# Changes to the proposed new medicinal products Directive have been approved by the EU Parliament – do they shift the balance between generics and innovators and are they TRIPS compliant?

**Dr Stephen Garner**

Mathys & Squire LLP

SGarner@mathys-squire.com

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## I. INTRODUCTION

*In April 2023 the EU published draft legislation which, if enacted, would represent a major shift in the regulatory and IP framework for pharmaceutical products in Europe.[1] As well as establishing a unitary SPC (to complement the recently-introduced unitary patent), the proposed legislation alters the regulatory exclusivity periods available for innovative products, and changes the Bolar exemptions. Overall, the proposed legislation strongly favours the generics industry and undercut the rewards available to pharmaceutical innovators.*

*Recently, the EU Parliament has approved some significant changes to the provisions which deal with regulatory exclusivities and the Bolar exemption.[2,3] These changes reduce the negative impact of the legislation on the period of exclusivity, and they reduce the burden on innovators to obtain regulatory exclusivity. The changes do, however, significantly extend the scope of the safe harbour available to generics manufacturers under the Bolar exemption. It also raises a serious question of whether the proposed Bolar provisions are compliant with the EU's obligations under TRIPS.*

## II. CHANGES TO THE PROPOSED EU PHARMACEUTICAL LEGISLATION FOR MEDICINAL PRODUCTS

### Changes to Regulatory Protection Periods

The initial proposal for the new Directive would have reduced the duration of *data exclusivity* for innovative medicinal products from 8 years to 6 years, whilst retaining the additional 2 years of *market protection* as at present (to a total of 8 years of regulatory exclusivity, as compared to 10 years at present). However, to "encourage innovation" the initial proposal provided various options for extending the exclusivity period, with the longest of these being an extra +2 years of *data exclusivity* available to certain innovators if the medicinal product is launched in all 27 EU member states. This seemed like an onerous requirement to restore the level of regulatory exclusivity to that which is currently provided.

[1] The main changes are summarized by Creemer *et al.*, *Pharm Pat Anal* (2023) 12(6):249-252

[2] The initially proposed Directive is COM(2023)192, "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", published 26 April 2023.

[3] The adopted text of the amendments to the Directive has reference T9-0220/2024 and is dated 10 April 2024.

In the latest changes, the period of *data exclusivity* for innovative medicinal products is increased to 7.5 years from the date of grant of the MA, and there is no longer any exclusivity benefit from launching in all EU member states.[4,5] There are also additional periods of *data exclusivity* available for:

(i) products which address an "unmet medical need" (+12 months, up from 6 months in the earlier proposal)[6],
(ii) medicinal products containing a new active substance, where the clinical trials supporting the initial MA application use a relevant and evidence-based comparator (+6 months, the same as the earlier proposal),[7] and
(iii) research collaboration with public entities such as university hospitals (+6 months, newly added as compared to the earlier proposal)[8].

The total period of regulatory *data exclusivity* may not exceed 8.5 years,[9] which means that not all of the above extensions may be applied simultaneously.

In addition to the extra *data exclusivity* which is available, the amended Directive allows an additional +1 year of *market protection* to be obtained (*i.e.*, in addition to the 2 years which is already provided) where an additional therapeutic indication is authorised which provides a "significant clinical benefit" over existing therapies.[10] This extension may only be granted once.

Overall, the changes to the regulatory exclusivity periods in the proposed new Directive seem broadly in favour of pharmaceutical innovators – they largely restore the extent of regulatory protection and they remove what would have been very onerous requirements to obtain additional protection (for those entities who were eligible to apply for the longest extensions to the periods of data exclusivity). Seen in this light, the changes which have been approved by the EU Parliament may be seen as balancing what would otherwise have been a heavily generics-friendly shift in EU law.

It may be noted that the latest changes do not alter the situation as regards orphan medicinal products, which are handled under a proposed new medicinal products Regulation.[11] For orphan drugs, the standard period of *market exclusivity* is to be reduced from 10 years to 9 years, and the existing 2 years of additional exclusivity for completing pediatric studies is to be abolished. However, options for extending the period of exclusivity are available, where the product addresses a high unmet medical need (+1 year) and/or is launched in all 27 EU member states (+1 year). An additional +1 year is also available for each new MA obtained for a new orphan indication of the product (up to an extra +2 years). It remains to be seen whether any further changes are made to these proposals, *e.g.* whether the reward for launching in all EU states is removed (as it has been in the new Directive).

