Position Paper

THE ANTI-COMPETITIVE EFFECTS OF PATENT LINKAGE

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EXECUTIVE SUMMARY

"*Patent linkage refers to the practice of linking the granting of MA, the pricing and reimbursement status, or any regulatory approval for a generic medicinal product to the status of a patent (application) for the originator reference product. Under EU law, it is not allowed*"

European Commission's 2009 Pharmaceutical Sector Inquiry – Final Report. [1]

The term "patent linkage" is used to refer to any link made between the granting of a marketing authorisation, or a market access decision (e.g. Pricing & Reimbursement, procurement, etc.) and the status of patents, with the potential effect of preventing effective entry of generic medicinal products on the markets immediately after substance patents expire.

The Commission has stressed on several occasions that patent linkage is "*unlawful*" under EU law,[2] and that it will "*strictly enforce the applicable rules [and] act against patent linkage*".[3] However, in several EU Member States, both marketing authorisation and P&R patent linkages still exist, or practices which have similar delaying effects ("delaying practises").

Any form of patent linkage practice has the following effects:

- In contrast to the EU legislative framework, it undermines the *Bolar* provision and frustrates the objective of having generic and biosimilar medicines on the market as soon as protections expire;
- It dramatically increases, unjustifiably, the amount of patent litigations and the costs linked to it, to the detriment of generic medicines SMEs particularly;
- It delays effective generic entry to the detriment of access to cost-efficient medicines for patients and healthy competition; and
- It affects and delays competition on the market with severe impact on prices of medicines and on the overall sustainability of the pharmaceutical budgets of EU Member States.

Therefore, national authorities should comply with EU law and immediately remove any form of patent linkage, as well as refrain from introducing it in the future.EU Member States should avoid any practice that impedes the effective entry of generic medicinal products immediately after constraining patents expire.

[1] "Pharmaceutical Sector Inquiry – Final Report", 8 July 2009, DG Competition, European Commission, p. 130. http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf

[2] "Pharmaceutical Sector Inquiry – Final Report", pp. 315.

[3] "Pharmaceutical Sector Inquiry – Final Report", p. 475.

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1. Background

The European Commission has strongly addressed the practice of *patent linkage*, in particular in its Final Report of the Pharmaceutical Sector Inquiry of 2009, defining it an "*unlawful*" practice.[4]

As stated by the European Commission in its Final Report of the Pharmaceutical Sector Inquiry (DG Competition),

> "*Patent linkage refers to the practice of linking the granting of MA, the pricing and reimbursement status or any regulatory approval for a generic medicinal product to the status of a patent (application) for the originator reference product. Under EU law, it is not allowed*".[5]

There are several major forms of patent linkage:

i) one that makes a marketing authorisation (MA), or a MA application, a potential act of infringement and therefore triggers litigation;

ii) one that makes a Pricing & Reimbursement (P&R) decision or P&R application for a generic medicine a potential act of infringement, and therefore triggers litigation;

iii) one that prevents a generic medicine to enter into prescription databases;

iv) one that prevents generic medicines to be procured if any patent (incl. irrelevant secondary patents) exists.

Despite the fact that the European Commission considers patent linkage unlawful under EU law, as described below, patent linkage practices or legislations still exist in several EU Member States.

2. Patent Linkage under EU law

The European Commission has stressed that *"[u]nder EU law, patent protection is not a criterion to be considered by the authorities when approving prices or granting reimbursement status*",[6] since it is contrary to Directive 2001/83/EC and Regulation 726/2004. Linking MA and P&R decisions to the status of patents has indeed resulted in significantly delaying market entry of generic medicines, with a huge impact on healthcare costs and patient access to medicines.

