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Gómez-Acebo & Pombo

No. 12 | 2019

Life Sciences Newsletter

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Design and layout: Rosana Sancho • Translation and adaptation: John Woodger

Legislation

European Union

New European Union regulation of veterinary medicinal products and medicated feed

Three regulations on veterinary medicinal products and medicated feed were published in the Official Journal of the European Union on 7 January 2019. These are: (a) Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC; (b) Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC; and (c) Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018 amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use.

Although these regulations entered into force on the twentieth day following that of their publication in the Official Journal of the European Union, they will only apply from 28 January 2022 (with the exception of certain provisions of Regulation [EU] 2019/5).

For a more detailed analysis, please refer to my *Análisis Farmacéutico* of January 2019.

Opinion of the European Economic and Social Committee on 'Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No. 469/2009 concerning the supplementary protection certificate for medicinal products'

The Opinion of the European Economic and Social Committee ('EESC') on 'Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products' *(COM(2018) 317 final — 2018/0161 (COD))* (2018/C 440/16) was published in the Official Journal of the European Union C 440/100 of 6 December 2018.

The aforementioned proposal - dated 28 May 2018 - seeks to amend Article 4 of Regulation (EC) No 469/2009 in order to introduce a provision according to which a supplementary protection certificate ('SPC') would not confer protection against a particular act against which the basic patent

conferred protection, provided that the act comprises making for the exclusive purpose of export to third countries or any related act that is strictly necessary for that making or for the actual export itself, and the other conditions laid down are met.

For a more detailed examination of this matter, see García Vidal, Ángel, "Propuesta de modificación del Reglamento sobre los certificados complementarios de protección de medicamentos para introducir el límite de la fabricación para la exportación (manufacturing waiver)", https://www.lexology.com/library/detail.aspx?g=0a42f6a2-130e-4abd-be33-db31ccb503d5.

It should be noted from the Opinion that the EESC supports the amendment of Regulation (EC) No 469/2009, as proposed by the Commission, and "understands the Commission's position that, although it would be advantageous, the Commission will not be tabling a proposal for a unitary SPC at the moment, as the unitary patent package has not yet come into force".

As specific comments, the EESC states that the Commission may use EU funds to support the building of manufacturing capacity in Member States for export purposes during the SPC term. It also states that the Commission "may support the activities of interested NGOs for developing indicators for monitoring and evaluating the new SPCs for the future development of the EU market share of EU-manufactured generics and biosimilars".

Amendment of Regulation (EC) No 1907/2006 AMENDMENT OF REGULATION (EC) NO 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals

OJ No. 308 of 4 December 2018 publishes Commission Regulation (EU) 2018/1881 of 3 December 2018 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes I, III,VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances. Available at https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R1881&from=EN

Judgments and decisions

European Union

Repackaging of a medicinal product for off-label use

1. In many cases, in order to be able to use a medicinal product outside its marketing authorisation (MA), it is first necessary to repackage said product, altering its original presentation and strength. This gives rise to serious legal doubts, some of which have recently been examined by the Court of Justice in its judgment of 21 November 2018 in Case C-29/17, *Novartis Farma SpA v Agenzia Italiana del Farmaco (AIFA), Roche Italia SpA, Consiglio Superiore di Sanità.*

   The dispute, where the questions referred for a preliminary ruling by the Court of Justice are raised, concerns a biotechnological medicinal product, Avastin, of which Novartis Farma, Spa is the proprietor and whose MA covers cancer treatments exclusively. However, Avastin is often prescribed for treating ophthalmological diseases which are not mentioned in the MA, in particular age-related macular degeneration, a use for which there are other authorised medicinal products, such as Lucentinus of Roche Italia Spa. In order to be used for such treatments, Avastin must be extracted from its original vial and divided into single-use 0.1 ml syringes for intravitreal injection.

   In this way, Avastin used off-label for the treatment of eye diseases, is entered onto the list of medicinal products reimbursed by the Italian National Health Service (when used for ophthalmologic purposes the repackaged Avastin costs the SSN EUR 82 per dose and Lucentis EUR 902).

