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EU Pharma Package – Bolar exemption under scrutiny and first amendments being proposed

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In April 2023, the European Commission (EC) published the pharmaceutical legislation package, including the proposal for a Pharmaceutical Directive[1] , and further proposals for regulations on SPCs[2].

Article 85 of the proposed Directive aims at providing an amended provision for the so-called Bolar exemption, currently codified in Article 10(6) of Directive 2001/83/EC. The initial EC proposal intends to[3] *inter alia* increase competition from earlier market entry of generic and biosimilar medicinal products. The proposal aims to broaden the scope of the Bolar exemption and harmonise the application in the Member States: "*Taken together, these measures will facilitate earlier market entry of generics and biosimilars, thus increasing competition and contributing to the objectives of promoting affordability of medicinal products and patient access*".

Notwithstanding the unclear wording of the newly proposed Bolar exemption and the many critical voices that the proposed provision effectively narrows down, instead of broadens, the scope of the Bolar exemption as it was (at least in the *pre*-UPC era[4]) implemented by the majority of the Member States[5], the proposed wording has been recently subject to further amendments proposed by the European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI). The ENVI draft report already proposes an amendment of the recitals that reduce the scope of the activities intended to be covered under the Bolar exemption:

"Amendment 22 – Recital (63)

The exemption must be confined to conduct studies and trials and other activities needed for the regulatory approval process, health technology assessment ***and pricing reimbursement request, even though this may require substantial amounts of test production to demonstrate reliable manufacturing****."* (Text in bold is proposed to be deleted)

The reference to price and reimbursement is also deleted in recital 64. This is reflected in the proposal for an amended wording of Article 85 of the proposed Directive:

"*Patent rights, or supplementary protection certificates under the* […] *shall not be regarded as infringed when a reference medicinal product is used for the purposes of:*

- *studies, trials and other* ***necessary*** *activities conducted to generate data for an application, for:*

- *(i) a marketing authorisation ~~of generic, biosimilar, hybrid or bio-hybrid medicinal products and for subsequent variations~~;*
- *(ii) health technology assessment as defined in Regulation (EU) 2021/2282;*
- *~~(iii) pricing and reimbursement.~~*
- *the activities conducted exclusively for the purposes set out in point (a), may cover the ~~submission of the application for a marketing authorisation and the offer,~~ manufacture, sale, supply, storage, import, use and purchase of patented medicinal products or processes, including by third party suppliers and service providers.*

This exception shall not cover the placing on the market of the medicinal products resulting from such activities."

The European Parliament's Committee on Industry, Research and Energy (ITRE) has also provided their draft opinion on the proposed Directive. The short justification already mentions that to avoid the weakening of IP rights for pharmaceuticals, the Bolar exemption should be limited to activities solely related to obtaining marketing authorisation. The ITRE draft opinion provides for the following amended wording of the Bolar exemption under Article 85:

"Patent rights, or supplementary protection certificates under the […] *shall not be regarded as infringed when a ~~reference~~ medicinal product is used for the **exclusive** purposes of:*

- ***Necessary** studies **and** trials ~~and other activities~~ conducted to generate data for an application for **a marketing authorisation**.*
- *~~(i) a marketing authorisation of generic, biosimilar, hybrid or bio-hybrid medicinal products and for subsequent variations;~~*
- *~~(ii) health technology assessment as defined in Regulation (EU) 2021/2282;~~*
- *~~(iii) pricing and reimbursement.~~*[6]
- ***any necessary activity** ~~the activities conducted exclusively for the purposes~~ set out in point (a), **which** may **include the** ~~cover the submission of the application for a marketing authorisation and the offer~~, manufacture, sale, supply, storage, import, use and purchase of patented medicinal products or processes, including by third party suppliers and service providers.*

*This exception **shall cover the submission of the application for marketing authorisation. It** shall not cover the placing on the market of the medicinal products resulting from such activities."*

The discussed amendments raise concerns as both proposals, if implemented and pricing & reimbursement activities have to be done post patent expiry[7], may hinder the envisaged Day-1 availability of generic and biosimilar medicines in the EU market. The suggested amendments focus primarily on acts for obtaining innovative marketing authorizations and significantly limit the intended scope of the Bolar exemption as proposed by the EC.

