

Summary of *‘Follow-On Drugs and Due Diligence under the EU-SPC System: A Comparative Analysis with the US-PTE System’* by María Victoria Rivas Llanos

The present dissertation discusses legal questions concerning the prolongation of patent protection for pharmaceutical products. It proposes, by means of a comparative analysis with the US-PTE System, several amendments to the EU-SPC System, namely allowing SPCs for certain follow-on drugs and introducing a due diligence control mechanism.

Both the US-PTE System and the EU-SPC System were introduced, among other things, to promote innovation in the pharmaceutical sector. The underlying reason was that medicinal products are often allowed onto the market only when the patent protecting them is close to the end of its lifespan. Against this background, each of the systems had to solve a conflict of different interests: (a) the interest of originator pharmaceutical companies to obtain sufficient compensation for their investment in bringing new drugs onto the market, (b) the interest of generic drug producers to enter the market as soon as possible upon patent expiry and (c) the interest of consumers to access medicines at an affordable price. While balancing these interests was a key concern in the US and the EU, the approaches pursued for finding that balance differed.

This dissertation compares the solutions found in both systems with a view of taking the US-PTE System as a model to improve the EU-SPC System. In this context, two hypotheses serve as a starting point for the present research. The first hypothesis confirmed by this dissertation is that the US-PTE System, while pursuing similar goals, contains certain “advantages” over the EU-SPC System (see Part I, Chapter A). The US-PTE System has been more faithful to its rationale, in particular by achieving an adequate distribution between the rights and benefits of the parties involved. By way of example, the patent extension is compensated with a due diligence control mechanism preventing the PTE applicant from abusing the system through delaying tactics. The EU SPC-System, on the contrary, lacks such counterbalancing measures.

The second hypothesis confirmed by this dissertation is that, while the US-PTE System is better fit for purpose, its overall structure is sufficiently similar to the EU-SPC System to allow, in principle, the transfer of specific features from one system to the other (see Part I, Chapter B). The US-PTE System was found to be not only drafted clearer than the EU-SPC System but also more open to different types of follow-on innovation (i.e. derivatives of known substances). Despite such differences, nothing in the institutional framework nor in the granting requirements and procedure of either system poses an obstacle for the above-mentioned transfer.

Building up on these findings, the present dissertation argues that, taking the US-PTE System as a model, the EU-SPC System could be improved by making two amendments. Firstly, this author holds that the EU-SPC System, like the US-PTE System, should be open for specific types of follow-on drugs, namely derivatives, such as salts and esters (see Part II, Chapter A). In this author's opinion, if there is no justification to deny such forms of innovation patent protection when they are able to prove novelty and inventive step by presenting an innovative therapeutic effect, there should, in principle, be no justification to deny them SPC protection. The counterarguments present in the literature, according to which SPCs for follow-on drugs could harm innovation and competition in the pharmaceutical sector, do not sufficiently consider that follow-on innovation is often as beneficial for society as the first-in-line product. That said, it will still be required that the patentee is able to demonstrate that the product's clinical studies consumed a considerable part of the patent lifetime, which justifies the grant of an SPC as a compensation. Therefore, an amendment of Article 1 of the SPC Regulation is proposed in order to introduce a definition of "new active ingredient" that comprises salts and esters.

Secondly, the present dissertation argues that the EU-SPC System could be improved by introducing a due diligence control mechanism against potential delaying strategies, as foreseen by the US-PTE System (see Part II, Chapter B). It is this author's position that establishing a due diligence mechanism is an adequate and necessary measure against the risk of abusive delaying practices by the SPC applicant. In order to be effective, the mechanism would have to be complemented with the requirement of an agency relationship between the patentee and the holder of the marketing authorisation. The control mechanism constitutes a counter-weight to the proposed opening of the EU-SPC System to certain follow-on drugs. Fears expressed in the past by the EU legislator, according to which such a control mechanism would entail excessive administrative burden, do not take adequately into consideration that similar controls have been implemented successfully in the US-PTE System without creating undue bureaucracy. Therefore, an amendment of Articles 7, 8 and 13 of the SPC Regulation, introducing due diligence and agency in the EU-SPC System, is proposed by this work.

The proposed amendments seem suitable for counteracting certain disadvantages of the EU-SPC System identified by the comparison with the US-PTE System. Opening the EU-SPC System for certain follow-on drugs and introducing a due diligence mechanism will make it, in this author's view, a fairer and better-balanced system.