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Gómez-Acebo & Pombo

Pharma & Healthcare

Ángel García Vidal

Professor of Corporate & Commercial Law, University of Santiago de Compostela

'Academic Counsel', Gómez-Acebo & Pombo

2022 No. 30

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Legislation and legislative proposals

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Unified Patent Court: rules of procedure and fees approved

The Administrative Committee of the Unified Patent Court has approved, at its meeting of 8 July 2022, the final version of the Rules of Procedure of the Unified Patent Court[1], as well as the amount of fees to be charged by the court[2]. The location of the various national and regional divisions of the court has also been approved[3] ; the location of the Central Division of the court, initially planned for London, has yet to be decided.

These decisions are a very important step towards the start of operations of the Unified Patent Court, which is expected by the Administrative Committee in the first months of 2023.

Clinical trials and protection of personal data and commercially sensitive information

The European Medicines Agency has published and submitted for public consultation, until 8 September 2022, draft guidance on the protection of personal data and commercially confidential information (CCI) in the Clinical Trials Information System (CTIS)[4].

Nucleotide or amino acid sequences in patent applications: World Intellectual Property Organisation Standard ST.26

On 1 July 2022, the World Intellectual Property Organization (WIPO) Standard ST.26, which sets out the new standard on the requirements for including nucleotide or amino acid sequences in patent applications, entered into force[5]. This new standard replaces the previous Standard ST.25. Among other changes, it incorporates new types of sequences, such as D-amino acids, linear portions of branched sequences and nucleotide analogues. In addition, whereas the previous standard required sequences to be in TXT or PDF format, it now requires sequence listings to be provided in XML. And, in order to facilitate the display of sequences in the new required XML

[1] https://www.unified-patent-court.org/sites/default/files/ac_04_08072022_rop_annex_1_en_final_tracked_for_publication.pdf

[2] https://www.unified-patent-court.org/sites/default/files/ac_05_08072022_table_of_court_fees_en_final_for_publication.pdf

[3] https://www.unified-patent-court.org/sites/default/files/ac_13_08072022_e_set_up_of_local_and_regional_divisions_decision_for_publication.pdf

[4] https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-training-support#protection-of-personal-data-and-commercially-confidential-information-(public-consultation)-section

[5] It can be viewed on the World Intellectual Property Organisation's website: https://www.wipo.int/standards/en/part_03_standards.html

format, the World Intellectual Property Organisation makes the WIPO Sequence software available to users. Also relevant is the WIPO Sequence Validator application, which allows patent offices to verify that the submitted sequence listings comply with the provisions of the aforementioned Standard ST.26.

Although the new rule applies to applications filed after 1 July, it is left to the discretion of the offices to determine whether it also applies to divisional patent applications whose parent applications are filed before 1 July, which is leading to a divergent practice among different offices.

Transitional rules for the packaging and labelling of veterinary medicinal products authorised or registered under previous EU legislation

Regulation (EU) 2022/839 of the European Parliament and of the Council of 30 May[6] lays down transitional rules for the packaging and labelling of veterinary medicinal products authorised or registered in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004.

The new regulation provides that veterinary medicinal products which have been authorised or registered in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 and which comply with Articles 58 to 64 of Directive 2001/82/EC, in the version applicable on 27 January 2022, may be placed on the market until 29 January 2027, even if their labelling and, where appropriate, package leaflet do not comply with the provisions of Regulation (EU) 2019/6.

Common specifications for certain *in vitro* diagnostic medical devices

Commission Implementing Regulation (EU) 2022/1107 of 4 July[7] lays down common specifications for certain class D *in vitro* diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council.

Drafting the above, the common technical specifications set out in paragraph 3 of Commission Decision 2002/364/EC for certain devices covered by Directive 98/79/EC (Directive that was replaced by Regulation (EU) 2017/746 of the European Parliament and of the Council) have been taken into account.

Tasks of and criteria for EU reference laboratories in the field of *in vitro* diagnostic medical devices

Commission Implementing Regulation (EU) 2022/944 of 17 June[8] lays down rules for the application of Regulation (EU) 2017/746 of the European Parliament and of the Council as regards the tasks of and criteria for European Union reference laboratories in the field of *in vitro* diagnostic medical devices.

