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Gómez-Acebo & Pombo

Newsletter

# *Pharma & Healthcare*

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# Contents

# Legislation and legislative proposals

## European Union

### The European Commission withdraws its Proposal for a Regulation of the European Parliament and of the Council on SEPs

As part of the so-called *patent package* (which also includes an initiative on compulsory licensing and other initiatives to reform the European system of supplementary protection certificates for both medicinal products and plant protection products), the European Commission drafted the Proposal for a Regulation of the European Parliament and of the Council on standard essential patents (Document COM/2023/232 final of 27 April 2023).

The proposal concerns any patent in force in one or more Member States of the European Union that is essential to a standard that has been published by a standard development organisation with which the patent holder has undertaken to grant licences on fair, reasonable and non-discriminatory (FRAND) terms and conditions.

These commitments may either be subsequently disregarded by patent holders, or may give rise to disputes as to whether or not certain conditions are fair, reasonable and non-discriminatory. So far, one of the main avenues of action against abusive conduct by patent holders has been through competition (antitrust) law, deeming that the bringing of actions for infringement of these patents may constitute an act of abuse of a dominant position (contrary to Article 102 of the Treaty on the Functioning of the European Union or, where applicable, the relevant national competition law).

The proposal aims to regulate these situations, but not only where there is abuse of dominance, but in general (without prejudice to the continued possibility of applying competition law in addition to new legislation in the pipeline)

However, as a lack of agreement was noted during the passage of the proposal, the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the Commission work programme 2025 (11 February 2025, COM(2025) 45 final) has withdrawn this proposal for a Regulation (*vide* Annex IV, No. 17); the Commission indicates that no agreement is foreseen and that it will assess whether a new proposal should be presented or whether another approach is preferable.

### Procedures for joint scientific consultations on medical devices and in vitro diagnostic medical devices

The *Official Journal of the European Union* of 27 January 2025 (L series) has published Commission Implementing Regulation (EU) 2025/117 of 24 January 2025 laying down rules for the application of Regulation (EU) 2021/2282 with

regard to the procedures for joint scientific consultations on medical devices and in vitro diagnostic medical devices[1].

This new regulation lays down detailed procedural rules for joint scientific consultations carried out pursuant to Regulation (EU) 2021/2282 as regards:

*a*) submission of requests from health technology developers for joint scientific consultations on medical devices and in vitro diagnostic medical devices;

*b*) selection and consultation of stakeholder organisations and patients, clinical experts and other relevant experts ('individual experts') in joint scientific consultation on medical devices and in vitro diagnostic medical devices;

*c*) cooperation, in particular by exchange of information, with the expert panels on joint scientific consultations on medical devices where a health technology developer requests the consultation to be carried out in parallel with the expert panel consultation.

## European Parliament resolution on the urgent need to revise the Medical Devices Regulation

The *Official Journal of the European Union* has published on 29 January 2025 (C/2025/485) the European Parliament resolution of 23 October 2024 on the urgent need to revise the Medical Devices Regulation (2024/2849[RSP]), in which the European Parliament calls on the Commission to propose "delegated and implementing acts to the MDR and the IVDR to address the most pressing challenges and bottlenecks in the implementation of the legislative frameworks and to propose the systematic revision of all relevant articles of these regulations, accompanied by an impact assessment, to be conducted as soon as possible".

It also calls, inter alia, for "the introduction of adapted rules for orphan and paediatric medical devices, without compromising patient safety, and emphasises the need for more efficient conformity assessment procedures tailored to medical devices and in vitro diagnostics serving relatively small markets, such as products for the treatment of children or rare diseases".

## Proposal for a Regulation laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest

The European Commission has presented a Proposal for a Regulation of the European Parliament and of the Council laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795 (Document COM/2025/102 final of 11 March 2025)[2].

As stated in the first article of the proposed regulation, its objective is to strengthen the security of supply and the availability of critical medicinal products within the Union, thereby

[1] See this ***link***.

