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Gómez-Acebo & Pombo

No. 5 | 2017

Life Sciences Newsletter

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Legislation

International Law

Exclusion of the patentability of plants and animals obtained by an essentially biological process

1. The Decision of the Enlarged Board of Appeal (EBoA) of the European Patent Office (EPO) of 25 March 2015, reached in case T 1242/06 (G 2/12 – Tomato II) and in case T 83/05 (G 2/13 – Broccoli II) in consolidated proceedings, analysed the effect of art. 53(b) of the Convention on the Grant of European Patents (EPC) on the patentability of a product claim or a product-by-process claim, concluding that the prohibition of patentability of essentially biological processes for the production of plants in art. 53(b) does not extend directly to a product claim or a product-by-process claim directed to plants or plant material. And, according to the EBoA, such claims are allowable even if the only known technique to produce the plant is an essentially biological process or if the claim takes the form of product by process claims and the process of obtaining the plant is essentially biological.

2. This decision of the EBoA generated a remarkable number of criticisms. Of particular relevance in this respect is the European Parliament resolution of 17 December 2015 on patents and plant breeders' rights (Resolution 2015/2981 (RSP)), in which it calls on the Commission as a matter of urgency, to clarify the scope and interpretation of Directive 98/44/EC "in order to ensure legal clarity regarding the prohibition of the patentability of products obtained from essentially biological processes, and to clarify that breeding with biological material falling under the scope of a patent is permitted". And calls on the Commission to "communicate its forthcoming clarification regarding the patentability of products obtained from essentially biological processes to the EPO so that it can be used as a supplementary means of interpretation".

3. In response to this request from the European Parliament, the Commission adopted the "Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions" (2016/C 411/03, 8/11/2016). The European Commission herein states that, although the EPO's decisions on the patentability of products obtained from essentially biological processes "are in line with the intentions of the drafters of the EPC, it is questionable whether the same result would have been reached in the EU context". And this is so because "the EU legislator's intention when adopting Directive 98/44/EC was to exclude from patentability products (plants/animals and plant/animal parts) that are obtained by means of essentially biological processes".

4. Following this notice, the EPO decided to stay all proceedings in examination and opposition cases in which the invention was a plant or animal obtained by an essentially biological process, as announced at https://www.epo.org/news-issues/news/2016/20161212.html

5. Finally, on a proposal of the EPO, its Administrative Council took a decision to amend the relevant Regulations in order to exclude from patentability plants and animals exclusively obtained by an essentially biological breeding process (http://www.epo.org/news-issues/news/2017/20170629.html). Rules 27 and 28 of the Implementing Regulations to the EPC were also amended, with effect from 1 July 2017.

European Union

Guide on biosimilar medicines for healthcare professionals

The European Medicines Agency (EMA) and the European Commission have published an information guide for healthcare professionals on biosimilar medicines, available at http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2017/05/WC500226758.pdf.

Amendment of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Regulation (EC) No 1907/2006 contains amongst its Annexes, Annex XIV ("List of substances subject to authorisation") and Annex XVII ("Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles").

These Annexes have been amended by two European Union regulations:

(a) Commission Regulation (EU) 2017/999 of 13 June 2017 amending Annex XIV to Regulation (EC) No 1907/2006 [OJ L 150, 14/6/2017, pp. 7-13, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0999&from=EN].

(b) Commission Regulation (EU) 2017/1000 of 13 June 2017 amending Annex XVII to Regulation (EC) No 1907/2006 as regards perfluorooctanoic acid (PFOA), its salts and PFOA-related substances [OJ L 150, 14/6/2017, pp. 14-18, http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R1000].

Setting-up of the Integrated Structural Biology — European Research Infrastructure Consortium (Instruct-ERIC)

The Commission Implementing Decision (EU) 2017/1213 of 4 July 2017 has set up the Integrated Structural Biology — European Research Infrastructure Consortium named 'Instruct-ERIC', notified under document C(2017) 4507] [OJ L 173, 6/7/2017, pp. 47-52, https://publications.europa.eu/en/

publication-detail/-/publication/4afe8d79-620e-11e7-9dbe-01aa75ed71a1/language-en/format-PDFA1A].

This Decision is addressed to the Kingdom of Belgium, the Czech Republic, the Kingdom of Denmark, the French Republic, the State of Israel, the Italian Republic, the Kingdom of the Netherlands, the Portuguese Republic, the Slovak Republic and the United Kingdom of Great Britain and Northern Ireland.

