May 2025

Need the explicit inclusion of "hospital tender bids" within the Bolar Exemption for European harmonisation

Denmark allows hospital tender for supply after the patent expiry under Bolar clause

The **tender process in Denmark** is often started up to **one year in advance the IP protection expires**, of course the patent must have expired before the actual delivery into the market.

AMGROS (National tender organisation in DK) provides an overview of medicines and extensions of indication that are expected to be marketed in Denmark within the next two to three years.

This enables Amgros to better prepare for upcoming price negotiations with suppliers and organize tendering procedures. For generics as well as biosimilars the results are very positive in Denmark since they normally can enter the hospital markets on Day One after patent expiry.

Compatibility with the World Trade Organisation's TRIPS Agreement

Under Article 30 of the TRIPS agreement, "*Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties*."

The inclusion in the Bolar of the possibility to participate in tender bids when the supply is foreseen *after* the protection expires does not *unreasonably conflict with a normal exploitation* of the patent and does not *unreasonably prejudice the legitimate interests* of the patent owner, taking account of the legitimate interests of third parties.

A generic participation in a tender would not impact the patent owner's powers associated with patent rights such as for instance exclusion of competitors or financial revenues through licensing. He would keep its exclusivity on the market and related powers until the protection expires. Participation in a tender bid is merely an administrative act and does not constitute a launch of the generic on the market.

Moreover, such participation would not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.[1] Participation in a tender does not cause an unreasonable loss of income nor is it against relevant public policies or social norms, rather the contrary: it would be justified by the legitimate interests related to public health and timely access to medicines, allowing immediate competition right after IP expiry as indeed supposed to occur in the current system This is the inherent purpose of the Bolar exemption.

In practice, originators can today delay generic entry beyond the term intended by the legislator (i.e., the regulatory or IP exclusivity), a strategy aided by the current EU pharmaceutical legal framework. If administrative acts such as P&R procedures delay generic or biosimilar entry, they inevitably prolong market exclusivity beyond

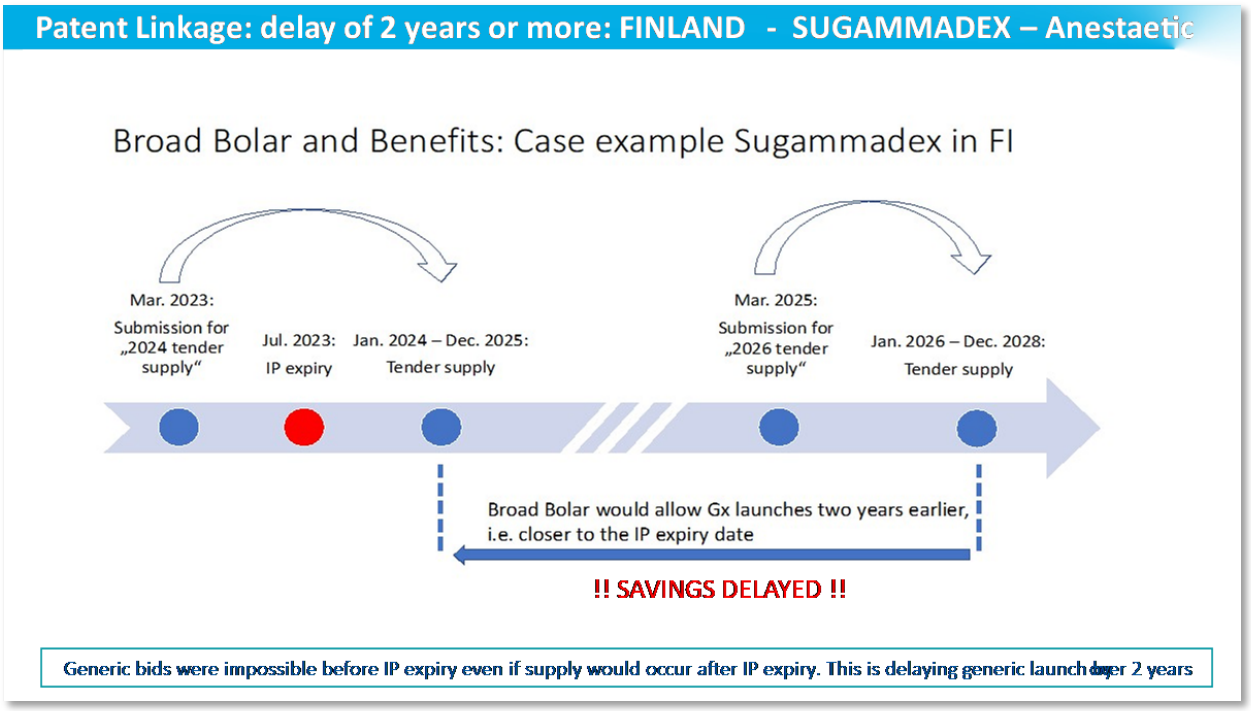
[1] Legitimate interests are defined as a normative claim calling for protection of interests that are "justifiable" in the sense that they are supported by relevant public policies or other social norms. Applied to the circumstances of that dispute, the Panel considered that: '[i]n our view, prejudice to the legitimate interests of right holders reaches an unreasonable level if an exception or limitation causes or has the potential to cause an unreasonable loss of income to the copyright owner' – see Canada Patents case (cite needed).

