GÓMEZ-ACEBO & POMBO

Newsletter Life Sciences

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Legislation

European Union

Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants

Published in OJ L 317, 23/11/2016 (available at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R2031&from=EN), this Regulation establishes rules to determine the phytosanitary risks posed by any species, strain or biotype of pathogenic agents, animals or parasitic plants injurious to plants or plant products ('pests') and measures to reduce those risks to an acceptable level.

Judgments and decisions

European Union

Repackaging of medicinal products by a parallel importer

The judgment of the Court of Justice of the European Union (CJEU) of 10 November 2016 in Case C-297/15, in response to a request for a preliminary ruling from the *Sø- og Handelsretten* (Maritime and Commercial Court, Denmark) in proceedings between Ferring Lægemidler A/S (acting on behalf of Ferring BV) and Orifarm A/S, addresses a recurrent theme in the pharmaceutical industry, namely the conditions under which the parallel importer may repackage medicinal products.

According to the CJEU, a trade mark proprietor may object to the continued marketing of a medicinal product by a parallel importer, where that importer has repackaged that medicinal product in a new, outer packaging and reaffixed the trade mark, where, first, the medicinal product at issue can be marketed in the importing State party to the Agreement on the European Economic Area (EEA Agreement) in the same packaging as that in which it is marketed in the exporting State party to the EEA Agreement and, second, the importer has not demonstrated that the imported product can only be marketed in a limited part of the importing State's market, and those are matters which it is for the referring court to determine.

A detailed analysis of this judgment can be found in: García Vidal, Á., "Reenvasado de medicamentos por parte del importador paralelo: ¿cuándo es una excepción al agotamiento del derecho de la marca farmacéutica?", Análisis GA&P.

Foods and food ingredients which have not hitherto been used for human consumption

The judgment of the CJEU of 9 November 2016 in Case C-448/14, in response to a request for a preliminary ruling from the *Bayerischer Verwaltungsgerichtshof* (Higher Administrative Court of Bavaria, Germany) in proceedings between Davitas GmbH and Stadt Aschaffenburg, has interpreted Article 1(2)(c) of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, as amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009.

Regulation (EC) No 258/97, which concerns the placing on the market within the European Union (EU) of novel foods or novel food ingredients, applies, according to Article 1(2), to the placing on the market within the Union of foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the EU.

Upon consideration of the questions referred, the CJEU concludes that Article 1(2)(c) of Regulation (EC) No 258/97 must be interpreted as meaning that the expression 'new primary molecular structure' relates to foods or food ingredients which were not used for human consumption in the territory of the EU before 15 May 1997.

Parallel imports of medical devices and assessment designed to certify the conformity of the information allowing identification

The judgment of the CJEU of 24 November 2016 in Case C-662/15, in response to a request for a preliminary ruling from the *Oberlandesgericht Düsseldorf* (Higher Regional Court, Düsseldorf, Germany) in proceedings between Lohmann & Rauscher International GmbH & Co. KG and BIOS Medical Services GmbH, formerly BIOS Naturprodukte GmbH, has interpreted Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007.

In particular, the CJEU interprets Article 1(2)(f) of Directive 93/42, which defines the concept of "manufacturer" as "the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party", adding that the "obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as devices with a view to their being placed on the market under his own name. This subparagraph does not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient".

Transitional measure in the Regulation on nutrition and health claims made on foods

1. Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, as amended by Regulation (EC) No 107/2008 of the European Parliament and of the Council of 15 January 2008, contains a transitional rule (Article 28(2)) that reads as follows: "Products bearing trade marks or brand names existing before 1 January 2005 which do not comply with this Regulation may continue to be marketed until 19 January 2022 after which time the provisions of this Regulation shall apply".

2. The above provision has been interpreted by the judgment of the CJEU of 23 November 2016 in Case C-177/15, in response to a request for a preliminary ruling from the *Bundesgerichtshof* (Federal Court of Justice, Germany) in proceedings between Nelsons GmbH, on the one side, and Ayonnax Nutripharm GmbH and Bachblütentreff Ltd, on the other.

   According to the CJEU, Article 28(2), first sentence, of Regulation (EC) No 1924/2006 must be interpreted as meaning that that provision applies in the situation in which a foodstuff bearing a trade mark or brand name was, before 1 January 2005, marketed as a medicinal product and then, although having the same physical characteristics and bearing the same trade mark or brand name, as a foodstuff after that date.

Medicinal product for human use prepared industrially or manufactured by a method involving an industrial process

The judgment of the CJEU of 26 October 2016 in Case C-276/15, in response to a request for a preliminary ruling from the *Bundesgerichtshof* in proceedings between Hecht-Pharma GmbH and Hohenzollern Apotheke, states that "Article 2(1) 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, as amended by Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011, must be interpreted as meaning that a medicinal product for human use, such as that at issue in the main proceedings, which, under national legislation, does not require a marketing authorisation by reason of the proven frequency with which it is the subject of medical and dental prescriptions, the essential manufacturing steps for such products are carried out in a pharmacy as part of the normal pharmacy business producing in the course of one day up to 100 packages ready for dispensation and intended for supply under the existing pharmacy operating licence, cannot be regarded as having been prepared industrially or manufactured by a method involving an industrial process, within the meaning of that provision, and consequently does not come within the scope of that directive, subject to the findings of fact which it is for the referring court to make".

The CJEU does add, however, that "should those findings lead the referring court to take the view that the medicinal product at issue in the main proceedings has been prepared industrially or manufactured by a method involving an industrial process, the answer must also be that point 2 of Article 3 of Directive 2001/83, as amended by Directive 2011/62, must be interpreted as meaning that it does not preclude provisions such as those laid down in Paragraph 21(2), point 1, of the Law on the marketing of medicinal products, read in conjunction with Paragraph 6(1) of the Regulation on the operation of pharmacies, in so far as those provisions, in essence, require pharmacists to comply with the pharmacopoeia when manufacturing officinal formulae. It is, however, for the referring court to determine whether, on the facts of the case before it, the medicinal product at issue in the main proceedings has been prepared in accordance with the prescriptions of a pharmacopoeia".

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