Greece, Spain, Sweden and the European Molecular Biology Laboratory have made known their decision to participate in Instruct-ERIC initially as an observer.

The United Kingdom is intended to be the host Member State of Instruct-ERIC, but if it ceases to be a Member State and without prejudice to the provisions of a possible withdrawal agreement, the Statutory Seat of Instruct-ERIC will be relocated to the territory of a Member State or associated country.

New Regulation on the European Union trade mark (codification)

1. As is well known, Council Regulation (EC) No 207/2009 on the Community trade mark has been amended several times. Among the most important amendments are those introduced by Regulation (EU) 2015/2424 of the European Parliament and of the Council of 16 December 2015 amending Council Regulation (EC) No 207/2009 on the Community trade mark and Commission Regulation (EC) No 2868/95 implementing Council Regulation (EC) No 40/94 on the Community trade mark, and repealing Commission Regulation (EC) No 2869/95 on the fees payable to the Office for Harmonization in the Internal Market (Trade Marks and Designs) [OJ L 341, 24/12/2015, pp.21-94].

2. Now, in order to have the European Union Trade Mark Regulation 'codified' (i.e., consolidated), Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark (codification) has been adopted [OJ L 154, 16/6/2017, pp. 1-99].

   Although this Regulation entered into force on the twentieth day following that of its publication in the *Official Journal of the European Union*, it applies as from 1 October 2017.

Judgments And Decisions

European Union

Advertising use of the term 'milk' to designate a purely plant based product

The Judgment of the Court of Justice (Seventh Chamber) of 14 June 2017 in Case C-422/16, *Verband Sozialer Wettbewerb eV v TofuTown.com GmbH*, states that Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013, establishing a common organisation of the markets in agricultural products, must be interpreted as precluding the term 'milk' and the designations reserved by that regulation exclusively for milk products from being used to designate a purely plant based product in marketing or advertising, even if those terms are expanded upon by clarifying or descriptive terms indicating the plant origin of the product at issue.

The only exception being where such product is listed in Annex I to Commission Decision 2010/791/EU of 20 December 2010 listing the products referred to in the second subparagraph of point III(1) of Annex XII to Council Regulation (EC) No 1234/2007.

Global marketing authorisations and regulatory data protection periods

The Judgment of the Court of Justice (Eighth Chamber) of 28 June 2017 in Joined Cases C-629/15 P and C-630/15 P, *Novartis Europharm Ltd v European Commission*, dismisses the appeals lodged by Novartis Europharm Ltd against the judgments of the General Court of 15 September 2015, *Novartis Europharm v Commission* (T-472/12), and *Novartis Europharm v Commission* (T-67/13), by which the General Court dismissed its actions brought against, respectively, Commission Implementing Decision C(2012) 5894 final of 16 August 2012 granting a marketing authorisation in accordance with Regulation No 726/2004 of the European Parliament and of the Council for the medicinal product for human use 'Zoledronic acid Teva Pharma - zoledronic acid' and Commission Implementing Decision C(2012) 8605 final of 19 November 2012 granting a marketing authorisation in accordance with Regulation (EC) No 726/2004 of the European Parliament and of the Council for the medicinal product for human use 'Zoledronic acid Hospira - zoledronic acid'.

In its actions, Novartis argued that it enjoyed a 10-year data protection period in respect of Aclasta in accordance with Article 13(4) of Regulation No 2309/93 and, in so far as the decisions at issue granted marketing authorisations for generic copies of Aclasta before this period elapsed, said decisions infringed the aforementioned article.

The Commission justified these decisions on the basis of the second subparagraph of Article 6 (1) of Directive 2001/83, which provides that when a medicinal product has been granted an initial

marketing authorisation, any additional strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions shall also be granted an authorisation or be included in the initial marketing authorisation. All these marketing authorisations shall be considered as belonging to the same global marketing authorisation.

Thus, since the marketing authorisation for Aclasta concerns only new therapeutic indications of the active substance of Zometa, the marketing authorisation for Aclasta is included in the marketing authorisation for Zometa, granted on 20 March 2001, which is a 'global marketing authorisation', within the meaning of the second subparagraph of Article 6(1) of Directive 2001/83, with the result that Novartis did not enjoy an independent regulatory data protection period for Aclasta.

