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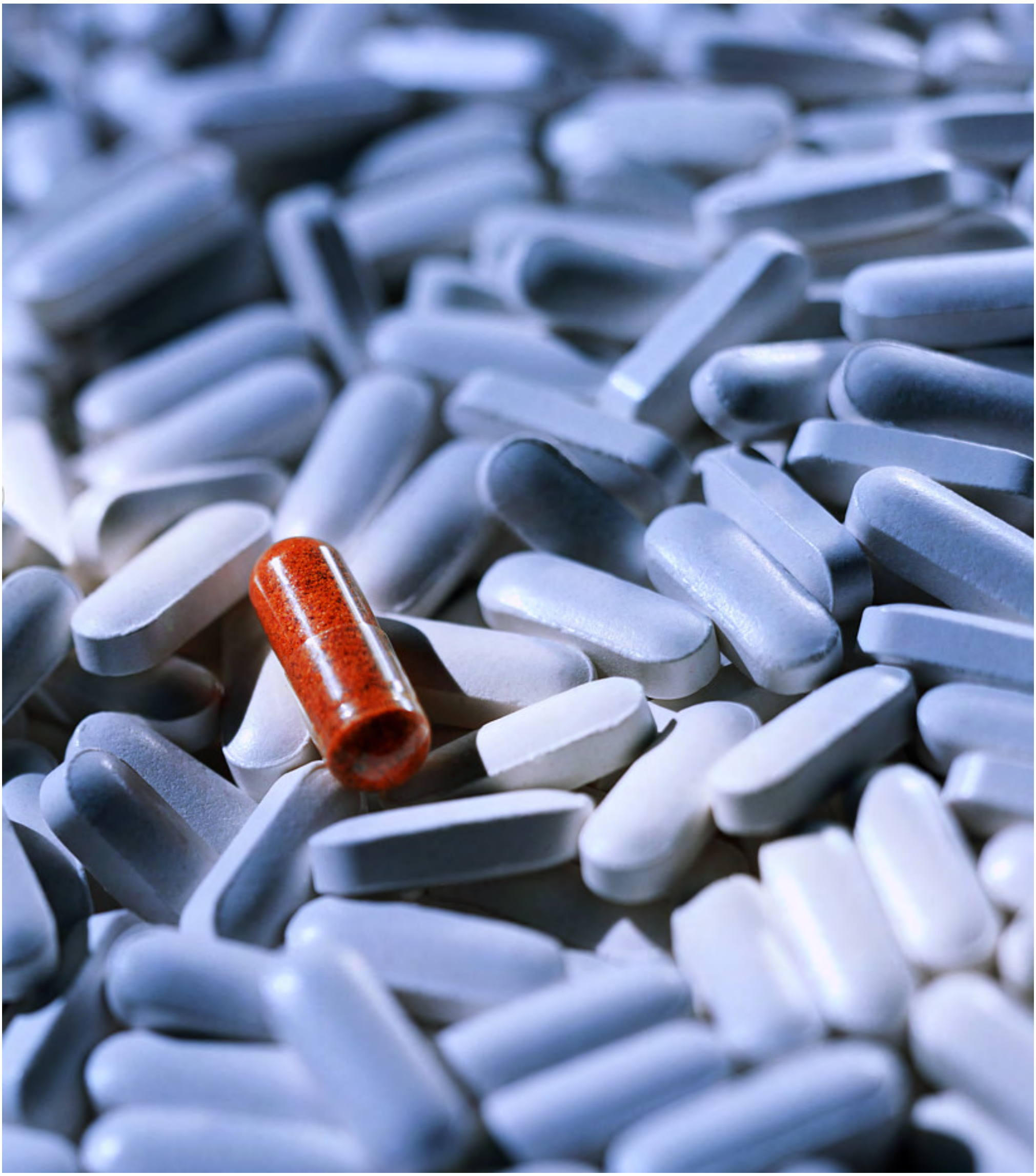

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Legal Developments In the Pharmaceutical Sector In Europe

By Catherine Mateu

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The past year was quite dense with regards to international protection of pharmaceutical products in Europe, with several crucial rulings from the European Court of Justice on referrals from member states jurisdictions.

