Why Clarification & Harmonisation of the Bolar Exemption and an Explicit Prohibition of Patent Linkage Is Needed in the European Union

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Executive Summary

The revised Pharmaceutical Legislation must deliver more access to medicines, fair competition and prevent artificial extensions of monopolies beyond what the EU system foresees.

In order to effectively allow timely access to generic and biosimilar medicines for patients and achieve the stated objectives of the 'Bolar exemption' (*ie*. early generic/biosimilar development and approvals for immediate competition after Intellectual Property expiry), it is pivotal to ensure that the final revised **Bolar leave no room for diverging interpretations in different Member States and provide clear, unequivocable provisions removing any grey area or legal uncertainty that may allow the use of 'patent linkage' to delay competition**.[1]

Since the primary objective of the Bolar is to ensure immediate generic/biosimilar competition at IP expiry, **if a generic medicine manufacturer cannot participate in necessary procedures that ensure such free and timely competition upon IP expiry, the primary objective of Bolar is frustrated, creating a distortion of competition**.

In addition to clarifying in the Bolar exemption that all regulatory and administrative acts are exempted from patent infringement, it is fundamental that the revised Directive also **include a formal prohibition of 'patent linkage'**, in line with the one proposed by the European Commission in 2012 in the proposal for a revised Transparency Directive.[2]

Recommendations

- Medicines for Europe supports a broad, harmonised and clear Bolar exemption for regulatory and administrative activities undertaken by generics, biosimilars, originators and third parties to enable effective access to these medicines in the EU on day 1 after IP expiry. This can only be achieved by explicitly and clearly including in the scope of the Bolar features already permitted by some EU Member States:
    - the conduct of studies, trials and other activities by all partners for the purpose of seeking marketing authorisations and subsequent variations, independently from who

[1] "*Patent linkage refers to 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 described (p. 130) and defined "*unlawful*" in Europe (p. 315), in the European Commission Sector Inquiry Report of 2009.

[2] Proposal for a Directive of the European Parliament and of the Council relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems

the final applicant/Marketing Authorisation holder is and where the medicine will be authorized (EU/ non-EU)

- all types of activity necessary for those purposes, *e.g.* offer, manufacture, supply, storage, import, export, use, sale and purchase, including by third party API suppliers

- the related activities needed to effectively enter the market on day 1 after expiry of the relevant patent or Supplementary Protection Certificates (SPC), *e.g.*, pricing & reimbursement (P&R) approval and listing, health technology assessments, tender bids for supply after IP expiry, and the conduct of any studies and trials to generate data in support of these activities.

- Medicines for Europe supports the long-standing objective to block artificial delays to patient access to generic and biosimilar medicines by formally prohibiting the unlawful practice of 'patent linkage' in relation to marketing authorisations, pricing and reimbursement (P&R) and tender bids.

- IP enforcement is not prevented by having a broad and clear Bolar exemption and an explicit ban on 'patent linkage'. These measures do not impact in any way the core rights of patent and SPC holders and do not preclude them from seeking preliminary injunctions where infringement of valid IP rights is feared, as they currently do against virtually every allegedly infringing launch of a generic or biosimilar product in Europe.

1. Background

The "Bolar" exemption was introduced in 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 the Bolar, conducting studies necessary to gain regulatory approval for generic and biosimilar medicines and the consequential practical requirements do not constitute acts that infringe patent rights or supplementary protection certificates.

The stated primary objective of the Bolar exemption 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."***[3]

The Bolar exemption provides a key legal framework for investment in development of active pharmaceutical ingredients (APIs) and generic and biosimilar medicines in the EU.[4]

[3] Impact Assessment accompanying the document Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products, p.15.
[4] Commission Staff Working Document, Evaluation of the Regulation (EC) No 469/2009 of the European Parliament and of the Council concerning the supplementary protection certificate for medicinal products; and Regulation (EC) No 1610/96 of the European Parliament and of the Council concerning the creation of a supplementary protection certificate for plant protection products, p.63.

Today, Bolar allows generic and biosimilar companies to obtain a marketing authorization and carry out activities for the purpose of consequential practical requirements during the protection period, but EU Member States have transposed the Bolar exemption into national law inconsistently[5] and/or interpret Bolar in different ways,[6] leading to

1. **legal uncertainty** as to whether the acts of third parties, which are involved in the development of generics, biosimilars and APIs, are covered by Bolar, contributing to investments on API development outside of Europe.

2. **its restrictive interpretation in certain Member States**, which blocks access for generics and biosimilars to administrative procedures (pricing and reimbursement, tender bids, etc.) **effectively creating 'patent linkage' (defined "unlawful" in Europe by the European Commission)[7]** that delays generic/biosimilar market entry with huge economic consequences for healthcare budgets and patient access to medicines.

Such legal uncertainty and 'patent linkage' is what the European Commission intends to remove by clarifying and harmonising the scope of the Bolar exemption in the revised EU directive in the context of the current reform of the EU pharmaceutical legislation.[8] Although the intentions of the Commission's proposal (as described in recitals 63, 64, 65) go in the right direction, the legal text proposed (art 85) may end up causing further inadvertent legal uncertainty.

In order to effectively achieve the objectives of the Bolar exemption, it is pivotal to ensure that the final revised Bolar leave no room for diverging interpretations in different Member States and provide **clear, unequivocable provisions by removing any grey area or legal uncertainty and prohibiting any actual or implicit form of 'patent linkage' which would delay competition**.

