Position Paper

Enlargement & Harmonisation of the Bolar Exemption

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Introduction

The "Bolar" exemption was introduced in the EU law in 2004 by Article 10(6) of Directive 2004/27 amending Directive 2001/83 on the Community code relating to medicinal products for human use. Under this rule, conducting studies and trials necessary to gain regulatory approval for generic medicinal products and the consequential practical requirements do not constitute acts infringing patent rights or supplementary protection certificates for medicinal products.

However, the Bolar exemption has been transposed in EU Member States in different ways. Some national legislations have given a broader interpretation of the Directive, some other a more restrictive one. As a result of this non-harmonised system and of the restrictive interpretation given by some Member States, a high level of uncertainty has been created with regard to the legality of certain actions. The generic and biosimilar medicines industries, as well as the originator and the Active Pharmaceutical Ingredients (API) ones have been directly affected by it, with a very negative impact on the latter, which has delocalized its activities outside Europe.

The entire pharmaceutical industry would benefit from a harmonised and broader Bolar provision that would bring more legal certainty and predictability.

Background

- There are differences among Member States on how they have implemented the Bolar exemption, with some Member States adopting a wider interpretation that covers all medicines, others adopting a narrower interpretation that covers generic and biosimilar medicines but not innovative medicines, and all with huge uncertainties about what specific actions can be conducted without infringing the patent. The different interpretations of the Directive have created significant uncertainties to European pharmaceutical companies over the last 16 years.
- In October 2015, the European Commission 'Single Market Strategy for Europe' identified the enlargement & harmonisation of the Bolar as a priority. The proposals aimed at clarifying the scope of the Bolar and harmonising it among the different EU Member States. As stated in the EC Strategy, on one side, some Member States do not allow the supply of active pharmaceutical ingredients (APIs) to EU generic manufacturers based in Europe for the purpose of seeking marketing authorisation. On the other side, in a number of Member States, it is not certain whether testing in the EU by originators and biosimilars can benefit from this exemption for the purpose of seeking marketing authorisation in the EU and/or in non-EU countries, or for facing emerging regulatory requirements (*i.e.* such as those related to health technology assessment

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or other administrative preparatory steps, like validation batches, escalation, etc., which are necessary to be done in advance of the launch of the product immediately after expiry of IP).

- In February 2016, the European Commission published a study conducted by Charles River Associate where it was clearly demonstrated how the harmonisation of the Bolar would have been beneficial for the entire pharmaceutical sector.
- In 2017, the EC Roadmap to optimise the IP legal framework also explored the reform of the Bolar and its benefits.
- In May 2018, the European Commission published a Max Planck Institute study where the results of a survey conducted among the Member States were published and the vast majority of them would be in favour of harmonising and enlarging the Bolar clause.
- The pharmaceutical strategy published in November 2020 includes Bolar among the priorities.

State of Play

- Even if in the last years the European Commission expressed several times the intention to harmonise the Bolar exemption, and despite supported by a number of studies, the legislative process has never been taken forward.
- The situation today is still characterised by a general uncertainty concerning the lawfulness of offering, manufacturing, selling and even buying patented APIs for regulatory or R&D purposes as well as all the actions needed to actually launch the product. This situation affects equally generic/biosimilars developers and API suppliers (*i.e.* third parties).
- To avoid any risks, API suppliers tend to offer, manufacture and sell patented APIs from affiliates located in countries where no patent exists (incl. outside Europe). This implies loss of EU revenues and unnecessary extra costs in terms of transportation, custom clearance, etc.
- Certain Members States have been modifying their national legislation to enlarge, to some extent, the Bolar in their territory. However, this only amplifies the differences among Member States and is not in line with the strengthening of a unified European single market strategy.

A broader and harmonised Bolar

- Since the primary objective of the Bolar is to "*ensure that a generic could enter the market as soon as possible after the expiry of patent/SPC protection […] based on the basic rationale that free competition should be allowed as soon as protection expires*" (European Commission Impact Assessment on the SPC manufacturing waiver, p. 15), the broad and harmonised Bolar exemption should cover, *inter alia*:
    - the conduct of the necessary studies and trials by all partners for the purpose of seeking marketing authorisation in the EU, independently from who the final applicant/MA holder is and where the medicinal product will be authorized (EU/ non-EU territory);
    - the offer, manufacture, sale (incl. by third party API suppliers) and purchase of patented APIs for the purpose of seeking marketing authorisation and for R&D purposes;
    - the subsequent administrative actions needed to effectively enter the market on day-1 after IP expiry (*i.e.* Marketing Authorisations, P&R listing, tender bids, etc.)

Conclusions

- Medicines for Europe calls for a rapid introduction of a broader Bolar clause and at the same time harmonisation of its application in EU Member States, as a follow-up to all the studies and policy priorities highlighted over the past years. This is in line with the objectives of the SPC manufacturing waiver, introduced in 2019, to allow generic and biosimilar medicines developers to produce their products in order to market them as soon as IP and other protections expire.

- A broad and harmonised Bolar clause would:
    - Facilitate a more equitable distribution of API investments among MS
    - stimulate investments in R&D and manufacturing of API in Europe;
    - increase stability and predictability of generic, biosimilar and value added medicines' development as well as development of new originator products when comparison with on-patent product is necessary;
    - rationalise strategic manufacturing and business planning for European companies;
    - provide a wider choice of API suppliers for European companies;
    - trigger increase in volume of supply from European API suppliers;
    - reduce legal uncertainty and legal costs for companies thanks to less differentiated legal advice.