**Changes to the Bolar Exemption**

The Bolar exemption available under existing EU legislation provides a limited safe harbour against infringement of patent or SPC rights in connection with conducting "necessary studies and trials" for seeking authorisation of a generic

[4] Article 81(1) of the new Directive as amended (Amendment 199 of T9-0220/2024).
[5] Articles 81(2)(a) and 82 of the new Directive are deleted (Amendments 200 and 207 of T9-0220/2024).
[6] Article 81(2)(b) of the new Directive as amended (Amendment 201 of T9-0220/2024).
[7] Article 81(2)(c) of the new Directive (not amended).
[8] Article 81(2)(ca) of the new Directive (newly added by Amendment 202 of T9-0220/2024).
[9] Article 81(3)(a) of the new Directive (newly added in Amendment 206 of T9-0220/2024).
[10] Article 80(2)(a) of the new Directive (newly added in Amendment 196 of T9-0220/2024). Note that the initial version of the new Directive provided a +1 year extension to the period of *data exclusivity* in these same circumstances (former Article 81(2)(d) of the new Directive, as deleted by Amendment 203 of T9-0220/2024).
[11] COM(2023)193, dated 26 April 2023. See especially Articles 71 and 72.

medicinal product.[12] There are, however, significant differences in the implementation of the current Bolar exemption across Europe. The uncertainty caused by the different interpretations currently adopted by the national courts could be resolved through judicial harmonisation, *e.g.* through rulings by the UPC or the CJEU, rather than by further regulation. Nevertheless, the proposed new Directive, in its initial version, seeks to clarify and expand the scope of the exemption. Thus, the proposed Bolar exemption references "biosimilar, hybrid or bio-hybrid medicinal products" explicitly alongside "generic" products.[13] This appears to clarify that the exemption should not apply to innovative medicinal products. The initial proposal also provides security for Third Party entities that supply the MA applicant with a patented product for use in trials, or who carried out such trials on behalf of the MA applicant (at least within Europe).

In the latest amendments, the EU Parliament has approved some major changes to the proposed Bolar provisions which are weighted heavily in favour of the generics industry. In doing this, they have apparently rejected alternative amendments which would seek to address concerns from pharmaceutical innovators about the initial version of the new Directive. In an Opinion on the new Directive, published in November 2023, the EU Committee on Industry, Research and Energy sets out reasons why the new Bolar provisions as originally proposed could weaken IP protection across Europe and damage confidence in the European IP framework.[14] In particular, that Opinion recommends limiting the Bolar exemption to activities solely related to obtaining MAs.[15] It appears that those proposals were purposefully rejected in the version approved by the EU Parliament.

As amended, the proposed Bolar provision of the new Directive reads:[16]

*"Patent rights, or supplementary protection certificates… shall not be regarded as infringed when necessary studies, trials and other activities are conducted for the purpose of:*

- *(i) obtaining a marketing authorisation and subsequent variations;*
- *(ii) conducting a health technology assessment as defined in Regulation (EU) 2021/2282;*
- *(iii) obtaining pricing and reimbursement approval; and*
- *(iiia) the subsequent practical requirements associated with such activities.*

*The activities conducted exclusively for the purposes set out in the first paragraph, shall cover as relevant 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."*

References to biosimilar, hybrid and biohybrid products are removed from Article 85, thus potentially opening the exemption to innovative products which happen to fall within the scope of pending patents. This appears to be consistent with the amended Article 85 not mentioning a "reference medicinal product"

[12] Article 10(6) of Directive 2001/83/EC (in its current form).
[13] Article 85(a)(i) of the new Directive (newly added in Amendment 211 of T9-0220/2024).
[14] 2023/0132(COD): "DRAFT OPINION of the Committee on Industry, Research and Energy for the Committee on the Environment, Public Health and Food Safety on the 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)0192 – C9-0143/2023 – 2023/0132(COD))".
[15] 2023/0132(COD) at Amendments 13 and 14, and their corresponding "Justifications".
[16] Article 85 of the new Directive, as amended by Amendments 209-215 of T9-0220/2024.

