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Legislation

European Union

UK Government guidance on the situation of patents in the absence of a Brexit deal

1. The United Kingdom notified its intention to leave the European Union on 29 March 2017, marking the point from which the parties began the Brexit negotiations. As a result of these negotiations, a "Draft Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community" was made public on 19 March 2018, highlighting those aspects on which an agreement had already been reached (pending only possible technical corrections) and those on which the parties had yet to reach a consensus position. The full document can be found at https://ec.europa.eu/commission/sites/beta-political/files/draft_agreement_coloured.pdf.

   Subsequently, on 19 June 2018, negotiators of the EU and the UK Government issued a joint statement on further progress made in the negotiations. (https://ec.europa.eu/commission/sites/beta-political/files/joint_statement.pdf)

   This draft agreement addresses a broad list of issues, including intellectual property rights, to which a full title of the draft agreement is devoted (Title IV of Part III).

   For an examination of all these issues, please refer to the GA_P document *"Brexit y derechos de propiedad industrial e intelectual: estado de la cuestión"* (García Vidal, September 2018), https://www.ga-p.com/publicaciones/brexit-y-derechos-de-propiedad-industrial-e-intelectual-estado-de-la-cuestion

2. Subsequent to the preparation of the above document in which I set out the situation as it stood, on 24 September 2018, the UK Government made public a document concerning the situation of patents if a 'no deal' scenario. The text, entitled "Guidance. Patents if there's no Brexit deal", is available online at the following link: https://www.gov.uk/government/publications/patents-if-theres-no-brexit-deal/patents-if-theres-no-brexit-deal.

3. The UK will explore whether it would be possible to remain within the Unified Patent Court and unitary patent systems if these come into force before the UK's departure. Should it have to withdraw from the unitary patent or the UPC, it is expected that the unitary patents already granted will give rise to an equivalent patent in the United Kingdom. It is recalled that UK nationals would always be able to obtain unitary patents and use the UPC, although in order to protect inventions in the UK they would have to apply for national patents (or classic European patents with effect in the UK) and use the UK courts.

4. With regard to supplementary protection certificates, the EU's legislation (or the national legislation that applies or incorporates it) will be kept in UK law according to the European Union Withdrawal Act 2018.

5. It is also recalled that the legal professional privileges given to patent attorneys will not be affected.

Refusal to authorise certain health claims made on foods and referring to the reduction of disease risk

The European Commission has refused to authorise several health claims made on foods in Commission Regulation (EU) 2018/1555 of 17 October 2018 (OJ L 261 of 18 October 2018, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R1555&from=ET).

The rejected nutrients and health claims are as follows:

a) Condensyl® - The combination of opuntia fruit dry extract standardised in quercetin and betalain, N-acetyl cysteine, zinc, vitamin B3, E, B6, B2, B9 and B12 in Condensyl® decreases sperm DNA damage (sperm nuclear decondensation index and DNA fragmentation index). High sperm DNA damage (sperm nuclear decondensation index and DNA fragmentation index) is a risk factor for male subfertility/infertility.

b) Sugar-free hard confectionery with at least 90 % erythritol - Sugar-free hard confectionery sweetened with at least 90 % Zerose® erythritol has been shown to reduce dental plaque. High content/level of dental plaque is a risk factor in the development of caries.

c) *Lactobacillus fermentum CECT* 5716 - Lactobacillus fermentum CECT 5716 decreases the Staphylococcus load in breast milk. High Staphylococcus load in breast milk is a risk factor for mammary bacterial dysbiosis/mastitis.

Refusal to authorise certain health claims on foods, other than those referring to the reduction of disease risk and to children's development and health

The European Commission has refused to authorise several health claims on foods in Commission Regulation (EU) 2018/1556 of 17 October 2018 (OJ L 261 of 18 October 2018, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R1556&from=EN).

