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Legislation and legislative proposals

European Union

Re-importation into the EU of medicines exported to the UK

At the end of February 2022, Commission Delegated Regulation (EU) 2022/315 of 17 December 2021[1] was published, amending Delegated Regulation (EU) 2016/161 as regards the derogation from the obligation of wholesalers to decommission the unique identifier of medicinal products exported to the United Kingdom.

The new rule deals with medicinal products exported to the United Kingdom which are subsequently re-imported into the Union. To this end, the aim is to ensure that medicinal products re-imported into the Union are only placed on the markets of Northern Ireland, Cyprus, Ireland and Malta, and to this end it is necessary to ensure that the repositories system provides an alert when the medicinal product is verified elsewhere in the Union.

Entry into force of the Protocol on the Provisional Application of the Agreement on a Unified Patent Court

Following the deposit of the instrument of ratification by Austria, the Protocol to the Agreement on a Unified Patent Court on provisional application of 1 October 2015 entered into force on 19 January 2022.

This marks the beginning of an interim period during which various technical aspects will be completed in order to make the court operational, such as the election of judges, the implementation of the court's IT systems or the provision of an early *optout* period (see below).

It should be recalled in this respect that the Agreement on a Unified Patent Court (UPC) not only allows actions for infringement or for revocation of European patents without unitary effect (and of Supplementary Protection Certificates based on such patents) to continue to be brought before national courts for a transitional period, but also provides for the possibility for the holders of these rights to exclude them entirely from the jurisdiction of the Unified Patent Court.

Article 83(3) of the agreement stipulates that the proprietor of or applicant for a European patent granted or applied for before the end of the transitional period (seven or, where appropriate, fourteen years), as well as the holder of a supplementary protection certificate issued for a product protected by European patent, shall have "the possibility to opt out from the exclusive competence of the Court". This is known as the 'opt-out'. To this end, it is stipulated that such proprietors, applicants or holders "shall notify their opt-out to the Registry by the latest one month before expiry of the transitional period". And the "opt-out shall take effect upon its entry into the register". In any case, for the opt-out to be possible, it is essential that no

[1] OJ L 55, 28.2.2022, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R0315&from=EN

prior action has been brought before the Unified Patent Court.

Well, the protocol allows for the early application of Article 10, concerning registration, so that opt-out applications can be filed before the entry into force of the Unified Patent Court Agreement. This is known as the 'sunrise period'.

Changes to the European Patent Office's examination guidelines

The European Patent Office has published the new version of the Guidelines for Examination which entered into force on 1 March 2022[2].

European Parliament resolution on the fight against cancer

In its resolution of 16 February 2022 on strengthening Europe in the fight against cancer – towards a comprehensive and coordinated strategy[3], the European Parliament expresses its support for a wide range of measures. Among others, the Parliament supports the objective of achieving at least a 10% reduction in harmful alcohol consumption by 2025; "supports the provision of better information to consumers by improving the labelling of alcohol beverages to include health warning labels and introducing the mandatory indication of the list of ingredients and nutritional information, and in addition, by introducing digital labelling", and emphasises the role of a healthy diet in preventing and limiting the incidence and the recurrence of cancer.

It is also relevant to note that the European Parliament encourages Member States to use pricing policies - such as value added tax differentiation - and marketing controls to influence demand for, access to and the affordability of food and drink low in saturated fats, trans-fats, salt and sugar; "supports Member States in revising the relevant provisions to restrict the advertising of sweetened beverages and processed food products high in fats, salt and sugar, including advertising on social media, and calls on the Commission to come forward with a proposal for a comprehensive EU-wide regulation to prohibit such advertising to minors".

Judgments, rulings and decisions

European Union

The right of residence and the requirement to have comprehensive sickness insurance cover

Directive 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States provides in

[2] Hyperlink showing modifications: https://documents.epo.org/projects/babylon/eponet.nsf/0/E5CF26FC37C06F00C12587F700552B22/$File/epo_guidelines_for_examination_2022_hyperlinked_showing_modifications_en.pdf

[3] Document 2020/2267(INI), https://www.europarl.europa.eu/doceo/document/A-9-2022-0001_EN.html.

Article 7 that all Union citizens have the right of residence in the territory of another Member State for a period of more than three months if they *(a)* are employed or self-employed in the host Member State or *(b)* have sufficient resources for themselves and their family members not to become a burden on the social assistance system of the host Member State during their period of residence and have comprehensive sickness insurance cover in the host Member State.

The Court of Justice - in its judgment of 10 March 2022, C247/20, ECLI:EU:C:2022:177 - has held that "neither a child, a Union citizen, who has acquired a right of permanent residence, nor the parent who is the primary carer of that child is required to have comprehensive sickness insurance cover, within the meaning of Article 7(1)(b) of that directive, in order to retain their right of residence in the host State".

On the other hand, "as regards periods before a child, a Union citizen, has acquired a right of permanent residence in the host State, both that child, where a right of residence is claimed for him or her on the basis of that Article 7(1)(b), and the parent who is the primary carer of that child must have comprehensive sickness insurance cover within the meaning of that directive".