A clarification of the Bolar exemption is warranted for two reasons. The uncertainty of whether the above activities are within the scope of the Bolar exemption negatively impacts both originators and generic medicine manufacturers.[9] Second, a narrow interpretation of the Bolar exemption that does not explicitly include studies and trials to support pricing & reimbursement applications and

[5] Van Gend en Loos v Nederlandse Tariefcommissie (case 26/62) (1993) ECR 1.
[6] Annex I of this study provides a comprehensive overview of the features included in the different Bolar provisions of the EU Member States.
[7] "*Patent linkage refers to 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 described (p. 130) and defined "unlawful" in Europe (p. 315), in the European Commission Sector Inquiry Report of 2009.
[8] https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en.
[9] UK IPO, (2011) "The research and Bolar exemptions: an informal consultation on patent infringement in pharmaceutical clinical and field trials". Respondents to the initial consultation included: the Association of the British Pharmaceutical Industry (ABPI), BioIndustry Association (BIA), Bird & Bird, Boehringer-Ingelheim, Cancer Research UK, Chartered Institute of Patent Attorneys (CIPA), CRO personnel, Eli Lilly, EGA, IP Federation, Interpat, Japan Intellectual Property Association (JIPA), Japan Pharmaceutical Manufacturers Association (JPMA), Johnson & Johnson, Merck, Novartis. Respondents to the final consultation included: the ABPI, BIA, the British Generic Manufacturers Association (BGMA), CIPA, Eli Lilly, Ethical Medicines Industry Group (EMIG), Fujifilm Diosynth Biotechnologies, GlaxoSmithKline, Intellectual Property Lawyers Association (IPLA), IP Federation, ISIS (University of Oxford Technology Transfer Company), JIPA, Licensing Executives Society (LES), Patent Judges, Pharmaceutical Life Cycle Management Solutions, Polpharma, PraxisUnico, personnel at pharmaceutical company, Wellcome Trust, Welsh Assembly Government.; European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Fischer, R., Débarbat, G., Koustoumpardi, E., et al., Assessing the economic impacts of changing exemption provisions during patent and SPC protection in Europe, Publications Office, 2017, https://data.europa.eu/doi/10.2873/673124.

processes or tender participation (for supply after IP expiry) opens the door to the introduction of unlawful 'patent linkage' at the Member State level and unduly delays competition.

A clarification of the Bolar exemption along these lines would remove legal uncertainty - rather than create it, as maintained by a minority of stakeholders - and would ensure that generic and biosimilar medicines could effectively enter the market the day after the relevant patent or SPC for the originator product expires, for the benefit of patients, healthcare budgets and healthy competition.

The unlawful linkage between patents (private rights) and regulatory and administrative decisions (public decisions) does not exist in some EU Member States, where today P&R decisions can be negotiated or obtained before the relevant patents expire, such as Denmark, Czeck Republic, Slovakia, Spain, Sweden, Belgium, etc. In these countries, generic medicines can obtain all authorizations in advance and enter the market the day after protections expire, without illicit earlier launch - as surprisingly feared by a minority of stakeholders -, showing that there is no need in the revised Bolar for any unnecessary safeguard that would only formally create - rather than eliminate - 'patent linkage' and be a further tool to delay generic entry going clearly against the Bolar's objectives.

Should the revised Bolar not explicitly include the conduct of studies and trials to generate data to support P&R decisions, it becomes possible for Member States to formally introduce (or maintain) the unlawful 'patent linkage' that the new Bolar is actually trying to eliminate; and the launch of generic and biosimilar medicines would then be delayed.

It is therefore fundamental that the revised Directive also include a **formal prohibition of 'patent linkage'**, in line with the one proposed by the European Commission in 2012 in the proposal for a revised Transparency Directive.[10]

Annex I - List of activities covered by EU national Bolar exemptions
Annex II - List of some examples of patent linkage as reported by Medicines for Europe Members

2. The main elements of a clarified Bolar exemption

Conducting studies for marketing authorisations to be sought in any country (EU and non-EU)

While currently all EU Member States allow for studies to be conducted for the purpose of obtaining an EU marketing authorisation, eight specific Member States do not allow studies to be conducted in the EU for the purpose of obtaining marketing authorisations outside of the European Union.[11]

Restricting the scope of the Bolar exemption to studies conducted for the purpose of obtaining marketing authorisations inside the EU severely limits the economic potential of the EU as a research and development powerhouse. Besides potentially limiting investments into medicinal development

[10] Proposal for a Directive of the European Parliament and of the Council relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems.
[11] Annex I of this study provides a comprehensive overview of the features included in the different Bolar provisions of the EU Member States.

in Europe, this prevents non-EU countries from tapping into the clinical trial expertise and knowledge that exists in the EU pharmaceutical market.

How a clarified Bolar would help:

Explicitly including within Bolar studies and other activities conducted for the purpose of obtaining marketing authorisations outside the EU will further stimulate the manufacturing industry in Europe and disseminate the EU's excellent clinical trial expertise for use outside of its borders.[12] This is also in line with the newly adopted Supplementary Protection Certificate (SPC) manufacturing waiver, which envisages manufacture in the EU during SPC term for export to non-EU countries.[13]

A clarified Bolar exemption also exempting from patent infringement studies conducted for obtaining marketing authorisations outside of the EU will increase the number of countries from which patients can be recruited to support marketing authorisations in any country.[14] It is likely to reduce the need to run additional bioequivalence studies to support marketing authorisations in non-EU countries.[15] Professor Correa, for example, has advanced that "*the broader the formulation of the exception in terms of covered products, sources of samples, type of studies allowed, time to undertake them, and geographical scope, the more competitive the environment is that will benefit consumers, health providers and other public agencies*."[16]

Explicitly Allow API Supply by Third Parties

Four out of twenty-seven Member States clarified their national implementation of the Bolar exemption to explicitly exempt from patent infringement a third-party manufacturer supply of a patent-protected API to a generic company for use in studies for the purpose of obtaining regulatory approvals. The remaining twenty-three Member States did not and there has been no or limited case law providing guidance as to whether this is permitted or not.