   This being the case, the dispute arises because Novartis Farma understands that there is a breach of EU law, and in particular of Directive 2001/83/EC on the Community code relating to medicinal products for human use and Council Directive 89/105/EEC relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems.

2. In the judgment under consideration, the Court of Justice underscores that the process of repackaging Avastin takes place prior to that medicinal product being placed on the market, after a doctor has prescribed its use in such conditions for a patient through an individual prescription. And the drawing off of liquid medicinal products from the original vials, as well as the transfer into ready-to-use syringes of the portions so drawn off, without any modifications of those products, is in reality analogous to actions which, in the absence of another undertaking's activities, could otherwise be, or have been, carried out, under their responsibility, by doctors prescribing the treatment or by pharmacies themselves in their dispensaries, or else in hospitals. Hence, the Court of Justice is of the opinion that the repackaging of Avastin under the conditions laid

down in the national measures at issue in the main proceedings, does not require an MA to be obtained in so far as that process is prescribed by a doctor by means of an individual prescription and undertaken by pharmacists for that medicinal product to be administered in hospitals.

Furthermore, since Avastin is, on the basis of an individual prescription, repackaged to be used off-label for the treatment of eye diseases, by a pharmacy lawfully authorised to that effect, for that medicinal product to be administered in hospitals, such a process falls within the exception under Article 40 of Directive 2001/83 and does not require manufacturing authorisation.

3. For a more detailed analysis, García Vidal, Ángel., "*Reacondicionamiento de un medicamento para su uso al margen de su autorización de comercialización (off-label use)*" (December 2018). https://www.ga-p.com/publicaciones/reacondicionamiento-de-un-medicamento-para-su-uso-al-margen-de-su-autorizacion-de-comercializacion-off-label-use/

Judgment of the General Court on reverse exclusion payments in light of competition law

1. The General Court of the European Union has handed down an interesting judgment, dated 12 December 2018, in case T677/14, Biogaran v Commission (ECLI:EU:T:2018:910), which contains seminal thoughts concerning patent settlement agreements. In particular, the General Court focuses on determining in which cases such agreements may be contrary to competition law. And it does so with specific reference to the litigation between holders of chemical-pharmaceutical patents and manufacturers of generic medicines.

2. The following conclusions can be drawn from the content of the judgement.

   (*a*) According to the General Court, there are a number of cases where a settlement agreement in patent litigation may not have any negative impact on competition. This is the case, for example, if the parties agree that the disputed patent is invalid and thus establish the immediate entry into the market of the manufacturer of generic medicines.

   (*b*) Settlement agreements often include clauses on non-challenge of patents and non-marketing of products. According to the General Court, these clauses do not present problems from the point of view of competition law if they are based on the acknowledgement by the parties of the validity of the patent in question (and, incidentally, of the fact that the generic products in question constitute an infringement).

   However, if patent validity is not a starting premise, the no-challenge clause is detrimental to the general interest of removing any obstacle to business activity which might be caused by the erroneous grant of a patent (see, in that regard, judgment of 25 February 1986, Windsurfing International v Commission, 193/83, EU:C:1986:75, paragraph 92) and the non-marketing clause leads to the exclusion from the market of one of the patent holder's competitors.

(*c*) With regard to reverse payments, the General Court states that a payment from the reference medicine company to the generics company is doubly suspicious in the framework of a settlement agreement. Firstly, it must be remembered that the purpose of a patent is to reward the creative effort of the inventor by allowing him to obtain a fair return on his investment and that, therefore, a valid patent must, in principle, allow a transfer of value to its owner - for example, by means of a licensing agreement - and not the other way round. Secondly, the existence of a reverse payment introduces a suspicion that the settlement is based on the acknowledgment by the parties to the agreement of the validity of the patent in question.

(*d*) Notwithstanding, the mere presence of a reverse payment cannot lead to the conclusion that there is a subject-matter restriction and that, therefore, we are always faced with an act contrary to competition. That will only happen if there is a reverse payment not justified in the conclusion of the settlement agreement. In such a case, if payment is made for the manufacturer of generic medicines to be subject to no-marketing and no-challenge clauses, it must be concluded that there is a subject-matter restriction. In such a case, the General Court holds, the restrictions on competition introduced by the no-marketing and no-challenge clauses are no longer linked to the patent and the settlement agreement, but are explained by the payment of an advantage that encourages the manufacturer of generic medicines to renounce its competitive endeavours.