the intention of the legislation and the basic principles inherent in the IP and competition systems, distorting competition and generating unjustifiable losses of savings for healthcare systems.

For this reason, the **European Commission** states in the 2009 Pharmaceutical 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)

Some examples of undue delay

- **2 years delay:** the table below shows an ongoing case of unjustified generic delay by 2 years



- **4 years delay in Romania:** *Eg*. in 2019, in Romania, biosimilar medicines were unlawfully blocked from participating in a tender for Trastuzumab and Rituximab, with additional costs for the healthcare system of $100million. As a result, the Romanian Competition authority fined the originator company 9,47 million EUR.

The UK Case Law

In England and Wales, the case law has developed to allow generic companies to participate in tenders before patent expiry as long as the launch onto the market is foreseen after patent expiry. In *Gerber v. Lectra*, ([1995] RPC 383) the High Court (Lord Justice Robin Jacob) decided that the offer for sale of a patented product during the period of validity of the patent for a supply after the expiry of the patent does not constitute an infringement of the patent.

Such an approach is in line with the rationale of the system to protect innovation with long exclusivities and, once the exclusivities expire, ensure immediate competition. Any tender delays and subsequent artificial extension of the monopoly beyond IP expiry is contrary to the EU system and anticompetitive.

Article 85
Exemption to the protection of intellectual property rights

1. The protection provided by p~~P~~atent rights, or supplementary protection certificates **of medicinal products ~~under the [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted]~~ shall not be regarded as infringed when **the necessary studies, trials and other activities are conducted** ~~a reference medicinal product is used~~ for the purposes of:
(a) ~~studies, trials and other activities conducted to generate data~~ **necessary** ~~for an application, which are necessary~~ for:
~~(i)~~ **obtaining** a marketing authorisation of **medicinal products, in particular of** generic, biosimilar, hybrid or bio-hybrid medicinal products and for subsequent variations;
(aa)~~(ii)~~ **conducting** health technology assessment as defined in Regulation (EU) 2021/2282;
(ab)~~(iii)~~ **obtaining** pricing and reimbursement **approval;**

(ac) complying with subsequent practical requirements associated with activities referred to in points (i)-(iii).

*** Tenders ***

Council proposal
(ad) submitting an application on procurement tenders are submitted, in compliance with Union and national law, to the extent that it does not entail the sale or offering for sale of the marketing of the ~~patented~~ medicinal product concerned during the protection period provided by patent rights or supplementary protection certificate.

Alternative wording
to include tenders under the Bolar clause to ensure clarity of the legal text and avoid litigation at national level and deliver on Day1 launch for hospital medicinal products. A reference to "hospital" may be a good way to address some of the pricing issues raised in the past. And the reference below to "actual" sale or "effective placing on the market" confirms that good faith of intending to effectively launch only after IP expiry.

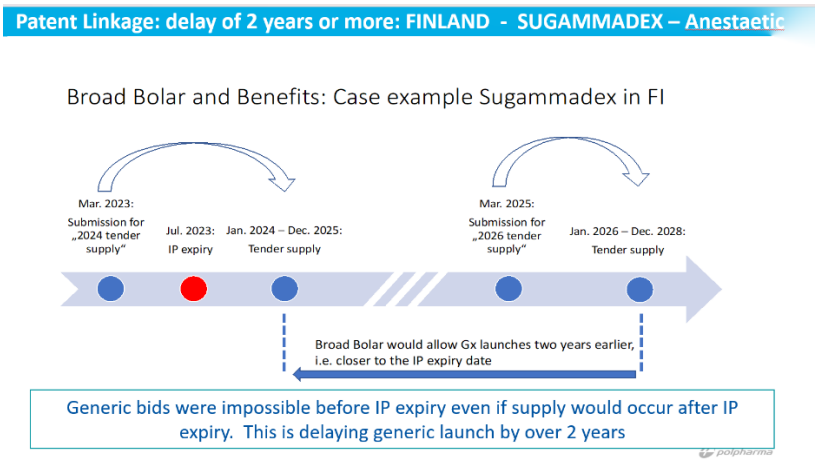
(ad) submitting an application on hospital ~~procurement~~ tenders are submitted, in compliance with Union and national law, to the extent that it does not entail the actual sale or ~~offering for sale of the marketing~~ effective placing on the market of the ~~patented~~ medicinal product concerned during the protection period provided by patent rights or supplementary protection certificate.