Specifications that medicinal products derived from plasma must be obtained from plasma collected in a specific Member State are contrary to EU law

The Judgment of the Court of Justice (Third Chamber) of 8 June 2017 in Case C-296/15, *Medisanus d.o.o. v Splošna Bolnišnica Murska Sobota*, concludes that Article 2 and Article 23(2) and (8) of Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts, and Article 34 TFEU read in conjunction with Article 36 TFEU, must be interpreted as precluding a clause in the tender specifications for a public contract which, in accordance with the law of the Member State to which the contracting authority belongs, requires medicinal products derived from plasma, which are the subject matter of the public procurement at issue, to be obtained from plasma collected in that Member State.

Plant protection products and competition law

The Judgment of the General Court (First Chamber) of 16 May 2017 in Case T-480/15, *Agria Polska and Others v Commission*, dismisses the action brought against Commission Decision C(2015) 4284 final of 19 June 2015 (Case AT.39864 — BASF (formerly *AGRIA and Others v BASF and Others*), which rejected the complaint of infringement of EU competition law by manufacturers and distributors of plant protection products.

Lis pendens in the event of simultaneous actions brought on the basis of EU trade marks and national trade marks

1. Art. 109(1) of Regulation No 207/2009 provides as follows:

> "Where actions for infringement involving the same cause of action and between the same parties are brought in the courts of different Member States, one seized on the basis of an [EU] trade mark and the other seized on the basis of a national trade mark:

(a) the court other than the court first seized shall of its own motion decline jurisdiction in favour of that court where the trade marks concerned are identical and valid for identical goods or services. The court which would be required to decline jurisdiction may stay its proceedings if the jurisdiction of the other court is contested;

(b) the court other than the court first seized may stay its proceedings where the trade marks concerned are identical and valid for similar goods or services and where the trade marks concerned are similar and valid for identical or similar goods or services."

2. This provision is to be interpreted by the Court of Justice in Case C-231/16 (*Merck KGaA v Merck & Co. Inc. and Others*).

This case arises as a result of the EU trade mark infringement proceedings brought by Merck KGaA before the Hamburg *Landgericht* (Regional Court), a German court sitting in its capacity as an EU trade mark court, and against Merck & Co. Inc., Merck Sharp & Dohme Corp. and MSD Sharp & Dohme GmbH, in the understanding that the use of the term Merck, on internet sites accessible in the European Union and on the Facebook, Twitter and YouTube online platforms, constitutes an act of infringement.

However, when the German court became seized, an action was already pending between those same companies, with the exception of one of the defendants, before a court of the United Kingdom. These parallel proceedings comprise, amongst other things, an action for infringement based on the use of the term 'Merck', to which the national trade marks relate, on the internet.

In these circumstances, the German court expresses doubt as to the interpretation of Article 109(1)(a) of Regulation No 207/2009 and refers a number of questions to the Court of Justice for a preliminary ruling.

Although the German court is inclined to the view that the provision does not enable it to decline jurisdiction in part, as regards one Member State only, the Advocate General Szpunar, in his Opinion of 3 May 2017, proposes that the Court should answer the questions referred for a preliminary ruling as follows:

"Article 109(1)(a) of Council Regulation No 207/2009 of 26 February 2009 on the EU trade mark must be interpreted as meaning that, where two actions for infringement are brought before courts of different Member States, the first on the basis of a national trade mark, concerning infringement within the territory of a Member State, and the second on the basis of an EU trade mark, concerning infringement in relation to the entire territory of the European Union, those actions coincide only partly, to the extent that they concern the territory of that Member State.

The EU trade mark court, where it is the second court seised, must of its own motion decline jurisdiction as regards the part of the action which concerns the territory common to both actions."

Attention should be paid to the judgment finally delivered by the Court of Justice.

Liability for damage caused by a defective vaccine: proof of damage and of the causal link between the defect and the damage

1. Art. 4 of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products stipulates that "the injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage".

2. In Case C-621/15 (*W and Others v Sanofi Pasteur MSD SNC, Caisse primaire d'assurance maladie des Hauts-de-Seine and Carpimko*) the Court of Justice is asked about the interpretation of the aforementioned provision. And the Court (Second Chamber), in its judgment of 21 June 2017 (ECLI: EU: C: 2017:484), has held that art. 4 of Directive 85/374/EEC must be interpreted as not precluding national evidentiary rules such as those at issue in the main proceedings under which, when a court ruling on the merits of an action involving the liability of the producer of a vaccine due to an alleged defect in that vaccine, in the exercise of its exclusive jurisdiction to appraise the facts, may consider that, notwithstanding the finding that medical research neither establishes nor rules out the existence of a link between the administering of the vaccine and the occurrence of the victim's disease, certain factual evidence relied on by the applicant constitutes serious, specific and consistent evidence enabling it to conclude that there is a defect in the vaccine and that there is a causal link between that defect and that disease. National courts must, however, ensure that their specific application of those evidentiary rules does not result in the burden of proof introduced by Article 4 being disregarded or the effectiveness of the system of liability introduced by that directive being undermined.

