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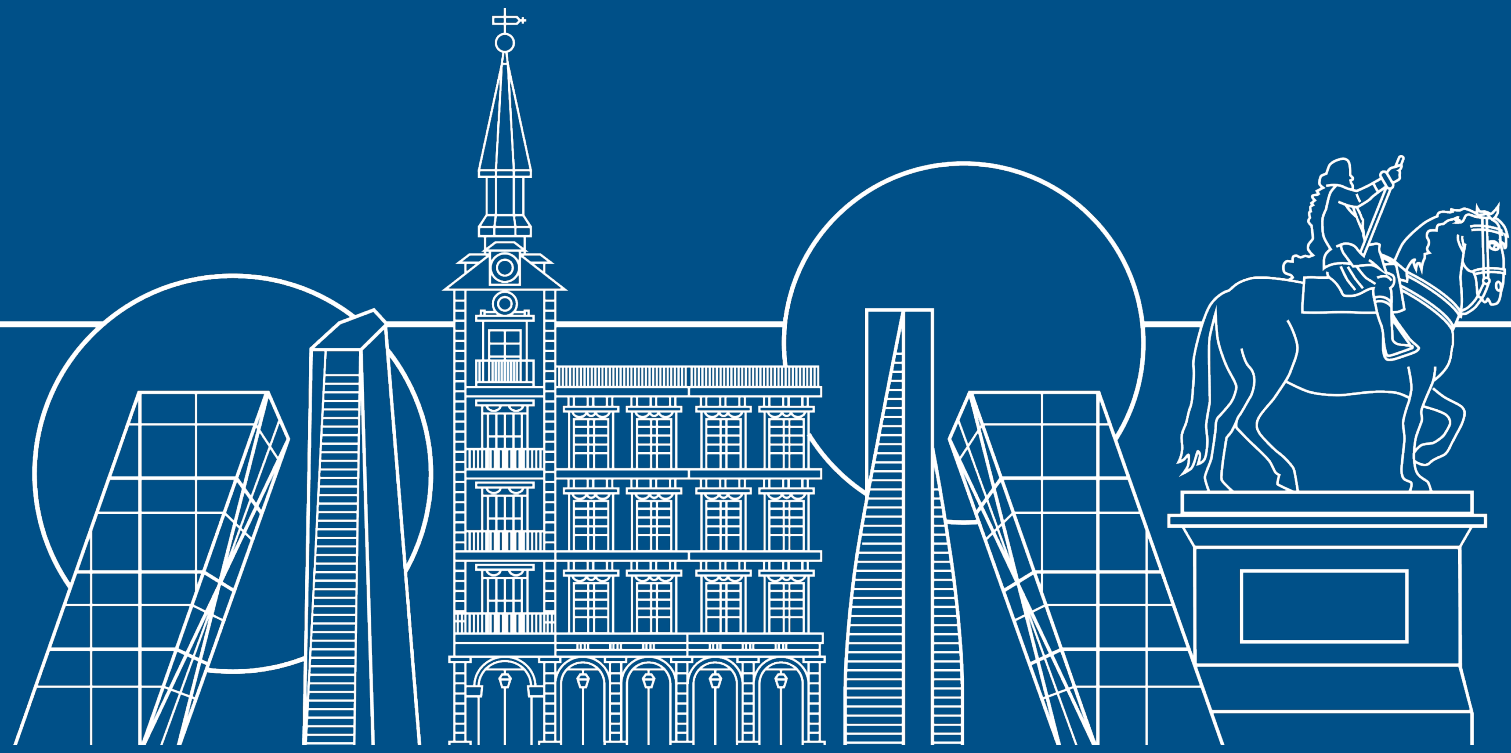

Patent Linkage

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STRENGTHENING THE PRACTICE OF THE INDEPENDENT IP ATTORNEY

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Introduction

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Patent linkage in EU

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PRESENTATION OUTLINE

- What is patent linkage
- The effects of patent linkage
- The applicable legal framework in the EU: the Bolar exemption
- The relationship between the Bolar exemption and patent linkage
- Examples of patent linkage in the EU
- Proposals to eliminate patent linkage

WHAT IS PATENT LINKAGE?