(b) **T**the activities conducted exclusively for the purposes set out **the first subparagraph** ~~in point (a)~~, may cover**, where 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.
2. Decisions adopted concerning the activities referred to in paragraph 1 shall not be considered as infringing intellectual property rights, within the meaning of that paragraph.
3. This exception **provided for in this Article** shall not cover the placing on the market of the medicinal products resulting from such activities.

JUSTIFICATION

The questions should not be whether offering for sale is a commercial or pre-commercial act or not.

The core problem is that without participating to a **hospital** tender, there is no way a generic or any producer can effectively launch on Day 1 after IP expiry. Therefore, if we accept the principle that the day after IP expiry generics should enter the market, then we need to be clear that whatever is needed for that to happen has to be covered by Bolar. If, on the contrary, one (originators) wants to stick to the interpretation of some MSs saying that participating to a tender may be potentially considered a commercial act (remember that in UK the "offering for sale" is allowed before IP expiry) then the whole purpose of the Bolar is frustrated and originators continue to keep an artificial, undue and illegal (because not foreseen by EU law) extension of the protection. If, by allowing generic medicines to participate to a hospital tender for supply after IP expiry, prices of originators in some MSs are lowered earlier that the generic entry, the generic industry constructively commit to support national discussions to make sure that this does not happen. **Referring to «HOSPITAL tenders» may be a good way to address some of the pricing issues raised in the past**.



<u>The UK Case Law</u>

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Such an approach is in line with the rationale of the system to protect innovation with long exclusivities and, once the exclusivities expire, ensure immediate competition. Any tender delays and subsequent artificial extension of the monopoly beyond IP expiry is contrary to the EU system and anticompetitive.

Hungarian Presidency Proposed text	**EFPIA amendments**	**EFPIA rationale**	**Medicines for Europe comments**
Article 85			
Exemption to the protection of intellectual property rights			
1. The protection provided by patent rights, or supplementary protection certificates **of medicinal products** shall not be regarded as infringed when **the necessary studies, trials and other activities are** for the purposes of:	1. Subject to the conditions under Article 85a, ~~**The protection provided by p**~~atent rights, or supplementary protection certificates **of medicinal products** under the [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted] shall not be regarded as infringed when **the necessary studies, trials and other activities are** conducted exclusively for the purposes of:	As per international law, any limitation to individual acquired rights should be clearly defined and only implemented if there is no other means to pursue a public interest. Its interpretation should be construed narrowly to protect the effectiveness of the rights. As such, the extension of the Bolar exemption shall be limited to strictly necessary activities.	*(For the reference to article 85a, see below at article 85a)* In agreement with the EFPIA rationale, the Bolar should clearly define what is exempted (the current uncertainties have led to different MSs approaches) and should include the strictly necessary activities to allow immediate day1 launch after patent expiry, as intended by this reform.
~~(a) studies, trials and other activities conducted to generate data for an application, **which are necessary** for:~~			

(a) obtaining a marketing authorisation of **medicinal products, in particular of** generic, biosimilar, hybrid or bio-hybrid medicinal products and for subsequent variations;	**(a) obtaining** a marketing authorisation for a ~~of~~ **medicinal products~~, in particular of~~** ~~generic, biosimilar, hybrid or bio-hybrid medicinal products~~ and for subsequent variations;	There is no reason to restrict the Bolar exemption to certain beneficiaries rather than others (i.e. generics/hybrid vs. innovators products). A harmonized approach with respect to the beneficiaries of the exemption was the primary reason to review and clarify the scope of the exemption and one of the only ones which was subject to an impact assessment. A clearly defined Bolar exemption that can facilitate efficient regulatory approval is important. The suggested change provides for a broader scope which has already been implemented in many member states and should not be controversial.	Agree with the EFPIA rationale
(aa) conducting health technology assessment as defined in Regulation (EU) 2021/2282;	**(aa) conducting** ~~health technology assessment as defined in Regulation (EU) 2021/2282;~~	Both the Commission proposal and the amendments proposed by the Hungarian Presidency on expanding the Bolar scope have the objective of facilitating "Day One" generic launch. "Day One launch" is not something EFPIA is opposed to, as long as launches are after expiration of all legitimate acquired rights (i.e. not, in fact, before "Day One",	We welcome the generosity of EFPIA in agreeing that generics/ biosimilars should be able to launch after expiration of patents (not before – which no one has ever requested), but EFPIA has failed to show real or systemic examples of launches before expiry, since, out of half a million (!) approved products in Europe, they always refer to two very old cases where the court blocked