[2] See this ***link***.

ensuring a high level of public health protection and supporting the security of the Union. It also aims to improve the availability and accessibility of other medicinal products, where the functioning of the market does not otherwise sufficiently ensure the availability and accessibility of those medicinal products to patients, whilst giving due consideration to the appropriateness to ensure the affordability of medicinal products.

To achieve these objectives, the proposed Regulation sets out a framework to *a*) facilitate investments in manufacturing capacities for critical medicinal products, their active substances and other key inputs in the Union; *b*) lower the risk of supply disruptions and strengthen availability by incentivising supply chain diversification and resilience in the public procurement procedures for critical medicinal products and other medicinal products of common interest; *c*) leverage the aggregated demand of participating Member States through collaborative procurement procedures; and *d*) support the diversification of supply chains also by facilitating the conclusion of strategic partnerships.

# Judgments, rulings and decisions

## European Union

### Pharmacy advertising or medicine advertising?

1. In practice, it is very common for advertising carried out by pharmacies to generate controversy from the point of view of the application of *advertising of medicinal products*. In this regard, the first question to be analysed when faced with a given pharmacy campaign is whether it is an advertisement for the pharmacy as such or whether it is an advertisement for one or more of the medicinal products marketed in the pharmacy.

   Such a determination is indispensable, since the *advertising of medicinal products* is subject to a number of regulatory provisions (contained in particular in Directive 2001/83/EC on the Community code relating to medicinal products for human use, and in the national laws transposing it), which do not apply if the subject matter of the promotion is not medicinal products but pharmacy services.

   This important question of the correct delimitation of the subject matter of advertising has been addressed by the Court of Justice in its recent judgment of 27 February 2025, *Apothekerkammer Nordrhein v DocMorris NV* (C-517/23, ECLI:EU:C:2025:122), a judgment which joins others that the Court of Justice

has delivered in recent years: the *DocMorris* and *Euroaptieka* judgments[3].

2. Indeed, in its judgment of 25 January 2025, the Court of Justice builds on its previous case law, recalling that the concept of *advertising of medicinal products* covers promotion, both in respect of a specific medicinal product and unspecified medicinal products, but not an "campaign which seeks to influence not the customer's choice of a given medicinal product but the choice, taken at a later stage, of the pharmacy from which that customer would purchase that medicinal product". Accordingly, the Court holds that, "in order to determine whether an advertising campaign designed to encourage the purchase of prescription-only medicinal products from a pharmacy's entire product range falls within the concept of '*advertising of medicinal products*' within the meaning of Article 86(1) of Directive 2001/83, it is necessary to determine whether that campaign is intended to promote the prescription, supply, sale or consumption of medicinal products, even if unspecified, or whether it is intended only to influence the choice of pharmacy from which the customer will purchase prescription-only medicinal products".

   In light of the foregoing, the Court considers that, in order to reach such a determination in relation to the advertising campaigns in the present case, it is necessary to distinguish them "according to whether the advertising message is limited to prescription-only medicinal products or whether that message also relates to non-prescription medicinal products".

3. As regards campaigns in which the advertising message is limited to prescription-only medicinal products, the judgment refers to campaigns in which the customer who buys prescription-only medicinal products is offered an immediate cash discount or is given - in return for sending in their medical prescription and participating in a medication check - reward of between EUR 2.50 and EUR 20 per prescription, without it being possible to know the exact amount of that reward. According to the Court, "it cannot be considered that the message of those campaigns promotes the prescription or consumption of unspecified prescription-only medicinal products, since the decision to prescribe such medicinal products is the sole responsibility of the doctor. As is clear from recital 50 of Directive 2001/83, a prescribing doctor is required to carry out his or her functions objectively and, from the point of view of professional conduct, not to prescribe a given medicinal product if it is not fitting for the therapeutic treatment of his or her patient".