And in such a case, when an incentive is held to exist, the parties can no longer claim their acknowledgement, in the framework of the settlement agreement, of the validity of the patent. The fact that a judicial or administrative authority confirms the validity of the patent is, in this respect, indifferent.

Supplementary protection certificate and marketing authorisation for a medicinal product constituting a new formulation, protected by a basic patent, of a previously authorised active ingredient

Advocate General HENRIK SAUGMANDSGAARD ØE, in his Opinion delivered on 13 December 2018 in Case C-443/17, *Abraxis Bioscience LLC v Comptroller-General of Patents*, ECLI:EU:C:2018:1020, has proposed that the Court of Justice answer that "Article 3(d) 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 precludes the grant of such a certificate where the marketing authorisation relied upon in support of the application for a supplementary protection certificate under Article 3(b) of that regulation is not the first marketing authorisation for the active ingredient or combination of active ingredients at issue as a medicinal product. This is so even in a situation, such as that at issue in the main proceedings, where the marketing authorisation relied upon is the first to cover the formulation protected by the basic patent relied upon in support of the application for a supplementary protection certificate under Article 3(a) of that regulation."

Does using a trade mark to distinguish a medicinal product in the context of a clinical trial constitute genuine use for the purposes of preventing such trade mark from lapsing by non-use

On 9 January 2019, Advocate General MACIEJ SZPUNAR delivered his Opinion in Case C 668/17 P, Viridis Pharmaceutical Ltd v European Union Intellectual Property Office *(EUIPO)*, ECLI:EU:C:2019:4.

This case is interesting because it discusses whether, in order to comply with the burden of mandatory use of a registered trade mark to distinguish medicinal products, it is necessary for the medicinal product to have obtained a marketing authorisation or whether, on the contrary, the use of the trade mark by distinguishing the product in the context of a clinical trial may constitute genuine use of the trade mark in question for a medicinal product. The following points of the Opinion stand out.

1.º The fact that there is not yet a marketing authorisation for the medicinal product does not mean that the trade mark cannot be put to "genuine use" within the meaning of Article 51(1)(a) of Regulation No 207/2009 (Article 58(1)(a) of Regulation No 2017/1001). It would therefore not be a prerequisite for genuine use.

2.º The legality of trial acts in which a trade mark is present does not automatically transform those acts into acts of genuine use of that trade mark.

3.º According to the General Court, the use of the disputed trade mark in the context of a clinical trial vis-à-vis third parties cannot be assimilated to marketing or to a direct preparatory act, since it takes place without being subject to any competition and without being aimed at obtaining or retaining market shares.

The Advocate General proposes that the Court should answer that the use of a registered trade mark for a medicinal product examined in the context of clinical trials does not constitute genuine use of that trade mark. However, the Advocate General understands that there are exceptions and that it cannot be concluded that in the absence of a marketing authorisation, a registered trade mark for a medicinal product which is the subject of a clinical trial may in no case be used genuinely.

By way of illustration, it is stated that under Article 83(1) and (2) of Regulation No 726/2004, notwithstanding Article 6 of Directive 2001/83, Member States may provide, for compassionate use, an unauthorised medicinal product to a group of patients suffering from a serious chronic or seriously debilitating disease or whose lives are considered to be endangered and who cannot be treated satisfactorily with an authorised medicinal product. Such a possibility exists in particular in respect of medicinal products examined in the framework of a clinical trial.

4.º In response to the appellant's argument that, in view of the specific features of the pharmaceutical sector, a period of five years must be regarded as too short, the Advocate General believes that the period of five years within which a trade mark must be used applies irrespective of the sector to which the goods or services for which a trade mark is registered belong. However, he adds that the particularities of the relevant economic sector are taken into account when assessing the circumstances which constitute (or do not constitute) genuine use according to the market for the goods or services in question, and circumstances in which the period of five years would be insufficient to commence genuine use of a trade mark may be taken into account in the context of examining the proper reasons for non-use.

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