		which EFPIA has various examples of as alluded to below). That said, even the Commission's own impact assessment has not sufficiently proven that there were issues with launches of generic after expiry of protection. EFPIA sees no reason to extend the Bolar exemption. However, if HTA is to be retained in a compromise it must be clarified that the exemption is limited to generating data for the purposes of a potential HTA process but shall not extend to actually conducting HTA activities - these are clear commercial activities, and in the absence of patent linkage, would severely undermine the ability for an innovator to defend its patent rights by seeking to obtain preliminary injunctions, contrary to the requirements of the Intellectual Property Rights Enforcement Directive. It should also be accompanied by adequate safeguards to basic legitimate interests of IP rights holders, as proposed in new Article 85a, and particularly a notification mechanism. No impact assessment has been conducted on the effect of an	the early launch and damages were paid (the court systems worked well) and two cases where there was real genuine doubt on the validity of the SPC: 1) Darunavir (2017), for which CJEU Advocate General concluded it was "likely invalid" and Dutch, Spanish & Swedish Courts considered it invalid! The case was ultimately settled. 2) Bortezomib (2017), whose SPC was invalidated in Canada invalidated (as not inventive) and generic company also got compensation for losses, and in Europe generics were NOT launched, but just included in P&R database in The Netherlands. **It is strange that EFPIA mentions there is not enough evidence that generics are delayed after patent expiry, because the 2022 IQVIA report done for EFPIA states the generics launch delay in EU4: "*the average is now 5.2 months*" (p.20)** On the doubts around timely preliminary relief, there is today no doubts because patent

		expansion of Bolar on getting timely preliminary relief to prevent an unlawful patent infringing launch. There are numerous examples showing that IP- infringing launches are a reality. It is at present already difficult to obtain timely preliminary injunctions in some countries. The expansion of the scope of the Bolar exemption makes IP enforcement very difficult as any act that would usually lead to action by the courts, such as manufacturing, selling, participating in tenders, etc., could be claimed to be carried out under the exemption. Additionally, this would result in legal uncertainty for both the generic/biosimilar manufacturer and the right holder, as courts would need to establish new case law and redefine what constitutes an actionable imminent infringement threat.	holders perfectly know what company is launching where, since no marketing authorization or P&R decision is secret. Moreover, **in countries where P&R decisions are allowed before patent expiry (eg. Denmark, Czeck Republic, Slovakia, Spain, Sweden, Belgium, etc.), generic medicines enter the market on day-1 after protections expire and there is NO illicit earlier launch, showing that there is NO need for any unnecessary safeguard that would only be a further tool to delay generic entry and go clearly against the Bolar's objectives.** **The legal uncertainty results from the current Bolar**. Multiple studies[1] (including Commission studies) show that the long-standing lack of harmonisation and clarification of the Bolar has been causing: **(1) disinvestments in Active Pharmaceutical Ingredients (API)** development in Europe and

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

			(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.
(ab) obtaining pricing and reimbursement **approval;**	**(ab) ~~obtaining~~** ~~pricing and reimbursement~~ **~~approval;~~**	Both the Commission proposal and the amendments proposed by the Hungarian Presidency on expanding the Bolar scope have the objective of facilitating "Day One" generic launch. "Day One launch" is not something EFPIA is opposed to, as long as launches are after expiration of all legitimate acquired rights	It is essential, instead, to clarify that the exemption allows to obtain a pricing and reimbursement decision or submit a hospital tender bid for supply after patent expiry. This is the only way to effectively allow day-one launch, which otherwise would be impossible.

[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.

		(i.e. not, in fact, before "Day One", which EFPIA has various examples of as alluded to below). That said, even the Commission's own impact assessment has not sufficiently proven that there were issues with launches of generic after expiry of protection. EFPIA sees no reason to extend the Bolar exemption to P&R. However, if P&R is to be retained in a compromise it must be clarified that the exemption is limited to generating data for the purposes of a pricing and reimbursement submission but shall not extend to actually obtaining pricing and reimbursement approval - these are clear commercial activities, and in the absence of patent linkage, would severely undermine the ability for an innovator to defend its patent rights, contrary to the requirements of the Intellectual Property Rights Enforcement Directive. Most countries use internal reference pricing systems, adjusting the innovative price once a generic price is registered.	**The impact assessment on the effects of P&R on timely relief already exists, and is provided by those Member States where P&R decisions are allowed before patent expiry (eg. Denmark, Czeck Republic, Slovakia, Spain, Sweden, Belgium, etc.), where generic medicines enter the market on day-1 after protections expire and there is NO illicit earlier launch, showing that there is NO need for any unnecessary safeguard that would only be a further tool to delay generic entry and go clearly against the Bolar's objectives.** Obtaining a price or a reimbursement status can NEVER be considered "early generic competition", even it has an effect on the originator price, simply because the generic is not able to launch until patent expiry. If an effect on the originator price exists, this is something that should be dealt with at national level (and Medicines for Europe is glad to cooperate to support that), otherwise, if the generic company can only obtain P&R after IP expiry, its launch would