which is a term used in the current legislation. This would also be consistent with an amendment made to one of the Recitals in the proposed new Directive which relates to the Bolar exemption, whereby the Recital no longer refers to *"the market entry of generics and biosimilars"* but instead to *"the timely market entry of medicinal products, in particular the market entry of generics and biosimilars"*.[17]

The proposed Bolar exemption does not adopt the amendment recommended by the EU Committee on Industry, Research and Energy, namely to state in the preamble that the product is used for the exclusive purpose of performing actions in pursuit of a MA. Whilst the second paragraph of the Bolar exemption characterizes what is covered by "activities conducted exclusively for the purposes set out in the first paragraph", it is not apparent that this statement necessarily limits the scope of the exemption to activities carried out exclusively for the aforementioned purposes. It is unclear, therefore, which other commercial activities might fall under the Bolar exemption. Given the concerns raised by the EU Committee on Industry, Research and Energy, it is perplexing that the amended Directive does not state in its preamble that the exempted activities must be conducted exclusively for the purposes set out in points (i) to (iiia) of paragraph 1, or otherwise make this point explicit in paragraph 2.

The proposed wording does clearly permit commercial, or at least pre-commercial, activities relating to *inter alia* manufacture, storage and offer for sale of patented products in the context of authorization and pricing approval. The final paragraph of the Bolar provision clarifies that the exemption *"shall not cover the placing on the market of the medicinal products resulting from such activities"* but it neither expressly forbids a party from offering to sell medicinal products during the term of a patent or SPC nor expressly prevents a party placing medicinal products on the market after patent or SPC expiry where those products have been made, stored and/or offered for sale during the lawful term of the patent or SPC.

All of the above observations indicate that the scope of the Bolar exemption will be significantly wider under the new Directive.

**Is the Bolar Exemption of the New Directive Compliant with TRIPS?**

The apparent breadth of the proposed new Bolar exemption, in particular as regards commercial or pre-commercial activities, raises a serious question of whether the EU will comply with its legal obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement") if it enacts the new Directive.

Article 30 of the TRIPS Agreement provides signatories with limited powers to implement an exception to the exclusive rights conferred by a patent, where such an exception *"do[es] not unreasonably conflict with a normal exploitation of the patent"*. The lawful extent of such an exception was addressed by the WTO panel in *Canada - Patent Protection of Pharmaceutical Products,* a complaint brought by the European Communities and their member states against proposed legislation from the Canadian government.[18] In that case, the WTO panel systematically reviewed the wording of Article 30 and the intention of the legislature, and held that a Bolar exemption which exempted acts carried out solely for the purpose of seeking regulatory authorisation would be permitted[19], but that the exemption of commercial acts would run contrary to Article 30. In particular, the WTO panel expressly disapproved of the notion that Article 30 would permit the exemption of commercial acts carried out in anticipation of a large-scale pharmaceutical product launch immediately after patent expiry, *e.g.* an act such as stockpiling.[20] The WTO panel held that a gradual process of market entry after patent

[17] Recital 64 of the new Directive (Amendment 47 of T9-0220/2024, emphasis added).
[18] See the decision of the panel in WT/DS114/R, 17 March 2000 ("*Canada v EC*").
[19] See *Canada v EC*, sections 7.45-7.50.
[20] See *Canada v EC*, sections 7.35-7.36.

expiry is part of the normal patent framework under TRIPS, and that a Bolar exemption cannot be used to flood the market with generic product immediately after patent expiry.

It is precisely such acts which the new Directive appears to endorse. Looking first to the Recitals of the new Directive, whilst Recital 63 states that *"[t]he 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"* and that *"there can be no commercial use of the resulting final medicinal products obtained for the purposes of the regulatory approval process"*, the indication in Recital 64 that the Bolar exemption *"will allow all necessary steps to support timely access to generic medicinal products, inter alia, to conduct studies to support pricing and reimbursement as well as the manufacture or purchase of patent protected active substances for the purpose of seeking marketing authorisations during that period"* calls into question how the term "commercial use" is being used. Indeed, Recital 64 goes on to state that the Directive will contribute to *"the timely market entry of medicinal products, in particular the market entry of generics and biosimilars on day one of loss of the patent or SPC protection"*.[21] In order to enter the market on "day one", a generic or biosimilar manufacturer must not only have completed all of the regulatory requirements, and sought agreement on pricing or completed offers for tender in at least some countries, but must also have manufactured and stockpiled the product ready to distribute and sell. These acts are clearly considered as being "commercial use" within the ruling of the WTO panel in *Canada v EC*.