The fact that a number of EU Member States do not explicitly deem third party API supply to be exempted from patent infringement, places these Member States at a commercial disadvantage, since it is not clear whether their local API manufacturers currently can manufacture API under the Bolar exemption. Further, API manufacturers in EU Member States which explicitly permit their activities under Bolar are unsure whether they can deliver APIs to generic companies based in EU Member States which do not. The same considerations also apply to other third parties involved in

[13] Regulation (EC) No. 469/2009. SPCs offer an extension of up to five years of the market exclusivity linked to a molecule patent. The SPC manufacturing waiver allows, among other things, generic and biosimilar manufacturers to manufacture commercial batches during the SPC protection period in the EU for export to third-country markets in the final six months preceding data exclusivity expiry.

[14] European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Fischer, R., Débarbat, G., Koustoumpardi, E., et al., Assessing the economic impacts of changing exemption provisions during patent and SPC protection in Europe, Publications Office, 2017, https://data.europa.eu/doi/10.2873/673124 P.10

[15] European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Fischer, R., Débarbat, G., Koustoumpardi, E., et al., Assessing the economic impacts of changing exemption provisions during patent and SPC protection in Europe, Publications Office, 2017, https://data.europa.eu/doi/10.2873/673124 P.10

[16] Correa CM (2016) The Bolar exception: legislative models and drafting options. Research Paper 66, South Centre. https://www.southcentre.int/wp-content/uploads/2016/03/RP66_The-BolarException_EN1.pdf.

the development of medicinal products, including those providing specific services such as micronisation.

The exclusion of third-party API supply in a national Bolar exemption contributes to legal uncertainty and negatively impacts API developers as well as generic and originator medicines manufacturers. This uncertainty and risk forces API suppliers to cease production or, in order to obtain certainty and reduce risk, to relocate to outside of the EU, which impacts generic and originator medicines industries reliant on the API supply, including frustrating the operation of the Bolar exemption entirely if API cannot be obtained.

How a clarified Bolar would help:

As highlighted in several studies published by the European Commission since the 2015 Single Market Strategy for Europe,[17] an explicit inclusion of third-party API supplies into the Bolar exemption therefore provides several benefits:[18]

1. ensures a consistent and reliable supply from European API supplies;
2. encourages future investments in API manufacturing in Europe;
3. there will be a wider range of API supplier options for medicines manufacturers in Europe;
4. a higher share of APIs used by European generic manufacturers will be sourced from European API suppliers rather than imports.[19]
5. It could be expected that more legal certainty regarding third party API supply within Europe would increase European API supply for development purposes.[20]

In conclusion, similar to a conclusion made in a study of the Max Planck Institute, legislators should clarify that the Bolar exemption covers the manufacture and supply of patented substance(s) by third-party suppliers, if the supplied party uses or intends to use the substance(s) in activities covered by the exemption.[21]

Generic and originator studies

By 2022, all EU Member States have adopted a Bolar exemption that exempted generic drug manufacturers from patent infringement for conducting bioequivalence studies or trials for the purposes of applying for marketing authorisation. At least twenty-four out of twenty-seven Member

[17] Single Market Strategy for Europe of 2015
[18] https://www.medicinesforeurope.com/wp-content/uploads/2021/11/Factsheet%20on%20Bolar%20Exemption%20-%20Medicines%20for%20Europe%20-%20Apr%202021.pdf.
[19] European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Fischer, R., Débarbat, G., Koustoumpardi, E., et al., Assessing the economic impacts of changing exemption provisions during patent and SPC protection in Europe, Publications Office, 2017, https://data.europa.eu/doi/10.2873/673124 P.12
[20] European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Fischer, R., Débarbat, G., Koustoumpardi, E., et al., Assessing the economic impacts of changing exemption provisions during patent and SPC protection in Europe, Publications Office, 2017, https://data.europa.eu/doi/10.2873/673124 P.12
[21] European Commission, Max Planck Institute Study: Study on the Legal Aspects of SPC – Final Report. 2018. P.654.

States also exempted originator drug manufacturers from patent infringement for conducting studies.[22]

A Bolar exemption that does not include originator studies, such as for comparative purposes, negatively impacts access to medicines. First, the exclusion of originator studies delays competition amongst originator medicines and prevents more clinically effective treatments from entering the market. Second, the exclusion of originator studies decreases the number of eligible originator medicines for which generic medicines can be developed.

How a clarified Bolar would help:

