively, cases C-175/18 P y C-178/18 P).

On 11 September the Advocate General Hogan delivered his opinion in both cases, proposing that the Court should set aside the judgments under appeal, believing that the General Court erred in law in so far as it concluded that there was no general presumption that CSRs should not be disclosed by reference to the first indent Article 4(2) of Regulation No 1049/2001. In any event, I also consider that the General Court erred in law in so far as it concluded that the disclosure of the report at issue would not compromise the appellant's commercial interests for the purposes of the first indent of Article 4(2) of Regulation No 1049/2001.

Supplementary protection certificate and concept of a 'product protected by a basic patent in force'

In *Royalty Pharma* (C-650/17) and *Sandoz y Hexal* (C-114/18) a series of questions are referred for a preliminary ruling to complete the case law settled by the Judgment of the Court (Grand Chamber) of 25 July 2018 in *Teva,* C-121/17, which rules that, where a product is composed of several active ingredients with a combined effect and the combination of active ingredients is not expressly mentioned in the claims of the basic patent, for such product to be 'protected by a basic patent in force', 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: a) 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 b) each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent.

Advocate General Hogan delivered his opinion, on 11 September 2019 (EU:C:2019:704), considering that:

a) the concept of the 'core inventive advance' of the patent does not apply and is of no relevance in the context of Article 3(a) of Regulation No 469/2009;

b) the Teva doctrine applies both to products consisting of a single active ingredient and products composed of several active ingredients;

c) 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 does not preclude the grant of a supplementary protection certificate for an active ingredient which is covered by a functional definition or a Markush formula provided, however, that the two-part test set out in the Teva judgment is satisfied;

d) the two-part test of the Teva judgment must be applied 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;

e) the first part of the two-part test is not satisfied and an SPC may not be granted in respect of a product if, 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 claims in a patent in relation to that product are not required for the solution of the technical problem disclosed by a patent;

f) the second part of the two-part test requires that it be established that a person skilled in the art would have been able, in the light of all the information contained in a patent, on the basis of the prior art at the filing date or priority date of the patent in question, to derive the product in question. This is not the case where, in the light of all the information contained in a patent, a product or constituent element of the product remains unknown to a person skilled in the art on the basis of the prior art at the filing date or priority date of the patent in question.

Suspension of marketing authorisation

The General Court, in its Judgment of 19 September, in case T 783/17, *GE Healthcare A/S*, EU:T:2019:624, dismisses the action seeking annulment of Commission Implementing Decision C(2017) 7941 final of 23 November 2017, concerning, in the framework of Article 31 of 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 (OJ 2001 L 311, p. 67), the marketing authorisations for gadolinium-containing contrast agents for human use which contain one or more of the active substances 'gadobenic acid, gadobutrol, gadodiamide, gadopentetic acid, gadoteric acid, gadoteridol, gadoversetamide and gadoxetic acid.

The General Court recalls that Article 116 of Directive 2001/83 provides that the competent authorities are to suspend, revoke or vary an MA if the view is taken that the medicinal product is harmful or where its therapeutic efficacy is lacking, or that the risk-benefit balance is not favourable, or where its qualitative and quantitative composition is not as declared. And, in this respect, sets out the following guidelines of interpretation:

a) Those conditions of variation, suspension or revocation of an MA are alternative and not cumulative. They must also be interpreted in accordance with the general principle, set out in the case law, that the protection of public health must unquestionably take precedence over economic considerations.

b) In accordance with the precautionary principle, the health risks which the grounds set out in the first paragraph of Article 116 of Directive 2001/83 aim to prevent need not be specific, but only potential.

c) It is for the competent authority, in this case the Commission, to establish that the conditions relating to the revocation, suspension or modification of an MA, set out in Article 116 of Directive 2001/83, are met. The competent authority is obliged to refer to the main reports and scientific expert opinions on which it relies and to explain, in the event of a significant discrepancy, the reasons why it has departed from the conclusions of the reports or expert opinions supplied by the undertakings concerned. That obligation is particularly strict in cases of scientific uncertainty. The consultation is to be inter partes and transparent in order to ensure that the substance considered has undergone an in-depth and objective scientific assessment, based on using the most representative scientific theories and scientific positions put forward by the relevant pharmaceutical laboratories.

d) The Court cannot substitute its own assessment for that of the Pharmacovigilance Risk Assessment Committee ('PRAC') and the Committee for Medicinal Products for Human Use ('CHMP'). Its power of judicial review is exercised only over the lawfulness of their operation, and over the internal consistency and reasoning of the PRAC's recommendation and the CHMP's opinion. With regard to the latter element, the courts may only examine whether the recommendation and the opinion contain a statement of reasons from which it is possible to ascertain the con-

siderations on which the recommendation and opinion are based, and whether they establish a comprehensible link between the medical or scientific findings and their conclusions.