   Furthermore, according to the Court, art. 4 of Directive 85/374 must be interpreted as precluding evidentiary rules based on presumptions according to which, where medical research neither establishes nor rules out the existence of a link between the administering of the vaccine and the occurrence of the victim's disease, the existence of a causal link between the defect attributed to the vaccine and the damage suffered by the victim will always be considered to be established when certain predetermined causation-related factual evidence is presented.

Veracity and accuracy of healthy claims insufficient per se for authorisation of the same or for the lawfulness of their use: Judgment of the Court (Eighth Chamber) of 8 June 2017 in Case C-296/16 P (Dextro Energy GmbH & Co. KG v European Commission)

Following an application for authorisation of certain health claims made on foods, the European Commission refuses such authorisation by way of Commission Regulation (EU) 2015/8 of 6 January 2015 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health.

The claims were as follows: "Glucose is metabolised within body's normal energy metabolism" and "Glucose contributes to normal energy-yielding metabolism" - targeted at the general population - and "Glucose supports normal physical activity", "Glucose contributes to normal energy-yielding metabolism during exercise" and "Glucose contributes to normal muscle function" - targeted at healthy active men and women who are well trained in endurance.

Although the above claims were assessed by the EFSA (European Food Safety Authority) Panel on Dietetic Products, Nutrition and Allergies with a favourable outcome, concluding that a cause and effect relationship had been established between the consumption of glucose and contribution to energy-yielding metabolism, authorisation was refused. As stated in recital 14 of the aforementioned Commission Regulation (EU) 2015/8, "the use of such a health claim would convey a conflicting and confusing message to consumers, because it would encourage consumption of sugars for which, on the basis of generally accepted scientific advice". Furthermore, "even if the concerned health claim was to be authorised only under specific conditions of use and/or accompanied by additional statements or warnings, it would not be sufficient to alleviate the confusion of the consumer, and consequently the claim should not be authorised".

In response to this refusal, the company that had applied for authorisation made an application for annulment of Commission Regulation (EU) 2015/8 before the General Court, which dismissed the action by way of Judgment of 16 March 2016 in Case T-100/15 (*Dextro Energy GmbH & Co. KG v European Commission*, ECLI: EU: T: 2016:150).

In its judgment, the General Court points out that, contrary to what the applicant sought, the Commission is not required to include the health claims at issue in the list of permitted claims solely because EFSA had issued positive opinions. The General Court recalls that, where such authority, following scientific assessment, issues an opinion in favour of the inclusion of the claim in the list of permitted claims, Regulation (EC) No 1924/2006 does not stipulate that the Commission must grant authorisation. On the contrary, art. 18(4) of Regulation (EC) No 1924/2006 provides that the Commission is to take a decision on the application, taking into account EFSA's opinion, any relevant provisions of EU law and other legitimate factors relevant to the matter under consideration, after having consulted the Member States.

An appeal, lodged with the Court of Justice against the above judgment of the General Court, was dismissed in Judgment of the Court of Justice of 8 June 2017, thus confirming the appropriateness of refusing authorisation.

In addition to recalling that the Commission has a broad discretionary power in an area such as that provided for by Regulation No 1924/2006, and that the review of the Union judge should be limited to examining whether the exercise of such power is not vitiated by a manifest error or misuse of power or whether the Commission has not manifestly exceeded the limits of its discretion, the Court of First Instance denies that the General Court erred in law in assessing the Commission's action. Moreover, the Court rejects the claim that prohibiting health claims which are scientifically established would be contrary to the objectives of the regulation, although it does so without examining the merits of such claim because the appellant merely repeated the arguments put forward before the General Court, without identifying the errors of law which the General Court was allegedly guilty of.

Maximum amounts of vitamins and minerals which may be used in the manufacture of food supplements

The Judgment of the Court of Justice (First Chamber) of 27 April 2017 in Case C-672/15, *Noria Distribution SARL* (with the French public prosecutor's office and French consumer organization 'Que choisir' acting as intervening parties), states that the provisions of Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements and those of the Treaty on the Functioning of the European Union (TFEU) relating to the free movement of goods must be interpreted as precluding legislation of a Member State, such as that at issue in the main proceedings, which does not provide for a procedure for the placing on the market of that Member State of food supplements whose content in nutrients exceeds the maximum daily doses set by that legislation and which are lawfully manufactured or marketed in another Member state.