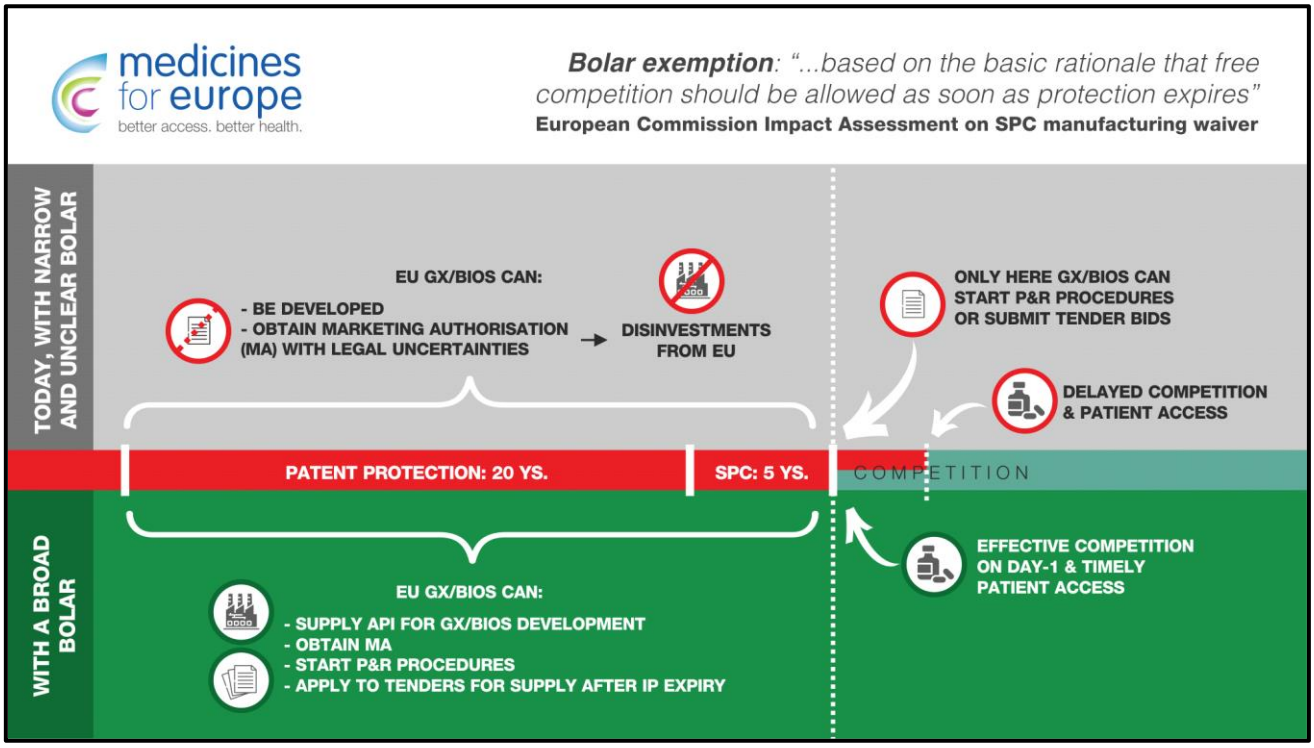
Confirmation that the Bolar exemption should apply to any medicines will remove the legal uncertainty and risk associated with running regulatory tests and other studies on medicines that do not follow the abridged marketing authorisation pathway.[23] This would be expected to reduce costs for originator medicines manufacturers on freedom-to-operate (FTO) studies, validity opinions, patent oppositions or costs of infringement proceedings.[24]

Pricing and reimbursement and tender bids

No Member States explicitly state that their Bolar exemption allows generic or biosimilar manufacturers to conduct activities to generate data to support applications for pricing and reimbursement (P&R) and obtain P&R determinations from health insurers and authorities or participate in a tender bid, despite these being regulatory or administrative acts necessary to prepare for market entry. As a consequence, in several EU Member States (eg. Germany, Italy, France, Portugal, Poland, Hungary, etc.), completion of certain regulatory or administrative procedures, such as P&R or even marketing authorisations, are blocked until patents expire or are invalidated. This delays timely competition and access to generic and biosimilar medicines.

However, in many EU countries, such as Denmark, Czeck Republic, Slovakia, Spain, Sweden, Belgium, etc., conducting activities for the purposes of P&R negotiations or obtaining P&R decisions/listing is not considered an act of patent infringement. In these countries, these procedures can take place before patent expiry and as a consequence generic and biosimilar medicines can rapidly enter the market after protections expire. Apparently, a minority of stakeholders fear illicit earlier launches but this is not proven in these countries. This demonstrates that there is no need in the revised Bolar for any unnecessary safeguard that would only formally create - rather than eliminate - the so-called 'patent linkage' and be a further tool to delay generic entry going clearly against the Bolar's objectives.

[22] We could, however, not find evidence of inclusion of originator drug manufacturer studies in the Bolar exemptions of Cyprus, Greece, and the Netherlands.
[23] European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Fischer, R., Débarbat, G., Koustoumpardi, E., et al., Assessing the economic impacts of changing exemption provisions during patent and SPC protection in Europe, Publications Office, 2017, https://data.europa.eu/doi/10.2873/673124 P.7
[24] European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Fischer, R., Débarbat, G., Koustoumpardi, E., et al., Assessing the economic impacts of changing exemption provisions during patent and SPC protection in Europe, Publications Office, 2017, https://data.europa.eu/doi/10.2873/673124 P.7



A narrow scope of the Bolar exemption that excludes administrative activities necessary for market entry, such as P&R procedures/decisions or participation in tender bids (for supply after relevant IP expiry), paves the way for Member States to allow 'patent linkage' strategies and delays to competition.

3. What is 'patent linkage'?

'Patent linkage' is defined by the European Commission as

> ***"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".***[25]

'Patent linkage' is considered "***unlawful***"[26] and anti-competitive in the European Union, since it can systematically delay generic/biosimilar market entry. It is considered in contrast with the EU legislative framework since regulatory, P&R or tender authorities, while making their (public) decisions on the approval of medicines, have no competence or knowledge to evaluate whether a patent (a private right) is valid or relevant. This is a competence of Courts.

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*"[27] and "*[u]nder EU law,* ***patent protection is not a criterion*** *to be considered by the authorities* ***when***

[25] European Commission Sector Inquiry Report of 2009, p. 130.
[26] European Commission Sector Inquiry Report of 2009, p. 315.
[27] European Commission Sector Inquiry Report of 2009, p. 328

approving prices or granting reimbursement status."[28] Therefore, "*Member States should* ***disregard third party submissions raising patent****, bioequivalence or safety issues*"[29] *(emphasis added)*

Indeed, 'patent linkage' reinforces the impact of patent strategies aimed at delaying competition. The existence of a patent monopoly, even if irrelevant to the entry of a generic or biosimilar, can enable originator medicines manufacturers to use de facto patent linkage mechanisms to delay P&R or tender procedures for generic and biosimilar medicines. Two possible patenting strategies which can be deployed to delay competition, widely recognised in Europe as well as in the U.S., include (1) divisional patent applications and (2) over-patenting. The pure existence of patents / SPCs can be relied on to prevent some of the necessary regulatory or P&R steps from taking place for generics/biosimilars to get on the market and an explicit ban on linkage practices is therefore necessary.