Starting with a regional point of view, on July 18 2013 (C-414/11), the European Court of Justice ruled that TRIPs provisions regarding patentability fell within the exclusive competence of the European Union, excluding therefore the competence of European Union member states. It also ruled that the invention of a pharmaceutical product, such as the active chemical compound of a medicine, is patentable subject matter according to article 27 of the TRIPs, and that according to TRIPS provisions, a patent obtained for a manufacturing process, after an application claiming the invention of both a product and its manufacturing process, did not automatically grant patent protection on the product. On the one hand, this ruling is quite revolutionary on its findings on the exclusive competence of the European Union that preclude member states competence on the TRIPs agreement and on its direct effect. On the other hand with regards to material law, this ruling is not surprising and follows the trend found in WTO Panel Reports rendered in cases WT/DS79/R (European Communities v. India) and WTO/DS114R (European Community v. Canada).

In the specific matter of supplementary protection certificate (here-after SPC), the European Court of Justice issued four rulings in the last quarter of 2013 that will have a significant impact in law and practice.

First, on 14 November 2013 (C-210/13), the Court held that, just as an adjuvant is not considered an 'active ingredient' within the meaning of provisions protecting SPCs, a combination of two substances, namely an active ingredient having therapeutic effects on its own and an adjuvant that, while enhancing those therapeutic effects, has no therapeutic effect on its own, does not fall within the definition of 'combination of active ingredients' within the meaning of provisions protecting SPCs.

Also on 14 November (C-617/12), the Court ruled that an administrative authorisation issued for a medical product by the Swiss Institute for Medicinal Products (SwissMedic), which is automatically recognized in Liechtenstein, must be regarded as the first authorisation to place that product in the European Economic Area market, where that authorisation predates marketing authorisations issued for the same medicinal product, either by the European Medicines Agency (EMA), or by the competent authorities of European Union Member States. This is in accordance with the requirements laid down in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001, on the Community code relating to medical products for human use, and with the requirements of the Republic of Iceland and the Kingdom of Norway. The facts that, on the basis of similar clinical data, the European Medicines Agency, unlike the Swiss authority, refused to grant a marketing authorisation for the product at the conclusion of its examination of the data, or that the Swiss authorisation was suspended by the Swiss Institute for Medicinal Products and subsequently reinstated only when the holder of the authorisation submitted additional data, were considered irrelevant.

More recently, the European Court of Justice ruled on December 12, 2013, (case C-484/12), on the basis of a basic patent and a marketing authorisation for a medical product consisting of a combination of several active ingredients, that a patent holder who has obtained an

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SPC for a combination of active ingredients may also obtain an SPC for an individual active ingredient of that combination.

The same day, the Court (case C-443/12) rendered a ruling regarding the particular situation where there is a patent protecting an active ingredient and a marketing authorisation for a medical product containing that ingredient as the single active ingredient, and the holder of that patent has already obtained an SPC for the active ingredient entitling him to oppose the use by others of that active ingredient, either alone or in combination with other active ingredients. The Court held that in such circumstances, European Union provisions concerning SPCs preclude the patent holder from obtaining a second SPC for a combination of active ingredients, on the basis of that same patent and on the basis of a subsequent marketing authorisation for a different medicinal product containing the patented active ingredient in conjunction with another active ingredient which is not protected by this patent.

Again on 12 December, the Court held (case C-493/12) that in order for an active ingredient to be regarded as 'protected by a basic patent in force' by an SPC for medical products, it is not necessary for the active ingredient to be identified in the patent claims by a structural formula. Where the active ingredient is covered by a functional formula, an SPC may be granted for that ingredient on condition that it is possible to reach the conclusion on the basis of those claims, interpreted inter alia in the light of the description of the invention, as required by Article 69 of the Convention on the Grant of European Patents and the Protocol on the interpretation of that provision, and that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question, which is a matter to be determined by the referring court.

Getting back to the global stage, two disputes are still pending before the WTO regarding pharmaceutical products on transit (disputes DS 408 and DS 409) filed in 2010, and respectively opposing India and Brazil to the European Union. Now that we have a new customs regulation in the European Union, it will be interesting to see the outcome of these disputes.

Finally, the transition period available to least developed countries (comprising today 34 WTO members) to implement the TRIPs agreement has been extended for a second time, until 1 July 2021.

Catherine Mateu, bilingual in French and Spanish, and fluent in English and Basque, holds a post-graduate degree in Domestic and European Business Law from Nancy II, an LLM in Common Law from UEA in the UK, a DESS in Industrial Property from Paris II, and a DEA in Private International Law from Paris I.

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