Without going into the full content of the new regulation, it is worth highlighting some of its provisions, such as the obligation for EU reference laboratories to document and justify the knowledge and experience requirements for staff needed to fulfil the tasks of these laboratories in the field of specific devices, categories or groups of devices, or the specific hazards related to a

[6] OJ L 148, 31.5.2022, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R0839&from=EN.

[7] OJ L 178, 5.7.2022, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R1107&from=EN.

[8] OJ L 164, 20.6.2022, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R0944&from=EN.

category or group of devices for which the EU reference laboratories are designated.

The EU reference laboratories shall also keep up-to-date documentation containing: *(a)* an explanation of which equipment (including specimens, control materials and reference materials) are necessary to carry out their assigned tasks; *(b)* evidence that they possess the equipment and a sufficient quantity of reference materials; and *(c)* a plan for the procurement of specimens, control materials and reference materials.

Equally important is the provision that reference laboratories shall have a confidentiality policy that includes the following: *(a)* the type of information that shall be considered confidential; *(b)* rules for the appropriate secure handling, storage and processing of confidential information and measures to prevent undue disclosure; *(c)* rules for sharing of confidential and non-confidential information with staff and the public; *(d)* rules for granting access to confidential information to a competent authority of a Member State upon its request in the context of market surveillance or vigilance activities by the competent authority; *(e)* rules for sharing confidential information, on the initiative of the EU reference laboratory, with a competent authority of a Member State and with the Commission where the EU reference laboratory has reason to believe that such sharing is in the interest of protection of public health.

Legislation concerning the fees that may be levied by EU reference laboratories in the field of *in vitro* diagnostic medical devices

Commission Implementing Regulation (EU) 2022/945 of 17 June[9] lays down rules for the application of Regulation (EU) 2017/746 of the European Parliament and the Council with regard to fees that may be levied by EU reference laboratories in the field of *in vitro* diagnostic medical devices.

The content of the new regulation includes the rule that the fees levied by reference laboratories shall be non-discriminatory, fair, reasonable and proportionate to the services rendered (Art. 2). Furthermore, with regard to the structure of the fees, it is provided (Art. 1) that the fees levied by the reference laboratories may cover the following categories of costs: *(a)* staff costs, including travel costs and associated accommodation and subsistence costs; *(b)* equipment costs, where the equipment is not provided by the manufacturer of the device to be tested; *(c)* costs of consumables, test specimens and reference materials; *(d)* shipping costs for samples; *(e)* translation costs; *(f)* general costs of the operation of the laboratory. And, where EU reference laboratories have concluded a contract with another laboratory, the fee levied by the EU reference laboratories may cover the amount they have paid to that laboratory in accordance with the contract for the performance of the requested task.

New protocols for the examination of certain varieties of agricultural plant species and vegetable species

Commission Implementing Directive (EU) 2022/905 of 9 June has amended Directives 2003/90/EC and 2003/91/EC as regards the protocols for the examination of certain varieties of agricultural plant species and vegetable species[10]. In particular, new protocols or updates

[9] OJ L 164, 20.6.2022, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R0945&from=EN.

[10] OJ L 157, 10.6.2022, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022L0905&qid=1664345436826&from=en.

of existing protocols approved by the Community Plant Variety Office are incorporated, concerning cocksfoot, lucerne, sand lucerne, small timothy, timothy, red clover, hemp, rye, triticale, spinach beet or chard, savoy cabbage, white cabbage and red cabbage, leaf chicory, watermelon, melon, fennel, lettuce, tomato, spinach and tomato rootstocks.

Medical devices: reclassification of products with no intended medical purpose

Classification rules 9 and 10 on active devices in Sections 6.1 and 6.2 of Annex VIII to Regulation (EU) 2017/745 on medical devices refer to an intended medical purpose and thus cannot be applied to active products without an intended medical purpose, which are to be classified as class I in accordance with rule 13 in Section 6.5 of Annex VIII to Regulation (EU) 2017/745.

The European Commission has presented and submitted for public consultation a draft regulation for the reclassification of products that have no intended medical purpose, such as laser or intense pulsed light devices for hair removal or skin treatment, liposuction equipment and brain stimulation devices[11] .

It is now intended that such devices should be classified according to their risks and be subject to the same pre- and post-market requirements as comparable medical devices.