Patent Linkage Examples

In Europe, there are several 'patent linkage' practices and/or legislations. These take different forms, are more or less onerous for generics/biosimilars, and can be linked to different activities, namely market approval, price and reimbursement activities and/or other market access activities (e.g. prescription lists of procurement). Some examples of forms of 'patent linkage' in the EU include:[30]

- **Italy** (pricing/reimbursement): grant of reimbursement status is subject to patents/SPCs listed in the so-called Balduzzi list upon declarations from the originator.
- **France** (pricing/reimbursement): under the framework agreement between the pricing authority (CEPS) and the pharma companies association (LEEM), originators can declare patents/SPCs for their reference products to the CEPS. The CEPS will not include a generic in the official list of reimbursed products until the 6 months prior to expiry of the patents/SPCs declared by the originator, unless the generic company, upon request from the CEPS, provides a statement that it believes it can launch the product without infringing such rights. The CEPS would then inform the originator that the generic company has provided such statement. This information from the CEPS to the originator is typically what triggers PI applications in France.
- **Germany** (pricing/reimbursement): IFA (private company publishing the Lauer-Taxe) holds a price list of products which, if listed, enables reimbursement from public health insurance funds. IFA does not list generic products while patents are still in force (which has the practical effect of preventing generic products to be sold in pharmacies). This is due to (threats of) injunctions against IFA from originators arguing that such listing is infringing, as was the case in the recent pemetrexed dispute with Eli Lilly.

More concrete examples of 'patent linkage' are described, country by country and molecule by molecule, in the table in Annex II below.

[28] European Commission Sector Inquiry Report of 2009, p. 330
[29] European Commission Sector Inquiry Report of 2009, p. 532
[30] More examples can be found here: "Anatomy of a Failure to Launch: a review of barriers to generic and biosimilar market entry and the use of competition law as a remedy" a Pinsent Masons Whitepaper, November 2020

The EU has taken several steps in the recent past to formally ban patent linkage:

- A 2012 *European Commission Proposal for a Revised Transparency Directive*[31], for example, included a prohibition of patent linkage, but the legislation was never adopted eventually.
- The *European Parliament Resolutions on Access to Medicines in 2017*[32] and the one *on the Pharmaceutical Strategy in 2021*[33] urged the Commission to end patent linkage to ensure immediate market entry for generic/biosimilar competitors.
- A *June 2021 study of the European Parliament*[34] confirmed the issue.
- A *2021 European Parliament Resolution on the IP Action Plan* urged the Commission to ban patent linkage.[35]
- Finally, a European Parliament Study on the unitary SPC refers to the "*prohibited practice of patent linkage*".[36]

The European Commission intends to remove this unlawful 'patent linkage'. This and the related legal uncertainties can be addressed by effective clarification and harmonisation of the Bolar exemption. Explicitly incorporating P&R within the scope of the Bolar exemption EU wide will overcome the 'patent linkage' examples described above and in Annex II. This would facilitate timely market entry for generics and biosimilars in those countries where today forms of 'patent linkage' delay day 1 competition. The intentions of the Commission's proposal (as described in recitals 63, 64, 65) go in the right direction, but as mentioned above the legal text currently proposed (art 85) may further lead to inadvertent legal uncertainty.

Since the primary objective of the Bolar is to ensure immediate generic/biosimilar competition at IP expiry, it follows that if a generic medicine manufacturer cannot participate in necessary procedures that ensure such free and timely competition upon IP expiry, the primary objective of Bolar is frustrated, creating a distortion of competition. And, whereas many countries already allow this, a Bolar exemption in the Directive which does not expressly exempt from patent infringement P&R procedures or participation in tender bids has the effect of delaying entry.

Indeed, applying for or obtaining a P&R status or participating in tender bids are time-consuming processes for generic and biosimilar manufacturers with the potential to postpone the entry of more affordable drugs, although such entry is supposed to occur upon expiry of SPC or key patent protection.

[31] Proposal for a Directive of the European Parliament and of the Council relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems
[32] European Parliament resolution of 2 March 2017 on EU options for improving access to medicines.
[33] European Parliament Resolutions on the Pharmaceutical Strategy in 2021
[34] European Parliament Study for the ENVI Committee "Access to medicinal products", June 2021
[35] European Parliament resolution of 11 November 2021 on an intellectual property action plan to support the EU's recovery and resilience
[36] European Parliament Study for the JURI Committee "The potential impact of the unitary Supplementary Protection Certificate on access to health technologies"

The table below shows the time needed for a biosimilar to obtain a P&R decision and the time it takes to launch in hospitals:[37]

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
8.The application for pricing & reimbursement is a:																												
Single process	✓		✓			✓	✓	✓	✓				✓	✓	✓	✓	✓	✓		✓		✓	✓		✓	✓	✓	✓
Separate process (One process for pricing and a separate process for reimbursement)		✓		✓	✓					✓	✓	✓							✓		✓			✓				
Comments												1																
9.On average, how long (in days) does it take for a biosimilar medicine to receive its P&R approval from the day of application ?																												
days	135	120	60	120	90	60	1	90	58		14	220	45	60	90	45	90	1	1	180	30	90	120	140	120	30	90	1
10.After being listed, how long does it take for a biosimilar medicine to be available in the hospital? (In days)																												
days	1	365	30		1	1	1	90	1		14	90	1	60	60	1	30	1	1	30	6	30	121	365	10	14	1	1

For those countries where patent linkage exists and therefore P&R procedures can be blocked until IP expiry, the biosimilar medicines will be able to obtain P&R and enter the market only after that number of days indicated in the table.