		If a generic company was to obtain a pricing and reimbursement approval and that price were to become known to the payer, this would de facto create early generic competition even if before the generic is actually commercialized. The effects of such early competition may have a snowball effect on prices in other countries who use International Reference Pricing, thereby creating significant cumulative price erosion. Even if the innovator price is not automatically decreased per national pricing rules, the price publication or reimbursement acceptance even before the generic is actually commercialized and becomes available to patients, can, in some systems, trigger a co-pay for the patient. This would arrive without warning at the point of prescription, effectively levying an unexpected tax on patients and undermining affordability. Clearly national pricing laws could and would need to be amended to accommodate this EU instrument. This is a federal	never be possible on day1 (on which EFPIA seems to agree), competition would be illegitimately delayed and the Member State would pay a higher price well beyond the patent expiry. **NB**: *The Commission, by including P&R in the Bolar, intends to remove 'patent linkage', i.e. to avoid that regulatory and administrative decisions (public decisions) be based on the status of patents (private rights issues to be dealt with in Court between private entities). Patent linkage in Europe is declared "unlawful" and anticompetitive – see AM below.* *By introducing any amendment NOT allowing to start P&R procedures or to obtain P&R decisions or introducing a notification system, the Directive would formally introduce a patent linkage, which is exactly what the new Bolar is trying to eliminate and that the Pharmaceutical Sector Inquiry Report of 2009, conducted by DG*

		EU diction of amendments of laws on Drug pricing (a clear national competence) via the backdoor. No impact assessment has been conducted on the effect of an expansion of Bolar on getting timely preliminary relief to PREVENT an unlawful patent infringing launch. There are numerous examples showing that IP- infringing launches are a reality. It is at present already difficult to obtain timely preliminary injunctions in some countries. The expansion of the scope of the Bolar exemption makes IP enforcement very difficult as any act that would usually lead to action by the courts, such as manufacturing, selling, participating in tenders, etc., could be claimed to be carried out under the exemption. Additionally, this would result in legal uncertainty for both the generic/biosimilar manufacturer and the right holder, as courts would need to	*COMPETITION, declared unlawful*[4]*.* EFPIA has failed to show real or systemic examples of launches before expiry, since, out of half a million (!) approved products in Europe, they always refer to two very old cases where the court blocked the early launch and damages were paid (the court systems worked well) and two cases where there was real genuine doubt on the validity of the SPC: 1) Darunavir (2017), for which CJEU Advocate General concluded it was "likely invalid" and Dutch, Spanish & Swedish Courts considered it invalid! The case was ultimately settled. 2) Bortezomib (2017), whose SPC was invalidated in Canada invalidated (as not inventive) and generic company also got compensation for losses, and in Europe generics were NOT launched, but just included in P&R database in The Netherlands. **The legal uncertainty results from the current Bolar**. Multiple

[4] https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf

		establish new case law and redefine what constitutes an actionable imminent infringement threat. Any changes to the current system should also be accompanied by adequate safeguards to basic legitimate interests of IP rights holders, as proposed in new Article 85a, and particularly a notification mechanism.	studies[5] (including Commission studies) show that the long-standing lack of harmonisation and clarification of the Bolar has been causing: **(3) disinvestments in Active Pharmaceutical Ingredients (API)** development in Europe and **(4)** patent linkage practices, considered anticompetitive by the European Commission[6] as they unduly **delay generic and biosimilar competition.** This is **well documented by national competition authorities and courts**,[7] 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.

[5] Links to independent studies, European Parliament reports, etc. can be found in this position paper.
[6] European Commission's Sector Inquiry Report, 2009
[7] See the decisions in the 2025 IGBA Report "Gaming the System" and in this position paper.