Looking to the language of Article 85 of the new Directive, this may (as noted above) permit aspects of manufacture and storage of a medicinal product which is then placed on the market in large scale immediately on patent expiry. Such a situation is expressly identified in *Canada v EC* as failing to be compliant with Article 30 of the TRIPS Agreement. The new Directive goes further than this, however, and also permits tenders or offers for sale that may occur during the pricing and reimbursement approval process. Obtaining pricing and reimbursement approval at least represents an implicit offer to sell a medicinal product in many countries, and in some other countries it can involve an explicit offer to sell or even sale of the product. "Offering for sale" and "selling" are two fundamental patent rights protected under Article 28 of the TRIPS Agreement and the reasoning set out by the WTO panel in connection with stockpiling arguably applies equally to any commercial or pre-commercial offer for sale. As such, the exception under part (iii) of Article 85, and the recital of "offer" and "sale" in paragraph 2 of Article 85 (insofar as it relates to pricing and reimbursement approval), would also fail to be compliant with Article 30 of the TRIPS Agreement.

## III. SUMMARY

The initial version of the proposed new Directive significantly reduced the amount of data exclusivity available and set onerous requirements for innovators to extend the exclusivity period. In the latest changes, the EU Parliament has approved a version which relaxes those requirements and largely restores the amount of regulatory exclusivity which is available. In this respect, it dials back the heavily pro-generic stance which was apparent in the initial version.

The changes made to the proposed Bolar exemption, however, provide for a wider exclusion from infringement which appears to swing the pendulum back in favour of the generics industry. Not only are new products arguably within the scope of the safe harbour, but there is also a lack of clarity around which other activities, including commercial activities, would be permitted during the term of patent or SPC protection. In particular, the wording of the new Directive does not

[21] Recital 64 of the new Directive (Amendment 47 of T9-0220/2024 with emphasis added), noting that the definition of "day one of loss of patent or SPC protection" is undefined in the new Directive.

expressly forbid that products manufactured or stored under the Bolar exemption are placed on the market on "day one" after patent or SPC expiry. Furthermore, the extension of the safe harbour to activities conducted in the process of seeking pricing approval undercuts another commercial activity (offer for sale) which would otherwise be protected by a patent or SPC. Absent an EU-wide mechanism to adjudicate when any given medicinal product comes off-patent (*i.e.*, a mechanism to help promptly and finally determine "day one" before it occurs – thereby providing well-needed certainty not only to the pharmaceutical industry, but also to patients, stakeholders and the public at large), the proposed pricing and reimbursement exemption may encourage generics manufacturers to offer a product for sale at an early stage when patent or SPC protection is still pending – this would be contrary to the interests of rights holders, of member states and of patients. The proposed Bolar exemption may thus be unworkable and fail to achieve its intended aims.

Finally, the extent to which the Bolar exemption has been widened merits an investigation of its compliance with Article 30 of the TRIPS Agreement. The jurisprudence which the EU itself (in an earlier guise) helped to develop sets limits on the extent to which Bolar exemptions may be defined; those limits are arguably exceeded by the new Directive as regards both the potential for stockpiling and the proposed pricing and reimbursement exemption.

If the Bolar exemption is considered as a 'grand bargain' between innovators and generics, under which generics can perform studies necessary for regulatory approval in advance of patent expiry, and in exchange for which innovators are provided additional term of exclusivity (*e.g.* by way of SPC protection), then the proposed new Directive rewrites that bargain in favour of an earlier market entry of generics without offering any compensation for innovators. This is particularly problematic in a regulatory environment where there is no clear determination of "day one" before it occurs. Overall, therefore, while the balance has shifted, the new legislation still looks to represent an erosion of the protections currently afforded to the innovator pharmaceutical industry and it raises serious questions of non-compliance with the EU's international legal obligations.