NOTE

The costs of proposals to introduce anti-competitive patent linkage in the Bolar Exemption

16.04.2025

Medicines for Europe is aware that the originator industry is proposing not only to extend the EU pharmaceutical regulatory protections (which are already the longest in the world), but also to block the harmonisation and clarification of the Bolar Exemption (Article 85 of the proposed Directive on Human Use Medicines).

Not only will this NOT stop originator pharmaceutical companies from transferring their R&D to the US, as several have already announced, but will also continue to allow the current misuses of the patent system to delay competition and affect patient access and public health budgets, which already struggle to finance the reimbursement of expensive drugs.

The note provides some important facts and new data for consideration to keep supporting the Hungarian compromise that the Council reached in December 2024. This includes the possibility to conduct administrative and regulatory activities (listed in the paragraph 1.a) required for a generic and biosimilar medicine are possible under the Bolar clause (obtaining a market authorisation, obtaining P&R decisions and tenders). Any change to this text would make the bolar clause unworkable.

Bolar Exemption: essential for competition and competitiveness of the EU manufacturing industry

The **Bolar exemption** was enacted to allow the development and approvals of generics and biosimilars for immediate competition at IP expiry. Multiple studies[1] (including Commission studies) show that the long-standing lack of harmonisation of the Bolar has been causing:

(1) **disinvestments in Active Pharmaceutical Ingredients (API)** development in Europe and

(2) patent linkage practices, considered anticompetitive by the European Commission[2] as they unduly **delay generic and biosimilar competition.**

This is **well documented by national competition authorities and courts**,[3] and confirmed by the fact that the Commission already tried to block these abuses in 2012 and ban patent linkage. These misuses of the patent and regulatory system create severe delays for patient access to medicines and massive costs for healthcare budgets, as shown in the multiple examples here.

The Hungarian Bolar blocks anticompetitive practices that cost billions to EU healthcare systems

Clarifying and harmonising the Bolar exemption has the stated objective to effectively allow immediate competition after patent expiry by allowing all regulatory/pricing and reimbursement activities during the protection. By blocking or watering down the proposed Bolar exemption and the related amendments applied by Parliament and Council, the EU and Member States would provide a **free ride to continue delaying competition** and blocking the needed savings for healthcare systems.

As shown in the Table below, the value of the products for which delaying strategies are applied is enormous and even a few days of artificial delays have a **very direct impact on healthcare sustainability**:

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[1] Links to independent studies, European Parliament reports, etc. can be found in this position paper.

[2] European Commission's Sector Inquiry Report, 2009

[3] See the decisions in the 2025 IGBA Report "Gaming the System" and in this position paper.