On the other hand, for example, the Standing Committee of European Doctors (CPME) has published their position paper, where it has highlighted that obstacles preventing generic and biosimilar medicines from entering the market on Day-1 after the protection expires should be removed. Amendments proposed by the CPME aim to clarify the Bolar exemption for it to be implemented effectively – acts of filing for pricing and reimbursement, as well as conducting health technology assessment are retained. Furthermore, the proposal suggests deleting the problematic part of *"when a reference medicinal product is used"* in the preamble and incorporates both *"offering"* and additionally also *"export"* as falling under the activities in point (a), notably

without the optional use of the word *"may"* under point (b).

In any case, the proposed Directive does not provide the required clarification on the scope of activities covered, *e.g.*, the unclear limitation as to *"when a reference medicinal product is used"* in the preamble, the use of the optional word *"may"* under point (b) that can lead to diverging implementation by the Member States and the fact that the regulation makes reference to a medicinal product but omits any activity required to manufacture or supply the active ingredient.

Notably, quite unnoticed, the Bolar exemption has recently made its way to the proposed SPC regulations[2] for medicinal products, which poses additional concerns. As it was already discussed on this blog, the European Parliament's Legal Affairs Committee (JURI) has proposed several amendments to the proposed SPC regulations. However, one of the proposed amendments may not have been visible at first glance. Article 5, paragraph 2, point (a) of the SPC Regulation lists certain acts for which the SPC shall not confer protection, if the conditions for obtaining the so-called SPC manufacturing waiver are met. The JURI Draft report on the proposal for a regulation on the unitary SPC for medicinal products as well as the Draft report on the proposal for a regulation on the SPC for medicinal products (recast) have both incorporated the following amendment in Article 5:

2. *By way of derogation from paragraph 1, the certificate shall not confer protection against certain acts which would otherwise require the consent of the certificate holder, if all of the following conditions are met:*

- *the acts comprise any of the following:*

[…]

(iva) any act in accordance with Article 85 of Directive (EU) … [2023/0132 (COD)] [1]

The purpose of such an amendment and its potential impact are not clear. One worrying and conflicting interpretation may possibly be that, whereas the Bolar exemption applies automatically, the exception (or a 'restriction' in the words of the JURI draft report[8]) under the SPC manufacturing waiver requires an active notification of the party wishing to avail from it. Hence, any interpretation subjecting the acts available under the Bolar exemption to an active notification by the exempted party should be strictly avoided, as the acts covered by the Bolar exemption do not require (and have never required) any notification whatsoever. It is also important to highlight that, the acts available under the Bolar exemption equally apply under (any) patent or SPC protection and no difference shall be made between the type of right under which the acts are conducted. Hence, the same act shall be automatically exempted, irrespective whether it is being carried out under patent or SPC protection. Therefore, this proposed amendment seems to bring more uncertainties rather than any clarification at all.

An alternative interpretation could be that, when reading the SPC waiver in conjunction with the Bolar exemption, companies making use of this would be allowed to make use of both exemptions at same time, *i.e.*, manufacture the product in large quantities[9] under the Bolar exemption and use the SPC waiver for export or Day-1 launch. However, this seems to be in contradiction with the Bolar exemption where it is stated, that such amounts cannot be later commercially placed on the market. This last sentence of the Bolar exemption seems to be against the aim of minimizing any destruction of potential commercial products and lowering of the environmental impact.

It remains to be seen what the final wording of the proposed Directive and the Bolar exemption included therein will be, as well as the final scope of the proposed SPC regulations, where the substantive conditions are seemingly not aimed to be altered, but in effect there are much more than mere procedural changes being amended in these proposals and it is not clear that the intended broadening of the Bolar exemption will be actually achieved by the current proposal.