   On this point, therefore, the Court of Justice follows the interpretation of the Advocate General, whom it expressly quotes, recalling that, "when the patient receives a medical prescription, the only choice that remains to be made, with regard to the prescription-only medicinal product, is that of the pharmacy from which he or she will buy that medicinal product". And, therefore, a campaign in which a customer who purchases prescription-only medicinal products is offered an immediate discount or a cash reward, constitutes a promotion concerning the choice of the pharmacy from which a patient purchases a

[3] Judgments of the Court of Justice of the European Union of 15 July 2021, *DocMorris* (C-190/20), and of 22 December 2022, *Euroaptieka* (C-530/20).

prescription-only medicinal product, with the result that such a campaign does not come within the concept of *advertising of medicinal products* within the meaning of Article 86(1) of Directive 2001/83.

4. With regard to campaigns offering discounts for the purchase of prescription medicinal products, consisting in the provision of a voucher for future purchases or the application of a percentage discount on such future purchases, the Advocate General was of the opinion that there would be promotion of the pharmacy marketing all such products, because these discounts apply to the pharmacy's entire range of non-prescription medicines, as well as to non-medicinal health and care products, so that medicines constitute only part of that range of products.

   However, the Court of Justice believes that this is not an advertisement for a pharmacy, but an advertisement for medicinal products in which the purchase of medicinal products not subject to medical prescription is encouraged. In the Court's view, in "the absence of an obligation to have recourse to a prescribing doctor, the recipient of the vouchers, attracted by the economic advantage they offer, may use the vouchers to obtain non-prescription medicinal products at a reduced price". And, contrary to the Advocate General's position, the Court states that such a finding cannot be called into question by the fact that the vouchers offered may also be used for the purchase of goods other than non-prescription medicines, such as health and care products.

## *Pharmacological action* in the legal definition of a *medicinal product*

In its judgment of 13 March 2025 (C-589/23, ECLI:EU:C:2025:173), the Court of Justice interpreted the concept of *pharmacological action* for the purposes of the legal concept of *medicinal product*. It should be recalled that, according to 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, a *medicinal product* is defined as follows: "*a*) any substance or combination of substances presented for treating or preventing disease in human beings; or *b*) any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product" (Art. 1(2) of Directive 2001/83/EC).

This being so, the Court of Justice addresses the interpretation of the concept of *pharmacological action* and states the following:

*a*) that the term "designates the effects of a substance on a living organism, notably for therapeutic or preventive purposes";

*b*) that - as already held in its judgment of 6 September 2012 in *Case* C-308/11 *Chemische Fabrik Kreussler* – "a substance the molecules of which do not interact with a human cellular constituent may nevertheless, by means of its interaction with other cellular constituents present within the user's organism, such as bacteria, viruses or parasites, have the effect of restoring, correcting or modifying physiological functions in human beings";

*c*) that the type of interaction required between the substance and the cellular constituent is defined relatively broadly in the Meddev Guidance and MDCG Guidance, that is to say, 'between molecules' or 'typically at a molec-

ular level', so that it cannot, a priori, be required that such an interaction should give rise to a modification of the molecular structure of the cellular constituent in question;

*d*) that the binding of a substance to the cellular constituent in question by means of a hydrogen bond constitutes an interaction that falls within the definition of *pharmacological means*;

*e*) that it does not follow either from Directives 2001/83 and 93/42 or from the Meddev Guidance and MDCG Guidance that the molecules of the substance concerned should necessarily have to interact with a cellular constituent by means of a binding that is permanent, and therefore it cannot be ruled out that a substance whose binding to a cellular constituent is reversible may be regarded as exerting a pharmacological action, within the meaning of Article 1(2)(b) of Directive 2001/83;

*f*) that the interaction between the substance concerned and the cellular constituent present within the user's organism must result in 'initiation, enhancement, reduction or blockade of physiological functions or pathological processes'; and that the process by which a substance attaches to a bacterium and thereby prevents that bacterium from adhering to a human cellular constituent must be regarded as a 'blockade of pathological processes'; and

*g*) that a narrow interpretation of the concept of *pharmacological action* - which would exclude interactions consisting, as in the present case, in a reversible binding of a substance to bacteria by means of a hydrogen bridge - could jeopardise the objective pursued by Directive 2001/83 of ensuring a high level of protection of human health.