In the table below, there are some examples of delayed market entry due to 'patent linkage' as reported by Medicines for Europe member companies:

Molecule	Treatment	Country	Originator approval	SPC Expiry	Generic Entry	Delay	Cost of Delay Lost Savings
Oxycodone/ Naloxone	severe pain	Germany		29/3/2017	15/11/2017	231 days	**€ 51,6 Mln**
Ezetimibe/ simvastatin	high cholesterol	Italy	18/11/2004	16/10/2017	9/3/2018	144 days	**€ 15,4 Mln**
Ezetimibe/ simvastatin	high cholesterol	Germany	18/11/2004	17/4/2018	15/5/2018	28 days	**€ 11,3 Mln**
Lenalidomide	multiple myeloma, cancer	Hungary	14/06/2007	19/6/2022	1/6/2023	347 days	**€ 1.9 Mln**
Pirfenidone	idiopathic pulmonary fibrosis	Germany	27/02/2011	27/2/2021	15/11/2022	626 days	**€ 32,1 Mln**
Tapentadol	severe pain	Germany	19/08/2010	07/12/2020	15/1/2023	917 days	**€ 184,6 Mln**
Dasatinib	chronic myeloid leukemia	Poland	20/11/2006	22/5/2022	01/01/2023	224 days	**€ 4,5 Mln**
					Total:	**2,517**	**€ 301,4 Mln**

[37] https://www.medicinesforeurope.com/wp-content/uploads/2023/09/Biosimilars-Market-Review-2023-final-06-09-2023.pdf

The table below shows another recent concrete example of undue delay significantly impacting patient access as well as healthcare budgets:

The HIV Case Study of Truvada (Emtricitabine/Tenofovir)

Critical medicine for HIV prevention & treatment (reduces HIV transmission by over 90%)

Patent expiry: July 2017 **SPC expiry: February 2020**

- The SPC challenged & invalidated in several EU national courts at different points in time & ultimately declared illegitimate by the CJEU
- Due to delayed national court decisions and 'patent linkage' in some countries, generics could NOT enter those markets despite invalidating decision all around Europe
  - The Netherlands: generic entry reduced price for 30-day supply from €344,28 to €47,95
  - Portugal: delayed court decision led to a loss of over €109 Million saving, equal to 1.1% of total 2018 health budget, impacting treatment for over 95.000 patients!

Should the revised Bolar not explicitly permit the activities required to negotiate and obtain P&R decisions, or should it include unnecessary safeguards, the Directive would open the door to the introduction of unlawful 'patent linkage' that the new Bolar is actually trying to eliminate; and in those abovementioned countries where today P&R procedures are allowed during IP protection, the launch of generic and biosimilar medicines would then be delayed.

How a clarified Bolar would help:

As a consequence, even though not regarded as patent infringement in many countries, explicitly exempting from patent infringement generic and biosimilar P&R applications/decisions as well as participation in tenders aimed at supplying after protections upon submission of a pricing and reimbursement application or participation in a tender would re-align the Bolar exemption with its own stated fundamental purpose and with the rationale of the EU pharmaceutical system, and would make timely generic entry more certain. This has the potential to result in faster and increased healthcare savings, timely patient access to affordable medicines and more health competition driving innovation.

A formal ban of 'patent linkage'

In addition to clarifying in the Bolar exemption that all regulatory and administrative acts should be exempted from patent infringement, it is fundamental that the revised Directive also **include a formal prohibition of patent linkage**, in line with the one proposed by the European Commission in 2012 in the proposal for a revised Transparency Directive.[38]

[38] Proposal for a Directive of the European Parliament and of the Council relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems

While the European Commission included in its proposal for a revised Directive a timid ban of patent linkage in a recital (65) only related to marketing authorisations, there is no explicit prohibition of patent linkage in the articles of the Directive, which should be finetuned to ban patent linkage not only related to marketing authorisations, but also to P&R and to tender bids (for supply after relevant IP expiry).

4. Conclusions

In order to effectively allow timely access to generic and biosimilar medicines and achieve the stated objectives of the Bolar exemption (*ie*. early generic/biosimilar development and approvals for immediate competition after Intellectual Property expiry), it is pivotal to ensure that the final revised Bolar leave no room for diverging interpretations in different Member States and provide clear, unequivocable provisions by removing any grey area or legal uncertainty and prohibiting any actual or implicit form of 'patent linkage' which would delay competition.

This can only be achieved by:

(1) **Explicitly and clearly including in the scope of the Bolar exemption features already permitted by some EU Member States**:

- the conduct of studies, trials and activities by all partners for the purpose of seeking EU marketing authorisation and subsequent variations, independently from who the final applicant/Marketing Authorisation holder is and where the medicine will be authorized (EU/ non-EU)
- all types of activity necessary for those purposes, e.g. offer, manufacture, supply, storage, import, export, use, sale and purchase, including by third party API suppliers
- the related activities needed to effectively enter the market on day 1 after expiry of the relevant patent or SPC, e.g., pricing & reimbursement (P&R) approval and listing, health technology assessments, tender bids for supply after IP expiry, and the conduct of any studies and trials to generate data in support of these activities.

A clarification of the Bolar exemption along these lines would remove legal uncertainty - rather than create it, as maintained by a minority of stakeholders - and would ensure that generic and biosimilar medicines could effectively enter the market the day after the relevant patent or SPC protections for the originator product expires, for the benefit of patients, healthcare budgets and healthy competition.

(2) **Including in the revised Directive on human use medicines a formal prohibition of 'patent linkage'** to avoid that patient access to generic and biosimilar medicines be unduly and artificially delayed.