- Patent linkage involves linking the market authorization decision (but also, more broadly: the decision regarding the price determination as well as the reimbursement decision) to the status of the originator's patent
- 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"

THE EFFECTS OF PATENT LINKAGE in the EU

- Patent linkage in the EU is considered anti-competitive (European Commission's inquiry into the pharmaceutical sector in 2009)
- This is due to the fact that it can systematically delay generic/biosimilar market entry, until later than the basic patent/SPC expiry date
- Problem: when making public decisions on the approval of medicines, regulatory, P&R and tender authorities are not able to evaluate whether a patent is valid or relevant, hence they should not base their decisions on the assumption of patent validity
- Patent linkage amplifies the impact of patent strategies aimed at delaying competition: divisional patent applications and over-patenting

THE APPLICABLE LEGAL FRAMEWORK: BOLAR EXEMPTION

- **Bolar exemption — introduced in EU law in 2004**
- Art. 126 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use:

an authorization to market a medicinal product shall not be refused, suspended or revoked except on the grounds set out in that Directive

- Art. 10(6) of Directive 2004/27 amending Directive 2001/83 on the Community code relating to medicinal products for human use:

Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.

THE APPLICABLE LEGAL FRAMEWORK: BOLAR EXEMPTION

- **Problem: harmonization across Member States** in terms of scope of application (approval for generics only or also innovative medicines using a patented active ingredient, e.g. for a previously unknown effect?) and of territory (authorizations for EU, Europe only or also for rest of the world)
- **Two main approaches** to intepretation of Bolar exemption
  - **Strict approach**: for studies directed to the marketing approval for generic medicines only, and **solely for Europe** (e.g. applied Belgium, the Netherlands)
  - **Broad approach**: Bolar applies also to studies for marketing approval of innovative medicines and **also for outside Europe** (e.g. Germany, France, Spain, UK, Switzerland)

THE APPLICABLE LEGAL FRAMEWORK: BOLAR EXEMPTION

- Unified Patent Court (Art 27 (d) UPCA): literally a strict approach, but a broad interpretation is possible, case law remains to be established
- Which approach can be applied depends on the type of patent/SPC
- Unified patents: Art 27(d) UPCA applies («strict» approach?)
- «Classic» European patents not opted-out: Art 27(d) UPCA also applies («strict» approach?)
- National patent and European patents opted-out: national Bolar interpretations apply

DOES PATENT LINKAGE UNDERMINE THE BOLAR EXEMPTION?

- Objective of the Bolar exemption: 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.”
- **Patent linkage clearly frustrates this objective: a generic medicine manufacturer cannot participate in procedures required for free and timely competition, i.e. entry into the market as soon as possible after the expiry of a patent.**
- **This way, the competition is distorted.**

DOES PATENT LINKAGE UNDERMINE THE BOLAR EXEMPTION?

- It is crucial to ensure that the Bolar provisions leave no room for diverging interpretations in different Member States and provide clear directions and remove any grey area or legal uncertainty that may prompt the use of ‘patent linkage’ to delay entry of generic players on the market.
- Recent cases: in July 2024, the Italian Supreme Court provides a narrow interpretation of Bolar exemption for API producers (also ruling on Solifenacin in Germany 2012)
- UPC: art 27(d) of UPCA lists the Bolar exemption (Article 13(6) of Directive 2001/82/EC (8) or Article 10(6) of Directive 2001/83/EC) as one of the limitations to the effects of a patent.

AND YET PATENT LINKAGE EXAMPLES ARE REPORTED IN THE EU

- While the European Commission position is very clear regarding the inadmissibility of tying the generic market authorization to the status of the patent for the original medicine, the situation might be more controversial in the case of pricing and reimbursement. The practice of the EU member states is not coherent in that respect.

EXAMPLES of patent linkage in the EU

GERMANY :

- **Dimethyl fumarate for treatment of multiple sclerosis:** P&R authority refused pricing request due to patents + wholesalers required indemnity agreements from generic manufacturer to avoid liability for patent infringement.
- **Ulipristal acetate for emergency contraception and ezetimibe/simvastatin:** generic manufacturer had to sue IFA to grant P&R decision for generic because of existing patents
- Lenalidomide for treatment of multiple myeloma, cancer: **private entity IFA GmbH required a declaration that Member and BMS have an agreement allowing generic manufacturer to launch Gx with full label before relevant patents expire.**
- Similar declarations were requested by the regulatory authorities to obtain pricing and reimbursement also in **Denmark, Hungary, Portugal and Poland**