Judgments, rulings and decisions

European Union

Impossibility of reviewing a national judgment after a judgment of the Court of Justice in a pharmaceutical market-sharing case

The Italian competition authority imposed a fine on two pharmaceutical companies on the ground that they had engaged in an anti-competitive practice, consisting of market sharing, contrary to the Treaty on the Functioning of the European Union. The fine was challenged in court and a question was referred to the Court of Justice for a preliminary ruling, which was answered by judgment of 23 January 2018 in Case C-179/16 *F. Hoffmann-La Roche and Others* (EU:C:2018:25). In that judgment, the Court of Justice held that, for the purposes of the application of Article 101 of the Treaty, a national competition authority may include in the relevant market, in addition to the medicinal products authorised for the treatment of the diseases concerned, another medicinal product whose marketing authorisation does not cover that treatment, but which is used for that purpose and is thus actually substitutable with the former.

The Court of Justice also found that an arrangement to disseminate to the European Medicines Agency, healthcare professionals and the gener-

[11] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12972-Medical-devices-reclassification-of-products-without-an-intended-medical-purpose_en

al public misleading information about the adverse reactions resulting from the off-label use of one of these medicinal products in order to reduce the competitive pressure resulting from such use on the use of the other medicinal product constitutes a restriction of competition.

On the basis of that 2018 judgment of the Court of Justice, the competent Italian court dismisses the appeals brought against the fine imposed on the pharmaceutical companies. In response, those companies requested a review of the Italian judgment, alleging an error of fact. They claim, inter alia, that the Italian court did not assess whether or not the information disseminated was misleading.

In those circumstances, the Italian court finds that, under Italian law, there is no procedural means of verifying that a decision given by a national court adjudicating at last instance is not contrary to EU law and, in particular, to the case law of the Court of Justice. It asks the Court of Justice whether or not such a situation is compatible with European Union law.

According to the Court of Justice in its judgment of 7 July 2022 (C261/21, ECLI:EU:C:2022:534), the Treaty on European Union, the Treaty on the Functioning of the European Union and the Charter of Fundamental Rights of the European Union must be interpreted "as not precluding provisions of procedural law of a Member State which, while observing the principle of equivalence, have the effect that, where the supreme court of the administrative system of that Member State gives a decision settling a dispute in which it had made a request to the Court of Justice for a preliminary ruling under Article 267 TFEU, the parties to that dispute may not seek a revision of that decision of the national court based on the contention that the latter disregarded the interpretation of EU law provided by the Court of Justice in response to that request".

Emergency ambulance transport services

In its judgment of 7 July 2022 (C213/21 and C214/21, *Italy Emergenza Cooperativa Sociale*, ECLI:EU:C:2022:532), the Court of Justice has held that Directive 2014/24/EU of the European Parliament and of the Council of 26 February on public procurement must be interpreted as "not precluding national legislation which provides that emergency ambulance transport services may be awarded, by contract, on a preferential basis, only to voluntary organisations, and not to social cooperatives which can offer rebates associated with their activities to their members".

Recognition of professional qualifications

With reference to Directive 2005/36/EC on the recognition of professional qualifications and the Treaty on the Functioning of the European Union, the Court of Justice of the European Union has held - in its Judgment of 16 June 2022, C577/20, ECLI:EU:C:2022:467 - that "the competent authority of the host Member State to which an application has been made for authorisation to pursue a regulated profession in that Member State, is required to regard a diploma issued by the authority of another Member State as bona fide and cannot, in principle, call into question the level of knowledge and qualifications which the applicant may be presumed to have acquired by virtue of that diploma. Only where it has serious doubts founded on specific information forming a consistent body of evidence which suggests that the diploma relied on by the applicant does not reflect the level of knowledge and qualifications which the applicant may be presumed to have acquired, the authority of the host Member State may request the issuing authority to review, in the light of such evidence, the grounds for awarding that diploma, the latter authority being required, if necessary, to withdraw it. That

evidence may include, where appropriate, inter alia, information submitted both by persons other than the provider of the training in question and by the authorities of another Member State acting in the course of their duties. Where the issuing authority has reviewed, in the light of that evidence, the grounds for awarding the diploma and has decided not to withdraw it, it is only in exceptional cases, where it is clear from the circumstances that the diploma is not bona fide, that the authority of the host Member State may call into question the grounds for awarding that diploma".