			On the competence on national pricing: national pricing would always remain a national competence. Including P&R in Bolar would not impose any decision on national authorities. They will continue to decide on their own whether to agree on a price and/or what price. **This would only allow them to take P&R decisions freely, without the fear of being sued or threatened to be sued by patent holders.**
(ac) complying with subsequent practical requirements associated with activities referred to in points (i)-(iii).	~~**(ac) complying with subsequent practical requirements associated with activities referred to in points (i)-(iii).**~~	This is not necessary in light of the reference to "other activities" in paragraph 1, as defined in subparagraph (b). As any exception, the Bolar exemption should be interpreted narrowly and name specific activities clearly - this paragraph is vague and therefore inconsistent with this principle.	A reference to "*subsequent practical requirements*" exists in the Bolar of today. By removing it, it would reduce its scope from the one of today. The text in the Council proposal just clarifies that all preparatory activities are covered by Bolar without leaving any uncertainty. Removing uncertainty seems to be a shared priority.
(ad) submitting an application on procurement tenders are submitted, in compliance with Union and national law, to the extent that it does not entail the sale or offering for sale of the marketing of the patented medicinal product during the	~~**(ad) submitting an application on procurement tenders are submitted, in compliance with Union and national law, to the extent that it does not entail the sale or offering for sale of the marketing of the patented medicinal product during the**~~	The submission of a procurement bid constitutes commercial use under the WTO Agreement on Trade- Related Aspects of Intellectual Property Rights (TRIPS): participation in a tender is a quintessentially commercial activity reserved to the	The submission of a hospital procurement tender bids is a necessary part of the process for securing market access for generics and biosimilars after patent or SPC expiration. Preventing generics or biosimilars from participating in

protection period provided by patent rights or supplementary protection certificate.	~~**protection period provided by patent rights or supplementary protection certificate.**~~	patent/SPC holder. This results in commercial damage to innovators undermining the value of patent rights, while also presenting legal challenges. Expanding the exemption from protection of intellectual property rights ("Bolar exemption") to submission or acceptance of procurement bids - as part of the Proposal for a Directive on the Union code relating to medicinal products for human use - raises significant cause for concern. Allowing generic or biosimilar MA applicants using a product protected by a patent or SPC to engage, in the context of procurement procedures, in commercial activities such as an offer for sale (tender) and potentially actual sales - which would otherwise be reserved to the patent/SPC holder during the patent or SPC term - will not be compliant with EU principles of proportionality and necessity and could cause considerable commercial damage. Furthermore, allowing generic and biosimilar manufacturers to participate in tenders would only encourage launches before IP	procurement tenders, even before they are commercially launched, will unnecessarily delay their entry into the market and limit competition. Several studies exist that demonstrate that including hospital tenders into the Bolar would not infringe any international law or EU law.

		protection (launches at risk). Apart from the irreparable commercial damage, this could also result in legal uncertainty for those manufacturers themselves and in supply disruptions, should an infringement case be initiated and ruled in favour of the rights holder, From a legal perspective, any proposal permitting the submission and acceptance of procurement bids is: inconsistent with the EU's obligations under Article 28.1 of TRIPS, because it does not satisfy all the cumulative conditions required under Article 30 of TRIPS; (ii) inconsistent with the EU's obligations under Article 27.1 of TRIPS, because it unjustifiably imposes differentially disadvantageous treatment to patent/SPC holders in the field of medicinal products compared to inventions in all other fields of technology; (iii) inconsistent with the EU's obligations under Article 1.1 of TRIPS because it limits the protection of patent and SPC rights without complying with the	

		relevant requirements in Articles 27.1 and 28.1 of TRIPS.	
(b) **T**he activities conducted exclusively for the purposes set out **in first subaragraph,** may cover**, where 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.	(b) **T**he **necessary** activities conducted exclusively for the purposes set out **in first subaragraph,** may cover**, where 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.	A clearly defined Bolar exemption that can facilitate efficient regulatory approval is important. To achieve harmonisation across the EU, the exemption shall apply to activities directed to generating data for the purpose of obtaining any kind of marketing authorisation. The exemption shall include strictly necessary activities to that purpose, including where conducted by third parties on a reactive basis. It should however be tightly framed, to prevent abuses and avoid IP- infringing launches, which have been a reality, as explained above.	It is important to refer to all the activities allowed, not just to MA application, otherwise any other activity done with the API would be an infringement, which is not the intention of the legislation. **'Export'** is also fundamental or otherwise EU API developers would be disadvantages vis-à-vis non-EU developers. *(In the first lines of the EFPIA rationale they refer to multiple IP-infringing cases mentioned below. Here they refer to cases mentioned above, but at the end there is no case mentioned…)*
2. Decisions adopted concerning the activities referred to in paragraph 1 shall not be considered as infringing intellectual property rights, within the meaning of that paragraph.	**2.** Provided conditions under Article 85a have been respected, d**ecisions adopted concerning the activities referred to in paragraph 1 shall not be considered as infringing intellectual property rights, within the meaning of that paragraph.**	See justification for the safeguards proposed in the suggested new Art. 85a.	Reference to the new proposed Article 85a would create a new type of patent linkage, which is what the EU wants to eliminate here because anticompetitive and "unlawful".
3. This exception **provided for in this Article** shall not cover the placing on the market of the medicinal products resulting from such activities.	**3.** This exception **provided for in this Article** shall cover the submission and decision on an ·application for marketing authorisation. It shall not cover during the period of protection by	It is advised to remove similar provision from (b) above, and rather express it clearly here. The scope of the exemption should be clearly and narrowly construed. Stockpiling for	A Bolar that covers only marketing authorization already exists and in some MSs (eg. Denmark, Czeck Republic, Slovakia, Spain, Sweden, Belgium, etc.) P&R procedures are possible