The CJEU refuses to examine the problem of SPC applications based on an authorisation issued to a third party

1. The High Court of Justice (England & Wales), Chancery Division (Patents Court) (United Kingdom), by decision of 4 March 2019,—*Eli Lilly And Company v Genentech, Inc* [2019] EWHC 388 (Pat)—, asked the Court of Justice of the European Union ('CJEU') whether Regulation No 469/2009 precludes the grant of an SPC to the proprietor of a basic patent in respect of a product which is the subject of a marketing authorisation held by a third party without that party's consent. This matter was the subject of analysis in my document: GARCÍA VIDAL, Á., "El certificado complementario de protección de medicamentos solicitado sobre la base de la autorización de comercialización de un tercero", https://www.ga-p.com/wp-content/uploads/2019/06/Analisis_Farmac%C3%A9utico_El-certificado-complementario-de-protecci%C3%B3n-de-medicamentos-solicitado.pdf.

2. Now, the CJEU, by way of Order of 5 September 2019 (C 239/19, EU:C:2019:687), has refused to examine the issue on the grounds that it does not concern an interpretative problem whose solution is necessary for the resolution of the dispute which the court is called upon to resolve. The CJEU bases itself specifically on the fact that the referring court held that the claims of the basic patent were invalid, which was liable to render the SPC application based on that patent invalid, without having to examine the preliminary question. That the question should be debated at different national courts does not justify the admissibility of the request for a preliminary ruling, which is here purely a request for an opinion on a hypothetical question and therefore inadmissible.

Novelty of a plant variety: commercial evaluation does not amount to commercial exploitation

The General Court, in its Judgment of 24 September 2019 ('*Pink Lady*', T 112/18, EU:T:2019:679), dismissed the action brought against the decision of the Board of Appeal of the Community Plant Variety Office (CPVO) dismissing the application for nullity in relation to the Cripps Pink Community plant variety right. The court is of the opinion that the novelty requirement was fulfilled and that evidence had not been provided of sales or disposals of the variety to third parties outside the European Union, by the breeder or with his consent, for purposes of exploitation of the variety prior to the grace period lade down in Regulation (EC) No 2100/94.

The court recalls that "a disposal for the purposes of testing of the variety which does not amount to sale or disposal to third parties for purposes of exploitation of the variety does not negate novelty for the purposes of Article 10 of the Basic Regulation" (judgment of 11 April 2019, Kiku v CPVO).

And it follows from this case law that "the concept of 'exploitation' of the variety within the meaning of Article 10(1) of the Basic Regulation relates to exploitation for profit, as further demonstrated by the provisions of the Basic Regulation relating to contractual exploitation rights, but this concept excludes commercial trials aimed at assessing varieties under commercial conditions across a range of soil types and different farming systems to determine their value to customers".

Thus, the court concludes that "the Board of Appeal correctly concluded that commercial evaluation did not amount to commercial exploitation and that, accordingly, sales or disposals made for testing purposes before the grace period were circumstances that did not negate novelty".

The advocate general makes a pronouncement on the scope of the breeder's right

The advocate general made public his opinion in case C-176/18 (CVVP, EU:C:2019:758), wherein he proposes that the Court should answer the questions referred as follows:

a) Article 13(2) of Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights must be interpreted as meaning that acts related to planting variety constituents of a protected variety and the harvesting of fruit do not fall within the category of acts referred to in that provision, the performance of which is subject to the authorisation of the rightholder;

b) Article 13(3) of Regulation (EC) No 2100/94 must be interpreted as meaning that the concept of 'unauthorised use' of protected variety constituents does not include acts effected in respect of those constituents, such as multiplication or marketing, in the time between publication of the application for a Community plant variety right and grant thereof.

Pre-emption right of employees of a municipal pharmacy

On 2 October 2019, Advocate General Hogan delivered his opinion in case C-465/18, *AV, BU,* EU:C:2019:812, suggesting that the Court should answer that Article 49 TFEU must be interpreted as precluding national legislation, such as that at issue in the main proceedings, which, in the event of the transfer of ownership of a municipal pharmacy, confers a right of pre-emption on the employees of the pharmacy in question.

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