Recognition of professional qualifications and public health protection

In relation to Directive 2005/36/EC on the recognition of professional qualifications, Advocate General Maciej Szpunar, in his Opinion of 10 March 2022, C577/20 (ECLI:EU:C:2022:179), has stated that while the protection of public health may justify a comparative examination of qualifications which is not based solely on the professional qualifications which can be presumed from the qualification relied on by the applicant, the competent authority is in any case obliged to take into consideration not only the professional competences which the applicant has actually developed, but all the relevant elements allowing access to the profession and its pursuit.

Consequently, the Advocate General considers that the Treaty on the Functioning of the European Union does not preclude the competent authority of the host Member State from taking into account information regarding the precise content of the training and the manner in which it is implemented, where it has obtained such information from reliable sources other than the training provider or the competent authorities of the home Member State, in order to determine whether there is a definite risk to patient safety. However, the competent authority of the host Member State may not rely solely on such information in order to refuse access to a profession and the pursuit of that profession to a national of a Member State who obtained his or her qualification at a university in another Member State".

Conditions for obtaining a licence to pursue as an independent practitioner the profession of doctor where the training was obtained in another State

A person obtains a basic medical training qualification in the United Kingdom, which gives him/her a restricted right to practise as a doctor in the United Kingdom. Subsequently, this person applies in Finland for authorisation to pursue the profession of doctor as a licensed practitioner. As the UK qualification did not give him/her the right to pursue the profession in full, he was granted authorisation in Finland to pursue the profession of doctor as an approved professional for a period of three years, under the direction and supervision of an approved doctor and on condition that he undergoes

specific training in general medicine in order to obtain in the host Member State permission to practise the profession of doctor on an independent basis.

In its judgment of 3 March 2022 in Case C-634/20 (ECLI:EU:C:2022:149), the Court of Justice held that the Treaty on the Functioning of the European Union precludes a Member State from granting such an authorisation: "National legislation which imposes, generally and without distinction, the same compensatory measures on all holders of an undergraduate degree in medicine obtained, in particular, in an EU Member State in which authorisation to pursue the profession of doctor is contingent upon completion of a postgraduate professional traineeship, does not appear to be consistent with the requirement of an effective comparison between, on the one hand, the specialised knowledge and abilities attested by the evidence of formal qualifications of the person concerned and, on the other, the knowledge and qualifications required by the legislation of the host Member State, or with the principle of proportionality".

META and METALGIAL trademarks: no likelihood of confusion

The EU trademark META, consisting of the word sign META for 'dietary supplements; dietary and nutritional supplements', was opposed by the proprietor of the earlier Spanish word mark METALGIAL for 'pharmaceutical and veterinary preparations; sanitary and hygienic preparations for medical use; dietetic substances for medical use, food for babies; plasters, materials for dressings; material for dental fillings and impressions; disinfectants; preparations for destroying vermin; fungicides, herbicides'.

The Opposition Division dismissed the opposition in its entirety, holding, in essence, that there was no likelihood of confusion between the conflicting signs for all the goods covered by the mark applied for. The Second Board of Appeal of the European Union Intellectual Property Office (EUIPO) dismissed the appeal.

Now, the General Court's judgment of 2 March 2022 (T192/21, ECLI:EU:T:2022:105) upholds the Board of Appeal's decision, holding that it did not err in finding that the relevant public was composed of the general public and the specialised public, whose level of attention is high, and that the relevant territory was Spain; that there was identity of goods and that there was a low degree of similarity between the signs visually and phonetically and that there was no conceptual similarity because neither for the public perceiving the sign METALGIAL as a fanciful word, devoid of meaning, nor for the public perceiving the concept of "metal" as a distinctive element is there any conceptual similarity with the sign META applied for.

Penalties for selling tobacco products to minors

The Court of Justice - in its judgment of 24 February 2022, C452/20, ECLI:EU:C:2022:111 - has held that the "principle of proportionality must be interpreted as not precluding national legislation which, in the case of a first infringement of the prohibition on the sale of tobacco products to minors, provides, in addition to the imposition of an administrative fine, for the suspension, for a period of 15 days, of the trading licence authorising the economic operator who has infringed that prohibition to sell such products, provided that such legislation does not exceed the limits of what is appropriate and necessary in order to attain the objective of protecting human health and reducing, in particular, smoking prevalence among young people".

Indication of vitamins in the list of food ingredients

The Court of Justice - in its judgment of 24 March, C533/20, ECLI:EU:C:2022:211 - has held that Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers must be interpreted as meaning that, where a vitamin has been added to a food, the list of ingredients of that food does not have to include, in addition to the name of that vitamin, the name of the vitamin formulation used.

Parallel trade in generic medicines after repackaging a reference medicine

In Opinion delivered on 13 January 2022 (C-253/20 and C-254/20, EU:C:2022:27), Advocate General Maciej Szpunar analyses a case in which companies of the same corporate group market a branded (reference) medicine and a generic version of such medicine, distinguishing each of the medicinal products with different trademarks belonging to the same proprietor. Thus, once they have been placed on the market in one EU Member State, a person acquires batches of the generic medicine and repackages them with the trademark of the reference medicine in order to resell them in another EU Member State under the trademark of the reference medicine.

The Advocate General considers that it is very difficult for two conditions to be met for the trademark owner not to be able to oppose such a trademark change: that the products are identical (because the generic and the reference product will generally not be identical) and that the replacement of the trademark is objectively necessary to ensure effective access of the product to the market of the importing State.

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