	intellectual property rights, the placing on the market of the medicinal products, stockpiling for the purpose of placing the medicinal products on the market, offering to place the medicinal products on the market, or indicating commercial availability of the medicinal products via listing or otherwise, resulting from such activities, unless provided for and subject to the conditions in Regulation (EU) 2019/933.	purposes of placing the product on the market should be clearly excluded as it constitutes an infringing act as established in the EU vs Canada WTO case arbitration outcome (DS 114, 2000). Similarly, to ensure an effective IP enforcement system, offering to place the product on the market or signalling commercial availability during the patent/SPC protection term should continue to be considered as signals of an imminent infringement that should be actionable in court.	already. By limiting the text in this way, these MSs would see huge delays of competition after patent expiry, which today they do not see. *Stockpiling* is not in the scope of the Bolar, but of the SPC manufacturing waiver (where by the way the notification system hugely limits the use and is being misused by SPC holders in all ways: see the 2024 Industry Report). A clarification of the part on "placing on the market" is necessary to avoid legal uncertainty. We propose the following text: "This exception shall not cover the placing on the market **in a Member State** of the medicinal products **manufactured for the purposes mentioned above, while the relevant patent rights or supplementary protection certificates are in force in that Member State**~~resulting from such activities~~."
	New Article 85a **1. To benefit from the exemption in Article 85, the holder or applicant for a marketing authorisation in accordance with Articles 9, 10, 11, 12 of [revised**	Appropriate measures should be put in place to safeguard the effectiveness of patents/SPC rights enforcement. The following notification system is proposed:	A notification system is an unnecessary, unjustified, anticompetitive mechanism that would further allow patent holders to misuse the system to delay generic and biosimilar

	Directive 2001/83] shall notify their intention to avail themselves of the exemption in writing, through appropriate and documented mean,1 the MAH of the reference medicinal product, no later than eighteen months before the submission of an application for pricing and reimbursement for the authorised product. **1a. The notification shall include all the following information:** **(i) the name and address of the holder or applicant for a marketing authorisation in accordance with Articles 9, 10, 11, 12 ;** **(ii) confirmation of submission or grant of the application for the marketing authorization, including sufficient information regarding the indication and formulation of the product for the rights owner to make an assessment of potential patent infringement;** **(iii) a list of the activities to be performed;** **(iv) the Member State(s) and addresses where the activities are taking place;**	o Any generic manufacturer would notify the innovator of its intention to perform allowed activities under the expanded Bolar exemption, mentioning amongst others, what their earliest commercial launch date is. o To guarantee the effectiveness of the notification in supporting patent/SPC enforcement, it must be sufficiently timely to enable at least trial proceedings to be concluded before actual launch, i.e., at least one and preferably two years before actual launch. We suggest using the application for pricing & reimbursement as the reference point, where applicable. The notification should be at least 18 months prior to launch. o Right holders need enough time to resolve patent disputes before they are exposed to irrecoverable damages if infringing generic products are launched before patent/SPC expiry. This means not just relying on preliminary injunctions but actually be able to resolve the dispute.	medicines entry, as very widely recognised. This is **well documented by national competition authorities and courts**,[8] 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 only other example of a notification mechanism, ie. the SPC manufacturing waiver, is regularly misused as a basis for cresting legal hurdles for generic market entry (see the 2024 Industry Report). On the contrary, this legislation is trying to remove patent linkage, whose prohibition is foreseen in Recital 65. Patent linkage occurs when generic & biosimilars' Marketing Authorisations/P&R decisions/hospital tender bids are

