Time for an EU action on equal access: No more delays for patients!

HIV medicines denied to patients

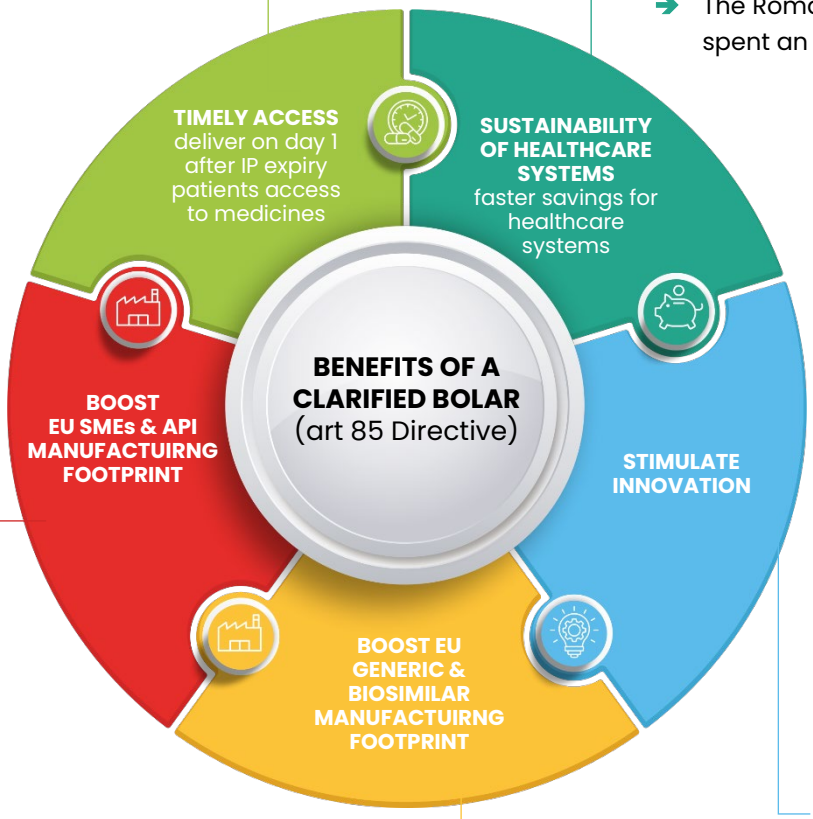
Truvada (Emtricitabine/Tenofovir) a *Critical medicine for HIV prevention & treatment (reduce HIV transmission by 90%) was refused to patients* **due to an invalid SPC (patent extension).**

- In Portugal alone, a 1 year delay of the generic impacted treatment for **95.000 patients**, implying a **loss of €109M** in savings (equivalent to 1.1% of 2018 health budget)

Cancer treatment

for chronic lymphocytic leukemia, breast cancer, ovarian cancer, kidney cancer**, delayed in Eastern Europe**

- In 2019, in Romania biosimilar medicines were unlawfully blocked from participating in a tender for Trastuzumab and Rituximab
- The Romanian healthcare system spent an additional **$100million!**



- **By reducing legal uncertainty** that drove investments on API out of Europe

- By **reducing illegal artificial delays** due to legal uncertainty and avoid delocalization especially of biosimilar production where Europe is innovation leaders.
- **EU need to keep biosimilar production in Europe**. When competition is delayed, also the stimulus to innovation is delayed!

- **By keeping IP protection untouched**
- By facilitating R&D on the API and through healthy and timely competition.

When competition is delayed, also the stimulus to innovation is delayed!

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Myths to be dispelled on article 85 of the Pharma Directive, so called "Bolar"

Why do we need a clarified/clear Bolar Clause?

- The Bolar patent exemption is essential to allow generic/biosimilar manufacturers to conduct all the necessary activities to obtain regulatory/administrative pre-launch approvals for day-1 launch after patent expiry. Without the bolar patent exemption, generic and biosimilar medicines would be delayed for several years after patent expiry with lost savings for healthcare budgets and reduced access to medicines for patients.
- The 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.*" (EC Impact Assessment on SPC Manufacturing Waiver Regulation, page 15)

Does the Bolar erode patent rights?

- No. The exemption does not affect the commercial monopoly of patent right holders. It only allows generic and biosimilar medicine manufacturers to prepare all necessary steps to launch their medicine after IP expires, ie. when competition is supposed to take place.
- In fact, the Commission has long considered delays to generic medicine launches as "*unlawful*". *According to* the 2009 EC Pharmaceutical Sector Enquiry, the artificial delay of off-patent medicines through patent linkage (the link between generic/biosimilar regulatory and administrative approvals and IP protections) should be considered an illegal anticompetitive act. Therefore, the bolar should ensure that all procedures for day-1 launch activities are clearly covered by the Bolar exemption.
- As the European Commission clarifies in the Sector Inquiry Report of 2009:

  "*[s]uspending the price approval procedure for any other reason than the ones indicated in the Transparency Directive is considered as a breach of the Directive*" and "*[u]nder EU law, patent protection is not a criterion to be considered by the authorities when approving prices or granting reimbursement status.*" Therefore, "*Member States should disregard third party submissions raising patent, bioequivalence or safety issues*".

More information can be found: Why Clarification & Harmonisation of the Bolar Exemption and an Explicit Prohibition of Patent Linkage Is Needed in the European Union"

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Why is the Bolar applied differently across Member States?

- In the current Pharmaceutical Directive (art 10(6) – art 85 in the new proposal, the bolar exemption is subject to different interpretations across EU Member States. Some cover a wide range of activities and enable day-1 launch. Others offer a more restrictive interpretation.
- The revision of the pharmaceutical legislation is the once-in-a-generation opportunity to solve this long-standing fragmentation to ensure more access to medicines by allowing timely (day 1 after IP expiry) generic and biosimilar market entry and generate savings that would significantly improve sustainability of all national healthcare systems.