Annex I

List of activities covered by EU national Bolar exemptions

Country	Legal Implementation	Bolar Exemption explicitly includes							
		Studies/ trials	Generic studies	Originator studies	EU Marketing Authorisation (MA)	Outside EU Marketing Authorisation (MA)	3rd Party API supply	Pricing & Reimbursement procedures or listing	Tender Bids (for supply after IP expiry)
Austria	Federal Law Gazette I 2005/30. The provisions of Art22. Patent Act and Art 4. Utility Model Act, which transposed Art 0.6 of the Directive, became effective on 9 November 2005	1	1	1	1	1	0	0	0
Belgium	Belgian Medicines Act 1964 under article 6bis§1 in fine by law dated May 2006, in force 26 May 2006.	1	1	1	1	0	0	0	0
Bulgaria	Medicinal Products in the Human Medicines Act (the 'MPHMA'), dated and in force from 3 April 2007.	1	1	1	1	0	0	0	0
Croatia	Patent Act, Art. 63	1	1	1	1	1	0	0	0
Cyprus	Law 75(I)/2006, the 'Medicines for Human Use (Quality Control, Supply and Prices)(Amendment) (No. 2) Law'	1	1	0	1	0	0	0	0

Czech Republic	Not implemented	1	1	1	1	1	0	0	0
Denmark	N/A	1	1	1	1	1	0		
Estonia	The amendment of the Medicines Act on 7 November 2005.	1	1	1	1	1	0	0	0
Finland	Directive 2004/27/EC was implemented by amending the Finnish Patent Act (550/1967) regarding the 'Bolar provision' and by amending the Finnish Medicines Act (395/1987) regarding the new data exclusivity periods. The amendment of the Patent Act came in force on 1 May 2006 and the amendment of the Medicines Act on 7 November 2005.	1	1	1	1	1	0	0	0
France	A law adopted on 26 February 2007 and published in JO (JO) number 49 of 27 February 2007 p. 3503 text n 3).	1	1	1	1	1	0	0	0
Germany	An amendment of the German Pharmaceuticals Act (Arzneimittelgesetz – AMG, Sections 24a and 24b) and the German Patent Act (Patentgesetz). The amendments came into effect on 6 September 2005.	1	1	1	1	1	1	0	0
Greece	Ministerial Decision DYG3(a)83657	1	1	0	1	0	0	0	0

	(Government Gazette Bulletin B' 59/24-1-2006 – the MD)								
Hungary	Act XXXIII of 1995 on the Patent Protection of the Inventions ('Patent Act').	1	1	1	1	1	1	0	0
Ireland	Section 42 of Irish Patents Act 1992	1	1	1	1	1	1	0	0
Italy	Legislative Decree No. 219 dated 24 April 2006 on the commercialisation of the medicinal products for human use.	1	1	1	1	1	0	0	0
Latvia	N/A	1	1	1	1	1	0	0	0
Lithuania	The Law on Pharmaceutics of the Republic of Lithuania, passed on 22 June 2006 and in force 18 July 2006, has implemented directive 2004/27/EC.	1	1	1	1	1	0	0	0
Luxembourg	The Directive 2004/27/EC has been implemented by a Grand-Ducal Regulation dated 26 September 2006 (the 'Grand-Ducal Regulation') which amends	1	1	1	1	0	0	0	0
Malta	The Bolar provision has been implemented into the Patents and Designs Act (Chapter 417 of The Laws of Malta, as amended to date), Art. 27	1	1	1	1	1	0	0	0

Netherlands	Art.53, Lid 3 & 4 Rijksoctrooiwet 1995	1	1	0	1	0	0	0	0
Poland	The Act of 30 June 2000 on Industrial Property (consolidated text, Journal of Laws of 2003, No 11 9, item 111 7, as amended, the 'Act') already includes the provision further introduced in the EU by 2004/27/EC as the Bolar provision.	1	1	1	1	1	1	0	0
Portugal	Article 19.8 of Decree-Law no 176/2006 in force 31 August 2006 implements the Bolar provision (Article 10.6 of Directive 2004/27 amending Directive 2001/83) nto national law	1	1	1	1	1	0	0	0
Romania	Romania revised its pharmaceutical legislation, by Law no. 95/2006 regarding reform in the health sector (the- 'New Pharma Law')	1	1	1	1	0	0	0	0
Slovakia	Directive 2004/27/EC has been implemented by the Act No 342/2006 Coll., which amended the Act No 140/1998 Coll. on Medicinal Products and Medical Aids (the 'Act'). The amendment was adopted on 25 May 2006	1	1	1	1	1	0	0	0

	came into effect on 1 June 2006.								
Slovenia	Otherwise, Directive 2004/27/EC has been implemented in Slovenia in Pharmaceuticals Act (Zakon o zdravilih). The Act came into force on April 8, 2006. The relevant articles from the Directive have been transposed into the Slovenian Act almost verbatim.	1	1	1	1	1	0	0	0
Spain	By means of the Spanish Act of warranties and rational use of pharmaceutical and sanitary products (Act 29/2006 of July26th, 2006), Directive 2004/27/EC has been implemented in Spanish Law.	1	1	1	1	1	0	0	0
Sweden	Directive 2004/27/EC has been implemented through 'Patentlagen' (SFS 1967:837) (Patent Act). The date of the implementation was 6 April 2006.	1	1	1	1	0	0	0	0

Annex II

List of some examples of patent linkage as reported by Medicines for Europe Member Companies