In addition, the Court interprets art. 5 of the aforementioned directive, which provides: "(1) Maximum amounts of vitamins and minerals present in food supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following into account: (a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups; (b) intake of vitamins and minerals from other dietary sources. (2) When the maximum levels referred to in paragraph 1 are set, due account should also be taken of reference intakes of vitamins and minerals for the population. (3) To ensure that significant amounts of vitamins and minerals are present in food supplements, minimum amounts per daily portion of consumption as recommended by the manufacturer shall be set, as appropriate. (4) The maximum and minimum amounts of vitamins and minerals referred to in paragraphs 1, 2 and 3 shall be adopted in accordance with the procedure referred to in Article 13(2)".

According to the Court, the provisions of Directive 2002/46 and those of the TFEU relating to the free movement of goods must be interpreted as meaning that the maximum amounts referred to in art. 5 of that directive must be set on a case-by-case basis and taking into account all of the elements in art. 5(1) and (2) of that directive, in particular of the upper safe levels established, with respect to the nutrients at issue, after a comprehensive scientific assessment of the risks for public health, based not on general or hypothetical considerations, but on relevant scientific data. It is for the referring court to assess whether the method for the setting of those amounts at issue in the main proceedings complies with those requirements.

Finally, the provisions of Directive 2002/46 and those of the TFEU relating to the free movement of goods must be interpreted as precluding that the scientific assessment of the risks referred to in art. 5(1)(a) of that directive, prior to the establishment of upper safe limits which must in particular be taken into account in order to set the maximum amounts referred to in art. 5 thereof, is carried out solely on the basis of national scientific opinions, even though recent international scientific opinions concluding in favour of the possibility of setting higher limits are also available on the date of the adoption of the measure at issue.

Excessive pricing of medicinal products and possible abuse of dominant position

On 15 May 2007 the European Commission opened a formal investigation into concerns that Aspen Pharma has abused a dominant market position through excessive pricing of five life-saving cancer medicines, which would be in breach of EU antitrust rules (art. 102 of the Treaty on the Functioning of the European Union (TFEU) and art. 54 of the European Economic Area (EEA) Agreement).

The investigation covers all of the EEA except Italy, where the Italian competition authority already adopted an infringement decision against Aspen on 29 September 2016.

For more information http://europa.eu/rapid/press-release_IP-17-1323_en.htm.

Closure of proceedings instituted by the CNMC against IMS Health, S.A. for possible abuse of dominant position

On 27 July 2017 the Spanish Competition and Markets Authority (*Comisión Nacional de los Mercados y la Competencia, CNMC*) agreed to shelve the penalty proceedings opened against IMS Health, S.A. (IMS), a company specialized in providing information on sales to the pharmaceutical industry, for possible abuses of a dominant position, contrary to art. 2 of the Competition Act 15/2007 of 3 July 2007 (*Ley de Defensa de la Competencia, LDC*) and art. 102 of the Treaty on the Functioning of the European Union (TFEU).

In particular, such abuses related to conditions that IMS established in the contracts with its customers which, in the CNMC's view, made market access difficult for other competing undertakings. According to the CNMC, activation of the 'multiple supply clause' when a wholesale distributor decided to compete directly with IMS or supply its sales data to other competitors allowed IMS to close the market for pharmaceuticals sales information services.

Following the submission of commitments by IMS, the CNMC has declared them adequate and sufficient to immediately resolve the competition concerns it had identified. In addition, it has agreed to shelve the penalty proceedings without a determination as to whether there has been an infringement of competition law.

Under the IMS commitments, IMS undertakes to waive certain contractual provisions of the 'multiple supply clause' contained in certain information supply contracts made between IMS and wholesale distributors of pharmaceutical products and not to include them in future contracts (which included a most-favoured-nation clause for the benefit of IMS and a right to early termination of the contract if the distributor supplied the information, in addition to IMS, to a competitor of IMS. IMS also undertakes not to alter the percentages set out in the current price reduction clause (provided for a multiple supply of information to IMS and other undertakings) until such time as there is a significant change in the structure, regulation or functioning of the markets concerned.

The commitments shall remain in effect indefinitely until such time as there is a significant change in the structure, regulation or functioning of the markets in question, a significant change which must be expressly verified and declared by the CNMC. Notwithstanding the foregoing, IMS may request the CNMC to review the content or duration of the commitments or to grant an individual exemption on the application of the commitments.

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