Has there been an assessment of a clarified Bolar exemption?

- Yes! The revised Bolar was a priority already in the EC 2015 Single Market Strategy and assessed in the 2016 EC published Charles River Associate study, in the 2017 EC Roadmap to optimise the IP legal framework and in the EC published Max Planck Institute Study of 2018.
- It was also a priority in the EC Pharmaceutical Strategy for Europe and in the 2021 EC "IP Action Plan".
- Moreover, the EC tried to formally ban 'patent linkage' in the 2012 Revised Transparency Directive, and its formal ban was requested in the 2017 EP Resolutions on Access to Medicines, the 2021 EP Resolution on the Pharmaceutical Strategy, and the 2021 EP Report on the IP Action Plan. Recently, the EP Studies on Access to Medicines and on the Unitary SPC referred to the "*prohibited practice of patent linkage*".

Do some MS interpret the current Bolar to include P&R activities before IP expiry/for day-1 launch and does this increase launch at risk?

- Yes! The countries include Denmark, Czech Republic, Slovakia, Spain, Sweden, Belgium, etc[1].
- In these countries, generic medicines can enter the market on day 1 after IP expiry and there is no evidence of launch at risk (generic medicines being commercialised before the expiry of the patent or SPC).
- The explicit inclusion of P&R and tender bids in the Bolar aims to remove an illegal practice of patent linkage that exists in countries such as France, Germany, Italy, Poland, Hungary, Portugal? etc.

Are there risks of generic or biosimilar launch before IP expiry?

- No! This could potentially also happen today in the EU Member States where P&R is allowed before IP expiry, or from foreign producers that have a competitive advantage due to less limiting Bolar exemptions than in Europe. However, this is not the case.

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- P&R procedures and decisions are allowed before patent expiry in Denmark, Czech Republic, Slovakia, Spain, Sweden, Belgium, etc. Generics/biosimilars can be launched on day-1 after IP expiry and there is NO illicit earlier launch, showing that there is NO need for anticompetitive safeguards that would only be a further tool to delay generic entry and go clearly against the Bolar's objective, which is to eliminate patent linkage.

Are there consequences if a company launches its product before IP expiry at risk?

- Yes! The EC Enforcement Directive (2004/48/EC) allows to immediately block the launch of generic/biosimilars before IP expiry.
- Moreover, it foresees, together with national laws, compensation for damages caused by a pre-expiry launch. The compensation is calculated based on the difference in price between the originator and the generic. The damages for pre-expiry launch definitely outweigh the benefits. Therefore, generic companies do not launch "at risk" if they believe the patent is valid.
- In contrast, generic manufacturers cannot receive damages if their launch has been unduly delayed by an invalid patent or a related strategy. There is therefore a clear financial incentive for originator companies to use bogus patent linkage strategies to delay generic and biosimilar competition.

Are the Bolar exemption and 'patent linkage' two separate issues?

- Yes! The Bolar covers a wide range of procedures to enable generic and biosimilar competition on day-1.
- No! 'Patent linkage' is "*the practice of linking the granting of [marketing authorisations], pricing and reimbursement status or any regulatory approval for a generic medicinal product, to the status of a patent (applications) for the originator reference product*". It is "unlawful" under EU law, despite existing in several Member States. (EC Sector Inquiry Report)
- By including explicitly such regulatory and administrative activities under the Bolar exemption, the EU would stop the illegal practice of patent linkage.

Would the inclusion of P&R and tender bids in the Bolar interfere with national competences?

- No! Such inclusion would not interfere with the competence of Member States to take their own decisions on P&R or tenders. It would just clarify that Member States would be free to take their decisions without the fear or threat of being sued by originator companies.

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- There is even a P&R Transparency Directive (89/105/EEC) regulating timelines for P&R decisions. Clarifying in the Bolar that participating to P&R and tenders is not IP infringement does not interfere with national competences.
- If such clarification were considered interfering with national competences, then also any EU IP legislation (IP law is national) would interfere with national competences, such as the SPC Regulation, the Unitary SPC Regulation, the Enforcement Directive, etc.

Are there any negative impacts on the originator industry with a clarified Bolar?

- No! Originators would continue enjoying their patent monopoly until IP protection expires.
- Bolar will only prevent unlawful artificial extensions of monopolies beyond the expiry of the IP, which are anticompetitive and reduce the stimulus to continue innovating.

Do originator companies need to block P&R procedures to prevent infringement of IP?

- No! Originators are NOT supposed to block P&R procedures. This is exactly what is "unlawful" in Europe, since it has anti-competitive effects, as stressed by the EC and competition authorities.
- The EC Sector Inquiry Report of 2009 and several European Parliament resolutions have requested to ban this patent linkage.
- According to EU law, it is illegal to block P&R or tender procedures because of IP status. This is why the European Commission is proposing to include P&R procedures under Bolar. This is why it should also include tender bids before IP expiry (for supply after IP expiry).

Would the gen/bios participation to tenders before IP expiry (but for supply *after* IP expiry!) have a negative impact on originators during IP protection?

- No! Originators would still enjoy their monopoly until the end of their IP protection period with their higher prices. Only after IP expiry, when the supply starts according to the tender, the originator would face competition. Any tender delays and subsequent artificial extension of the monopoly beyond IP expiry is anticompetitive.
- For this reason, the EC states in the 2009 Sector Inquiry Report that "***when loss of exclusivity approaches, tenders should be timed in such a way that generic companies can effectively participate.***" **(p. 499).**

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