Country	Molecule	Treatment	MA	P&R	Tender	Other	Patent linkage situation
CZ	bevacizumab	cancer			X		Member had to reassure tendering authority its biosimilar would not infringe carve-out indication patent
CZ	dimethyl fumarate	multiple sclerosis				X	Originator informed Customs Office that Member's generic infringed patent and Office seized products
CZ	fingolimod	multiple sclerosis		X			Due to an exclusive supply arrangement, P&R authority refused pricing request due to patents
DK	lenalidomide	multiple myeloma, cancer		X			P&R authorities required a declaration that Member and BMS have an agreement allowing Member to launch Gx with full label before relevant patents expire.
DE	lenalidomide	multiple myeloma, cancer		X			IFA required a declaration that Member and BMS have an agreement allowing Member to launch Gx with full label before relevant patents expire.
DE	tapentadol	severe pain		X			Member had to sue IFA to grant P&R decision for generic because of existing patents
DE	sorafenib	cancer		X			Member had to sue IFA to grant P&R decision for generic after Bayer informed of existing patent
DE	fingolimod	multiple sclerosis				X	Originator threatened wholesalers with legal action for patent infringement to prevent distribution of Members' generic
DE	dimethyl fumarate	multiple sclerosis		X			P&R authority refused pricing request due to patents
DE	dimethyl fumarate	multiple sclerosis				X	Wholesalers required indemnity agreements from Member to avoid liability for patent infringement

DE	pirfenidone	idiopathic pulmonary fibrosis	X			X	BfARM delayed generic approval because of patents and wholesalers requested indemnity agreements
DE	pemetrexed	cancer		X			P&R authority refused pricing request due to patents
DE	oxycodone/naloxone	severe pain		X			P&R authority refused pricing request due to patents
DE	ulipristal acetate	emergency contraception		X			Member had to sue IFA to grant P&R decision for generic because of existing patents
DE	ezetimibe/simvastatin	high cholesterol		X			Member had to sue IFA to grant P&R decision for generic because of existing SPC
EE	sorafenib	cancer				X	Originator warned wholesaler purchase of generic would infringe patent
FI	fingolimod	multiple sclerosis		X			P&R authority refused pricing request due to patents
GR	fingolimod	multiple sclerosis		X			P&R authority refused pricing request due to patents
FR	Sitagliptin & sitagliptin/ metformin	diabetes		X			Member had to reassure CEPS its generic would not infringe patent
FR	ulipristal acetate	emergency contraception		X			Member had to reassure CEPS its generic would not infringe patent
FR	fingolimod	multiple sclerosis		X			P&R authority refused pricing request due to patents
HU	lenalidomide	multiple myeloma, cancer		X			P&R authorities required a declaration that Member and BMS have an agreement allowing Member to launch Gx with full label before relevant patents expire.

HU	sitagliptin & sitagliptin/ metformin	diabetes	X				Hungarian Medicines Authority conditioned generic approval on awaiting expiry date SPC and non-infringement patents
HU	vildagliptin	diabetes	X				Hungarian Medicines Authority conditioned generic approval on awaiting expiry date SPC and non-infringement patents
HU	beclometasone & formoterol	pulmonary disease		X			P&R authority refused pricing request due to patents
IE	fingolimod	multiple sclerosis		X			P&R authority refused pricing request due to patents
IT	lenalidomide	multiple myeloma, cancer		X			P&R authorities required a declaration that Member and BMS have an agreement allowing Member to launch Gx with full label before relevant patents expire.
IT	brinzolamide timolol	ocular hypertension		X			P&R authority refused pricing request due to patents
IT	sitagliptin & sitagliptin/ metformin	diabetes		X			P&R authority refused pricing request due to patents
IT	dimethyl fumarate	multiple sclerosis		X			P&R authority refused pricing request due to patents
IT	tenofovir/emtricitabine	HIV		X			P&R authority refused pricing request due to patents
IT	ezetimibe/simvastatin	emergency contraception		X			P&R authority refused pricing request due to patents
LT	fingolimod	multiple sclerosis		X			P&R authority refused pricing request due to patents
LT	dimethyl fumarate	multiple sclerosis		X			P&R authority refused pricing request due to patents

PL	lenalidomide	multiple myeloma, cancer		X			P&R authorities required a declaration that Member and BMS have an agreement allowing Member to launch Gx with full label before relevant patents expire.
PL	dasatinib	chronic myeloid leukemia		X			P&R authorities required a declaration that Member and BMS have an agreement allowing Member to launch Gx with full label before relevant patents expire.
PL	sitagliptin & sitagliptin/ metformin	diabetes		X			Authorities first asked for acknowledgment of existing patents before P&R decision
PT	lenalidomide	multiple myeloma, cancer		X			P&R authorities required a declaration that Member and BMS have an agreement allowing Member to launch Gx with full label before relevant patents expire.
PT	fingolimod	multiple sclerosis				X	Originator sued P&R authority for P&R contracts with generic companies over existence patent right
PT	sitagliptin & sitagliptin/ metformin	diabetes	X				MA delayed due to existing patent right, litigation ongoing
PT	fesoterodine	overactive bladder	X				MA delayed due to existing patent right, litigation ongoing
PT	rivaroxaban	pulmonary embolism	X				MA delayed due to existing patent right, litigation ongoing
PT	ticagrelor	heart disease	X				MA delayed due to existing patent right, litigation ongoing
PT	dimethyl fumarate	multiple sclerosis	X				Originator sued P&R authority because listing of generic in hospital catalogue would infringe existing patent right
RO	sorafenib	cancer		X			Member had to sue P&R authority to grant P&R decision for generic after originator informed of existing patent

PT	sugammadex	neuromuscular blockade	X				MA delayed due to existing patent right, litigation ongoing
SK	fingolimod	multiple sclerosis		X			P&R authority refused pricing request due to patents
SK	dimethyl fumarate	multiple sclerosis		X			P&R authority refused pricing request due to patents
CH	etorixocib	arthritis		X			P&R authority refused pricing request due to patents