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[1] Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC (COM(2023) 192 final) 2023/0132(COD)

[2] Proposals for four regulations on SPCs for medicinal & plant protection products COM(2023)221, COM(2023)222, COM(2023)223, and COM(2023)231

[3] See footnote no. 1, page 17

[4] Noting that some Member States have, as of entry into force of the Agreement on a Unified Patent Court (UPCA), amended their national laws to reflect the substantive provisions in the UPCA, including Art. 27(d) UPCA applicable to both classical European patents and European patents with unitary effect, and merely referring back to Art. 10(6) of Directive 2001/83/EC and thereby possibly narrowing down the initially implemented scope of the Bolar provision under their respective national law.

[5] Study on the legal aspects of supplementary protection certificates in the EU – Final report, 2018 (page 634, point 24.3.5.2): *"The majority of the EU Member States provide for a Bolar exemption that is broader at least to some extent than the minimum standard laid down in Art. 10(6) Dir. 2001/83* […]*".*

[6] Although point (iii) is not explicitly noted in the ENVI draft opinion as being deleted, we understand this is a pure omission in the list of amendments, since the draft opinion includes a justification for the proposed amendments that "[…] *extending the Bolar exemption to cover commercial or pre-commercial actions at the national level, such as pricing and reimbursement applications, is unwarranted.*" and furthermore, the proposed amended wording of Art.85 ends with a full stop in point (a).

[7] The EC already stated in 2009, that applications for pricing & reimbursement status shall not constitute a patent violation, following the same logic as for marketing authorisations (Pharmaceutical Sector Inquiry – Final Report, 2009, point 1598)

[8] See Amendment 7 for recital 45 of the JURI Draft Report on the proposal for a regulation on the SPC for medicinal products (recast)

[9] See recital 63 of the proposed Directive: "[…] *even though this may require substantial amounts of test production* […]"

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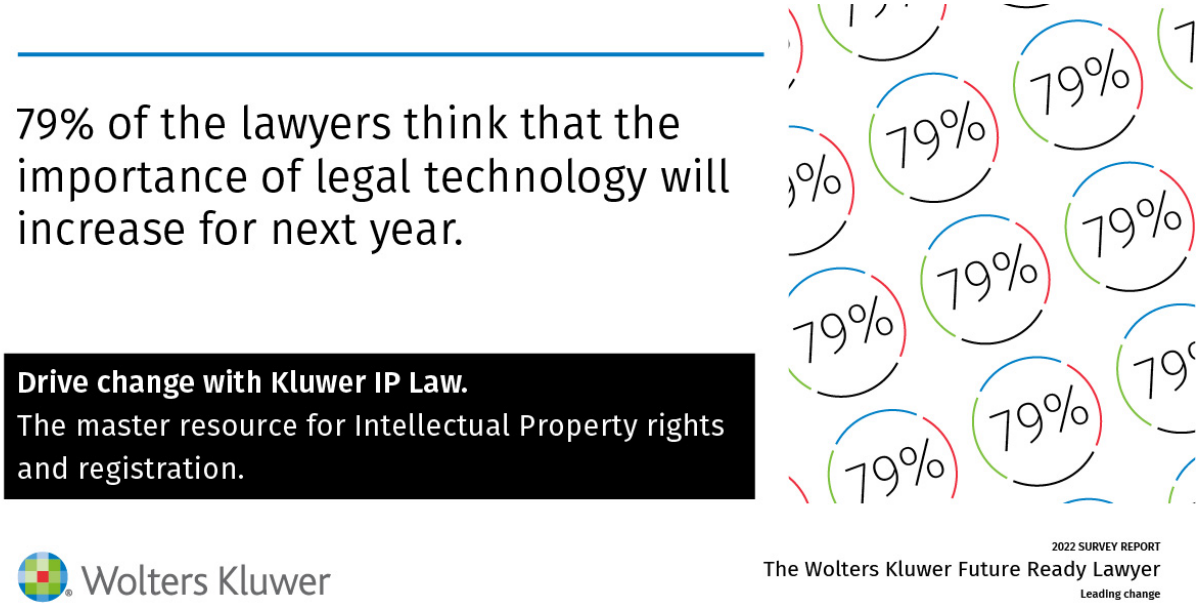

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