The rejected nutrients and health claims are as follows:

a) Stablor®, a drink preparation with defined macro- and micronutrient composition and specific proportion of amino acids (tryptophan to neutral amino acids ratio) - In the context of a well-balanced diet and a mild caloric restriction, the addition of Stablor® contributes to decrease

visceral fat while preserving lean mass in overweight or obese subjects with abdominal fat and cardiometabolic risk factors.

b) Curcumin - Curcumin contributes to the normal functioning of joints.

c) A carbohydrate:protein (CHO:P) ratio ≤ 1.8 on an energy basis in the context of an energy-restricted diet and body weight - Helps to achieve a reduction in body weight and body fat when consumed as part of an energy restricted diet (< 8 368 kJ/2 000 kcal/day) for a minimum of 12 weeks.

d) Vibigaba (germinated brown rice) - In the context of an energy-restricted diet contributes to weight loss. Contributes to the maintenance of normal blood glucose levels. Contributes to the maintenance of normal blood pressure. Contributes to the maintenance of normal blood cholesterol levels.

Commission Implementing Regulation (EU) 2018/1584 of 22 October 2018 amending Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control

Commission Implementing Regulation (EU) 2018/1584 of 22 October 2018 has been published in OJ L 264 of 23 October 2018, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R1584&from=EN.

The content of this new implementing regulation allows the use of minerals (trace elements included), vitamins, amino acids and micronutrients in the production of organic baby foods for infants and young children.

Until now, Regulation (EU) 2018/848 of the European Parliament and of the Council allowed the use of these substances in organic infant formula and follow-on formula and processed organic cereal-based foods and baby food when their use was authorised by the relevant Union legislation. The change is justified in the whereas clauses, stating that “in order to avoid a gap between the current interpretation of the use of these substances in foods for infants and young children and to ensure consistency with the upcoming organic legislation it is appropriate to allow their use in the production of organic baby foods for infants and young children”.

Judgments and decisions

European Union

Pharmaceutical trademarks: medical practitioners and patients as end consumers have a high level of attention

The Judgment of the General Court (First Chamber) of 20 September 2018 in Case T-266/17, *Kwizda Holding GmbH* v *European Union Intellectual Property Office*, has shown that, in assessing the likelihood of confusion between pharmaceutical trademarks, it must be assumed that the relevant public has a high and not just medium level of attention.

According to the General Court, "where the products in question are medicines or pharmaceutical products, the relevant public consists, on the one hand, of medical practitioners and, on the other hand, of patients as end consumers of those products".

It is also stated that "on the basis of case law it is also clear, on the one hand, that medical practitioners demonstrate a high level of attention when prescribing medicines. On the other hand, it follows, as regards end consumers, that when pharmaceutical products are sold without prescription, it must be assumed that they are of interest to consumers who are reasonably well informed and reasonably observant and circumspect, since those products affect their state of health, and that those consumers are less likely to confuse the various categories of products. Moreover, even where a medical prescription is mandatory, consumers may demonstrate a high level of attention when prescribed, given that the products in question are pharmaceutical products. Thus, medicines, whether or not prescribed, may be considered to benefit from a higher level of attention on the part of consumers who are reasonably well informed and reasonably observant and circumspect".

Moreover, this case law also applies where the pharmaceutical products in question are intended to treat minor ailments and disorders, and where the products in question are dietetic products in general and with supplements, which are not medicinal products in the strict sense of the term, but are products in the field of health, generally intended to improve the state of health, and may be regarded as benefiting from a higher level of attention on the part of consumers who are reasonably well informed and reasonably observant and circumspect.

Authorisation for a combined medical device and medicinal product and the Supplementary Protection Certificate

In the case resolved by the Court of Justice in its judgment of 25 October 2018 (Case C-527/17, *Boston Scientific Ltd, intervener: Deutsches Patent- und Markenamt*), the Court was asked whether Article 2 of Regulation (EC) 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, for the purposes of that regulation, an authorisation under Council Directive 93/42/EEC of 14 June 1993 concerning medical devices for a combined medical device and medicinal product within the meaning of Article 1(4) of that directive is to be treated as a valid marketing authorisation under 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, where, as part of the authorisation procedure laid down in Annex I, Section 7.4, first paragraph, to Council Directive 93/42, the quality, safety and usefulness of the medicinal product component has been verified by the medicinal products authority of a Member State in accordance with Directive 2001/83.

The Court holds that the aforementioned authorisation procedure under the directive concerning medical devices cannot be treated the same way as the authorisation procedure for medicinal products referred to in the regulation concerning supplementary protection certificates.

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