Cosmetic products that can be mistaken for foodstuff

The Court of Justice - in its judgment of 2 June 2022, C-122/21, ECLI:EU:C:2022:421-has analysed whether the fact that products have a shape similar to that of a foodstuff is sufficient to presume that the product in question poses a risk to the health of consumers. According to the court, Council Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers must be interpreted as meaning that "it is not necessary to demonstrate by objective and substantiated data that placing in the mouth, sucking or ingesting products which, although not foodstuffs, possess a form, odour, colour, appearance, packaging, labelling, volume or size, such that it is likely that consumers, especially children, will confuse them with foodstuffs and in consequence place them in their mouths, or suck or ingest them may entail risks such as suffocation, poisoning, or the perforation or obstruction of the digestive tract. Nevertheless, the competent national authorities must assess on a case-by-case basis whether a product meets the conditions listed in that provision and justify their assessment that that is the case".

Advertising of medicinal products in general (or a range of medicinal products) by offering a discount: does Directive 2001/83/EC apply?

In Case C-530/20, *Euroaptieka*, the Latvian Constitutional Court asks the Court of Justice whether a Latvian national provision which provides for a prohibition on including in 'advertising to the general public of a medicinal product any information which encourages the purchase of the medicinal product by justifying the need to purchase that medicinal product on the basis of its price, by announcing a special clearance sale, or by indicating that the medicinal product is sold as a bundle together with other medicinal products (including at a reduced price) or other types of product', is compatible with Directive 2001/83/EC.

Advocate General Maciej Szpunar delivered his Opinion on 9 December 2021 (ECLI:EU:C:2021:993), proposing that the Court of Justice of the European Union should declare *(a)* that the definition of *advertising* contained in Article 86(1) of the Directive also covers cases where a bundle of medicinal products is promoted and not a specific or particular one, and *(b)* that the prohibition laid down in Latvian law is compatible with Directive 2001/83/EC, since that Directive does not contain an express prohibition to that effect.

This interpretation advocating the application of Directive 2001/83/EC to the advertising of general and non-specified medicinal products could conflict with two previous rulings of the Court of Justice, which are in fact relied on in the proceedings and analysed by the Advocate General: *(a)* the judgment of 1 October 2020 (C-469/18, EU:C:2020:764), in which the Court concluded that Directive 2001/83/EC does not have to be taken into account when analysing whether EU law precludes national legislation which prohibits pharmacies from making promotional

offers relating to the grant of a discount on the total price of the order for medicinal products where that discount exceeds a certain amount, and *(b)* the judgment of the Court of Justice of 15 July 2021, *DocMorris,* C-190/20 (EU:C:2021:609), in which the court held that a promotional campaign that is aimed at mail-order services for medicines and not at specific medicines does not fall within the concept of *advertising of medicines*, because it "given medicinal product, but the choice of the pharmacy from which that customer purchases that medicinal product, a choice which takes place following that of the medicinal product".

As a consequence of this possible contradiction with previous case law, in January 2022 the Court of Justice decided to refer the case to the Grand Chamber, which has obliged the Advocate General to give his opinion again, which he has done in his Opinion of 9 June 2022 (ECLI:EU:C:2022:450), in which he maintains his proposed answer to the questions referred for a preliminary ruling.

Advertising of biocidal products: can Member States introduce restrictions in addition to those contained in the EU regulation?

Advocate General Nicholas Emiliou delivered his Opinion on 2 June 2022 (C147/21, ECLI:EU:C:2022:437) and proposes that the Court of Justice of the European Union declare that Article 72 of Regulation (EU) No. 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products precludes national rules requiring the inclusion of an additional statement in advertising addressed to professional users of biocidal products, but that neither that Regulation nor the Treaty on the Functioning of the European Union precludes national law from prohibiting the advertising of biocidal products belonging to the same categories addressed to the general public.

If you have any questions regarding the contents of this document, please contact any one of the following GA_P lawyers:

Irene Fernández Puyol
Tel.: (+34) 91 582 91 00
ifernandez@ga-p.com

Jesús Muñoz-Delgado
Tel.: (+34) 91 582 91 00
jmunoz@ga-p.com