## Supplier liability for damage caused by defective products

As already reported in the previous issue of this newsletter, the new Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October on liability for defective products and repealing Council Directive 85/374/EEC was published in the *Official Journal of the European Union* in November 2024; this new directive also applies to the field of medicinal products and medical devices.

Now, the Court of Justice has recently handed down a judgment interpreting Directive 85/374/EEC, whose doctrine is equally relevant in relation to the new directive. We are talking about the judgment of 19 December 2024 (C-157/23, ECLI:EU:C:2024:1045), which deals with the liability of the supplier of a defective product.

In this respect, Article 3 of Directive 85/374/EEC provides that 'producer' "means the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part and any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer" and that, where "the producer of the product cannot be identified, each supplier of the product shall be treated as its producer unless he informs the injured person, within a reasonable time, of the identity of the producer or of the person who supplied him with the product".

According to the Court of Justice, "the supplier of a defective product must be considered to be a 'person who ... presents him[- or her]self as ... [a] producer' of that product, within the meaning of that provision, where that supplier has not physically put his or her name, trade mark or other distinguishing feature on the product, but the trade mark which the producer has put on that

product is the same, on the one hand, as the name of the supplier or a distinctive element thereof, and, on the other hand, as the name of the producer".

In this way, an interpretation is established that will have a significant impact in cases where the producer's manufacturer and the supplier are companies of the same group and have common elements in their company names or use the same trademarks.

The Court of Justice acknowledges that it "is true that, by referring to a person 'who … presents him[-or her]self as … [a] producer' 'by putting' his or her name, trade mark or other distinguishing feature on the product, the wording of that provision might suggest that that classification requires active steps on the part of that person, consisting in putting that wording on the product in question him- or herself". But liability for the fact of presenting oneself as a producer is due to the fact that, by "putting his or her name, trade mark or other distinguishing feature on the product at issue, the person who presents him- or herself as a producer gives the impression that he or she is involved in the production process or assumes responsibility for it. Accordingly, by using such particulars, that person is effectively using his or her reputation in order to make that product more attractive in the eyes of consumers which, in return, justifies his or her liability being incurred in respect of that use". For that reason, "where that person supplies the product in question, it makes no difference whether that person him- or herself has actually put such wording on that product or whether his or her name contains the wording put on it by the manufacturer, which corresponds to the manufacturer's name. In those two cases, the supplier uses the similarity between the wording in question and that supplier's own company name in order to present him- or herself to the consumer as the person responsible for the quality of the product and to give rise to confidence on the part of that consumer comparable to that which he or she would have if the product had been sold directly by that supplier's producer. In both cases, that person must therefore be regarded as a person who 'presents him[- or her]self as … [a] producer'".

## New CJEU ruling interpreting the regulation on SPCs for medicinal products

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 provides in Article 2 that the certificate may cover a product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure in accordance with European Union law.

On that basis, Article 3 sets out the conditions to be met before a supplementary protection certificate (SPC) can be granted. Thus, the certificate shall be granted if, in the Member State in which the application is submitted and at the date of that application:

*a*) the product is protected by a basic patent in force;

*b*) a valid authorisation to place the product on the market as a medicinal product has been granted;

*c*) the product has not already been the subject of a certificate; and

*d*) this authorisation is the first authorisation to place the product on the market as a medicinal product.

In its judgment of 19 December 2024, Joined Cases C-119/22 and C-149/22, ECLI:EU:C:2024:1039, the Court of Justice held as follows:

1. Article 3(c) of Regulation (EC) No 469/2009 must be interpreted as not precluding the grant of an SPC for a product consisting of two active ingredients even if one of those two active ingredients has already been, alone, the subject of an earlier SPC and it is the only one to have been disclosed by the basic patent, whereas the other active ingredient was known at the filing date or priority date of that patent.