EXAMPLES of patent linkage in the EU

FRANCE :

- Originators can declare patents/SPCs for their reference products to the pricing authorities (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, when requested by the CEPS, states that it the product launch does not infringe such rights. The CEPS then **informs the originator** that the generic company has provided such statement. This information from the CEPS to the originator typically **triggers PI applications** in France.
- Sitagliptin & sitagliptin/ metformin for treatment of diabetes and ulipristal acetate for emergency contraception: **Member had to reassure CEPS its generic would not infringe patent**
- Fingolimod for treatment of multiple sclerosis: **P&R authority refused pricing request due to patents**

EXAMPLES of patent linkage in the EU

ITALY :

- Brinzolamide timolol for treatment of ocular hypertension or dimethyl fumarate for treatment of multiple sclerosis: **P&R authority refused pricing request due to patents**
- Lenalidomide for treatment of multiple myeloma, cancer: **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**
- **The so-called Balduzzi provision (**Decree-law no. 158 of 13 September 2012, converted with amendments into Law no. 189 of 8 November 2012). In practice, article 11(1) provides that generic drugs cannot be reimbursed by the National Health Service before the expiry date of the patent or SPC of the corresponding original drug. The generic drug, therefore, should be paid 100% by the patients in need of the treatment. In reality, this is equivalent to preventing the effective launch of the drug.
- The Italian Competition Authority (AGCM) has urged several times Italian Authorities to open up competition in the pharmaceutical market. Attempts to abrogate the Balduzzi decree by the Parliament were not successful.

EXAMPLES of patent linkage in the EU

POLAND :

- Dasatinib for treatment of chronic myeloid leukemia: **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.**
- Sitagliptin & sitagliptin/ metformin for treatment of diabetes: **Authorities first asked for acknowledgment of existing patents before P&R decision.**

EXAMPLES of patent linkage in the EU

PORTUGAL :

- A MA application is effectively considered an act of infringement, and originator companies systematically start IP litigation (within 1 months from MA publication) on each single generic product.
- Fingolimod for treatment of multiple sclerosis: **Originator sued P&R authority for P&R contracts with generic companies over existence patent right**
- Fesoterodine for treatment of overactive bladder: **MA delayed due to existing patent right, litigation ongoing**
- Dimethyl fumarate for treatment of multiple sclerosis: **Originator sued P&R authority because listing of generic in hospital catalogue would infringe existing patent right**

EXAMPLES of patent linkage in the EU

Hungary :

- Sitagliptin, vindagliptin: medicines regulatory agency requires declaration that (1) Generic companies will not launch product before expiration of relevant patent/SPC and (2) that there are no other valid patent or SPC rights relevant to planned distribution of the medicinal product.

EXAMPLES of patent linkage in the EU

- Other examples were reported in Czech Republic, Denmark, Estonia, Finland, Greece, Hungary, Ireland, Lithuania and Romania
- Overall: P&R decisions and tenders bids are not covered by national Bolar exemptions in **all 27 Member States**
- **Medicines for Europe documented 48 cases of patent linkage in EU Member states (report published on 20 October 2023)**

HOW TO FIX IT?

A. Clarify the Bolar exemption

B. Introduce the ban on patent linkage

HOW TO FIX IT?

Ad. A

CLARIFY THE BOLAR EXEMPTION

Features already permitted by some EU Member States should be explicitly and clearly included in the scope of the existing Bolar exemption:

- the conduct of studies, trials and activities by all partners for the purpose of seeking EU marketing authorisation and subsequent variations
- all types of activity necessary for those purposes, e.g. offer, manufacture, supply, storage, import, export, use, sale and purchase
- **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.

This way the Bolar exemption would be re-aligned with its objective.

HOW TO FIX IT?

Ad. B

INTRODUCE THE BAN ON PATENT LINKAGE

- Formally and explicitly prohibiting patent linkage in order to prevent a situation where the patient access to generic and biosimilar medicines is unduly and artificially delayed
- It could be in line with the ban proposed by the EC in 2012 proposal for 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

THANK YOU FOR YOUR ATTENTION!

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FICPI // Events 2025

FICPI Korean Symposium
2-5 April 2025
Jeju Island, Republic of Korea

FICPI World Congress & ExCo Meeting
12-18 October 2025
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