The global daily revenue losses at patent expiry

Drug	Company	2023 Sales	FDA Approval	US Patent Expiry	Daily Revenue Loss
Keytruda	Merck & Co.	$25.01 Bn	2014	2028	$54.81 Mn
Semaglutide	Novo Nordisk	$18.44 Bn	2017	2032	$40.41 Mn
Humira	AbbVie	$14.40 Bn	2002	2023	$31.56 Mn
Eliquis	Bristol Myers Squibb, Pfizer	$12.21 Bn	2012	2026	$26.76 Mn
Biktarvy	Gilead	$11.85 Bn	2018	2033	$25.97 Mn
Dupixent	Sanofi, Regeneron	$11.59 Bn	2017	2031	$25.40 Mn
Stelara	J&J	$10.86 Bn	2009	2023	$23.80 Mn
Darzalex	J&J	$9.74 Bn	2015	2029	$21.34 Mn
Eylea	Regeneron	$9.38 Bn	2011	2023	$20.56 Mn
Opdivo	Bristol Myers Squibb	$9.01 Bn	2014	2028	$19.75 Mn
Trikafta	Vertex	$8.95 Bn	2019	2037	$19.62 Mn
Gardasil 9	Merck & Co.	$8.90 Bn	2014	2028	$19.51 Mn
Skyrizi	AbbVie	$7.76 Bn	2019	2033	$17.01 Mn
Trulicity	Eli Lilly	$7.13 Bn	2014	2027	$15.63 Mn
Ocrevus	Roche	$7.10 Bn	2017	2027	$15.56 Mn
Xarelto	J&J, Bayer	$6.78 Bn	2011	2025	$14.86 Mn
Prevnar	Pfizer	$6.44 Bn	2010	2033	$14.12 Mn
Xtandi	Astellas, Pfizer	$6.26 Bn	2012	2027	$13.72 Mn
Revlimid	Bristol Myers Squibb	$6.10 Bn	2005	2022	$13.37 Mn
Entresto	Novartis	$6.04 Bn	2015	2025	$13.24 Mn
Farxiga	AstraZeneca	$6.00 Bn	2014	2025	$13.15 Mn
Tagrisso	AstraZeneca	$5.80 Bn	2015	2032	$12.71 Mn
Entyvio	Takeda	$5.51 Bn	2014	2032	$12.08 Mn
Tirzeptide	Eli Lilly	$5.34 Bn	2022	2036	$11.70 Mn
Cosentyx	Novartis	$4.98 Bn	2015	2029	$10.92 Mn
Imbruvica	AbbVie, J&J	$4.88 Bn	2014	2027	$10.70 Mn
Ibrance	Pfizer	$4.75 Bn	2015	2027	$10.41 Mn
Prolia	Amgen	$4.05 Bn	2010	2025	$8.88 Mn
Rinvoq	AbbVie	$3.97 Bn	2019	2033	$8.70 Mn
Enbrel	Amgen	$3.70 Bn	1998	2029	$8.11 Mn

A 2024 independent study **shows that, between 1995 and 2020, 91% of oncology products recouped R&D investments in 8 years.** Any artificial delays of generic and biosimilar medicines beyond the 15 years of effective monopoly enjoyed in the EU is **unjustifiable** and **detrimental for patients**, **competition**, **healthcare budgets** and the **competitiveness** of the EU manufacturing industry.

Should the EU lag behind internationally and undermine Member States healthcare sustainability to protect artificial monopoly extensions?

While the EU is negotiating the pharmaceutical legislation reform, the **United States are very active** to

(1) lower medicines prices[4] and

(2) block anticompetitive practices[5] that delay generic and biosimilar competition.

Without the needed Bolar reform, the EU would go exactly in the opposite direction against its own interests.

New attempt to introduce unlawful patent linkage in Bolar that would cost the EU billions

Attempts are being made to introduce notifications and a patent linkage system (similar to the one in the US) into the Bolar in order to create systemic litigation and blocking phantom 'early launch' of generic and biosimilar medicines. This is exactly what the US is investigating to block anticompetitive practices.

Not only did the originators fail to justify the need for such anticompetitive proposal,[6] but a 2023 Yale University Study shows that

> "***91% of drugs*** *that obtain patent term extensions* ***continue their monopolies well past the expiration of those extensions****, most often by relying on secondary patents …* ***costing the system*** *a conservatively estimated* ***$53.6 billion****".*

A US-like notification and patent linkage system would have equivalent effects in Europe and this is exactly why patent linkage is anticompetitive and "unlawful" in Europe.

The EU and its Member States should **defend the harmonization and clarification of the Bolar** exemption in the interest of timely competition and patient access, security of supply, sustainable healthcare systems and the competitiveness of the EU manufacturing industry.

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[4] 15 April 2025 Executive Order: https://www.whitehouse.gov/presidential-actions/2025/04/lowering-drug-prices-by-once-again-putting-americans-first/

[5] 9 April 2025 Executive Order: https://www.whitehouse.gov/presidential-actions/2025/04/reducing-anti-competitive-regulatory-barriers/

[6] This proposal had been already made in the Parliament without success.