2. Article 3(a) of Regulation No 469/2009 must be interpreted as meaning that it does not suffice that a product is expressly mentioned in the claims of the basic patent in order for that product to be regarded as being protected by that patent, within the meaning of that provision. It is also necessary, in order to satisfy the condition laid down in that provision, that that product necessarily fall, from the point of view of a person skilled in the art, and in the light of the description and drawings of that patent, under the invention covered by that patent at the filing date or priority date.

3. Article 3(a) of Regulation No. 469/2009 must be interpreted as meaning that a product consisting of two active ingredients (A+B) is protected by a basic patent, within the meaning of that provision, where A and B are expressly mentioned in the claims of that patent and the specification of that patent teaches that A may be used as a medicinal product for human use alone or in combination with B, which is an active ingredient in the public domain at the filing date or priority date of that patent, provided that the combination of those two active ingredients necessarily falls under the invention covered by the same patent.

## International jurisdiction in patent disputes

The Court of Justice has handed down an important patent judgment in which it delimits the scope of the international jurisdiction of the courts of a Member State to hear actions for infringement of patents granted by other States or having effect in other States. This is the judgment of 25 February 2025, *BSH Hausgeräte GmbH and Electrolux AB* (C-339/22, ECLI:EU:C:2025:108), in which the court:

1. Recalls that a court of one Member State may hear actions for infringement of a patent of another State, which is merely a manifestation of international jurisdiction based on the jurisdiction of the defendant's domicile, as provided for in Regulation (EU) No 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (Article 4(1)a).

2. Reiterates that Article 24 of Regulation (EU) No 1215/2012 grants exclusive jurisdiction over the validity of the patent to the courts of the State that granted the patent and that this exclusive jurisdiction applies whether the validity is raised by way of an action or as a defence.

3. Clarifies that, if an infringement of a patent of another Member State is claimed in one Member State and the defendant raises a plea of invalidity, the court cannot hear the invalidity plea, but it can rule on the infringe-

ment, as already indicated in the *Duijnstee* and *IRnova* judgments[4].

4. Insists that, on the other hand, Article 24(4) of Regulation (EU) No 1215/2012 cannot be regarded as applicable in a situation in which the patents concerned are granted or validated not in a Member State, but in a third State (such as Turkey), which is already apparent from the judgment of 8 September 2022, *IRnova*. The main novelty is the Court's further development of this last point, stating the following:

   *a*) In such cases where the patent has been granted in a State outside the European Union (such as Turkey), the court of the Member State hearing patent infringement actions in that third State, by virtue of the jurisdiction of the defendant's domicile, may, as a defence, rule on the validity of the patent [provided that the third State is not a member of the Lugano Convention - Convention on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters, signed in 2007 by the European Union, Denmark, Iceland, Norway and Switzerland - and that there is no bilateral agreement between that that State and the European Union to the contrary, or proceedings are not pending before a court of that third State, within the meaning of Articles 33 and 34 of Regulation (EU) No. 1215/2012]. 1215/2012].

   *b*) What it may not do is to make a declaration of invalidity entailing the cancellation of the patent with *erga omnes* effect. According to the Court of Justice, the principle of non-interference between States, which is inherent in international law, means that "only the courts of the third State in which a patent is granted or validated have jurisdiction to declare that patent invalid by a decision that may cause the national register of that State to be amended as regards the existence or content of that patent". By contrast, the court of the Member State in which the defendant is domiciled which is seised of an infringement action in the context of which the issue of the validity of a patent granted or validated in a third State is raised as a defence, does have jurisdiction to rule on that issue given that the decision of that court sought in that regard is not such as to affect the existence or content of that patent in that third State, or to cause its national register to be amended.

[4] Judgments of the Court of Justice of 15 November 1983, *Duijnstee*, (Case 288/82, EU:C:1983:326), paras. 22 and 23, and of 8 September 2022, *IRnova,* (C-399/21, EU:C:2022:648), para. 48.

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