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

	(v) the country where the applicant has submitted applications for HTA or pricing & reimbursement under paragraph 1 point (a), (ii) or (iii); **(vi) the reference of all relevant patent(s) and/or SPC;** **(vii) the earliest commercial launch date in the Member State or States concerned.** **1b. Such notification shall constitute an indication and threat of imminent launch and IP rights infringement, absent any binding commitment and measures taken to the contrary by the applicant for pricing & reimbursement approval, as per following subparagraphs c to d.** **1c. The applicant shall commit to respect the earliest launch date notified pursuant to Article 85a, paragraph 1(a)(vii), before which no product can be supplied or made commercially available in any way or form. In accordance with paragraph 2 below, no price or reimbursement for that product can be effective or listed before that date, and the beneficiary of the exemption shall therefore take necessary measures to that effect.**	o Even the Unitary Patent Court (UPC) takes 1 year (and the duration of appeal process remains unknown at this stage). National courts will (mostly) take longer and some courts very much longer (Italy). Preliminary injunctions alone can take 24-36 hours to obtain in some countries and more than year in countries like Portugal (many countries in the middle such as Denmark 4-6 months, with alone 1 week of court hearings). o Such a notification would be considered a reason for the innovator to take action in Court in case there are disagreements on the lawfulness of generic entry. A right holder should be able to avail themselves of the notification to initiate court proceedings to obtain preliminary injunctions. A Court could clarify in a transparent and binding manner when exclusivity expires before any commercial damage is done to either party. This transparency and clarity created early on for all parties would increase legal certainty for both innovators and generics, but also for healthcare systems.	blocked due to existing patents covering the reference product. The EC considers it "unlawful" and anti-competitive in its Pharmaceutical Sector Inquiry Report of 2009 (p.315), as it delays generic/biosimilar medicines systematically. The EU already attempted to ban patent linkage in the 2012 EC Proposal for Revised Transparency Directive . The European Parliament Resolutions on Access to Medicines in 2017 & on the Pharmaceutical Strategy in 2021 urged the Commission to end patent linkage to ensure immediate market entry for generic/biosimilar competitors. A June 2021 study of the European Parliament confirms the issue, and the European Parliament Report on the IP Action Plan urges to ban patent linkage and to address Bolar. Therefore, this article should ban patent linkage, instead of introducing it. **Very importantly, while the EU is negotiating the pharmaceutical**

	1d. The applicant shall exercise due diligence to identify relevant IP rights which would otherwise be infringed and take all necessary measures so that their use of the exemption does not unreasonably conflict with the normal exploitation of the IP rights or prejudice the legitimate interests of the IP rights owner. Where applicable, IPR holders are entitled to ask courts to assess whether such due diligence has been exercised and whether necessary measures have been taken by beneficiaries of this exemption to prevent their activities from unreasonably conflicting with the normal exploitation of the IP rights or prejudice the legitimate interests of the IP rights owner. **1e. The burden shall be on the beneficiary of the exemption to demonstrate that sufficient and reasonable efforts have been taken to prevent infringement or other activities unreasonably conflicting with the normal exploitation of the IP rights, or alternatively, that timely efforts**		**legislation reform, the United States are very active to** **(1) lower medicines prices[9] and** **(2) block anticompetitive practices[10] that delay generic and biosimilar competition.** **By introducing a mechanism that is widely recognised as anticompetitive, the EU would go exactly in the opposite direction against its own interests.** **This is a dangerous attempt 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,[11] but a 2023 Yale University Study shows that**

[9] 15 April 2025 Executive Order: https://www.whitehouse.gov/presidential-actions/2025/04/lowering-drug-prices-by-once-again-putting-americans-first/
[10] 9 April 2025 Executive Order: https://www.whitehouse.gov/presidential-actions/2025/04/reducing-anti-competitive-regulatory-barriers/
[11] This proposal had been already made in the Parliament without success.

	have been made to bring court proceedings sufficiently in advance to resolve potential IP rights disputes. **2. Competent national authorities, including those competent for the inclusion of products within the public health insurance system, shall set up mechanisms to allow completion of pricing &reimbursement procedures while ensuring the product, or its price, are not effective, available or publicly listed as available before the earliest commercial launch date as notified to the MAH of the reference product, unless the applicant and the MAH of the reference medicinal product or the owners of the relevant IP rights agree otherwise.** **3. The European Commission shall create a Working Group including representatives of Member States, national IP Courts, UPC, pricing & reimbursement authorities, pharmaceutical industry, to explore best practices and balanced mechanisms that can**		**"*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. And this is why the Parliament calls for banning it and the Commission has been trying to eliminate this practice for the past 15 years.** **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.**

	facilitate timely entry while preserving the effectiveness and integrity of IP rights. The European Commission should review and issue a report on the use of this exemption, the impact on generic and biosimilar entry as well as on the enforcement of IP rights within 3 years of its entry into force.		

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.