The European Commission has already addressed patent linkage issues due to their anticompetitive effects, and will "*strictly enforce the applicable rules [and] act against patent linkage*"[7]. The EC has stated that it "*may launch infringement proceedings against any Member State which infringes the Directive*".[8]

As the Competition Law Sector Inquiry notes, originator companies have threatened to sue national authorities for damages if any regulatory/P&R decision is made during the term of an existing patent.[9] However, for good reasons European Law requires national regulatory or P&R authorities to disregard the status of patents. This is due to the fact that, patent offices often grant low quality patents This is demonstrated by the fact that patents

[4] "Pharmaceutical Sector Inquiry – Final Report", p. 315.
[5] "Pharmaceutical Sector Inquiry – Final Report", p. 130.
[6] "Pharmaceutical Sector Inquiry – Final Report", p. 330.
[7] "Pharmaceutical Sector Inquiry – Final Report", p. 475.
[8] "Pharmaceutical Sector Inquiry – Final Report", p. 315.
[9] "Pharmaceutical Sector Inquiry – Final Report", p. 315.

which are challenged, either during litigation or by nullity proceedings, are often invalidated by Courts or are of no relevance for actual generic entry. According to the Sector Inquiry, indeed, between the years 2000 and 2007 generic companies won 62% of all patent litigations, and the Courts revoked the relevant patents in at least 55% of cases.[10]

Additionally, patent law typically requires patentees to actively enforce their rights, but patent linkage uses government regulatory authority to inhibit infringement. Since only a national court, can ultimately decide whether a particular patent is infringed or not, regulatory agencies are technically and legally not competent enough to determine the relevance and validity of patents. Patent linkage therefore places an undue burden on them. The task of the regulatory bodies is to verify whether a medicinal product is safe, effective and of good quality. Their main function is to ensure that the pharmaceutical products reaching market are not harmful to public health. Other factors, such as the patent status of product, should not be considered when assessing risk/benefit balance of medicines.

3. The concrete impact of patent linkage

Patent linkage related to Marketing Authorisations (MA)

Legislations considering the application or the approval of a MA for a generic medicines a patent infringing act give the patent holder the right to sue the generic company applying for or obtaining a MA. However, the so-called *Bolar* provision, embedded in Directive 2001/83/EC, allows generic companies to start developing their products for the purpose of obtaining a marketing authorisation, in order to avoid any delay in market entry once the protection for the reference product expires. Therefore, such a linkage is contrary to EU law and the rationale of the existing EU legislative framework.

Despite the clear positioning of the EU, in Portugal, for instance, a MA application is effectively considered an act of infringement, and originator companies systematically start arbitrations (with the new reform, IP litigation) on each single generic product. As a result, litigation has become so costly and burdensome in Portugal that it has already lead to a number of generic companies choosing to no longer designate Portugal in their decentralised procedures regulatory approvals.

This affects generic entry in small countries across Europe, reducing competition and perhaps even resulting in generic medicines not being as widely available or leading to potential shortages.

Patent linkage related to Pricing & Reimbursement decisions

Legislations considering the application or the listing of a price and a reimbursement plan (P&R) to be an infringing act give the patent holder the right to sue for infringement a generic company that, thanks to the *Bolar* provision described above, intends to enter the market immediately after patent/SPC expiry - and thereby provides for patent linkage.

In practical terms, a P&R patent linkage prevents a generic company from listing or applying for listing its products until the patent/SPC expires. As a consequence, if a new listing is not done on the exact date of expiry, generic entry would be delayed, even by up to 6 months. This is the case in Italy, for instance.

[10] "Pharmaceutical Sector Inquiry – Final Report", p. 224

Unfortunately, as described in the table below, a P&R patent linkage exists in several Member States' legislations or in their practice, leading to significant delays of generic entry. Not only Italy, but also Romania intended to introduce a P&R patent linkage.[11]

Patent linkage related to prescription listing

Listing a product in prescription databases is sometimes considered as an offer of that product, although the act of listing is not a commercial act in the same way that an offer is intended in civil codes. However, listing serves only as general information, mostly to prescribers, about products which may be available in a certain period. If a particular product is listed, but not actually on a market yet, there is no actual infringement, the product is in reality not available.

Not allowing the listing of a generic medicines for reasons linked to IP prevents prescribers from being informed about the fact that that medicine is available once the IP expires. As a result, the actual generic entry is delayed. Such delay can extend to weeks or even months, depending on when such listing is updated, with a *de facto* undue extension of the monopoly on the market. This is a problem in the Netherlands and Germany.

Patent linkage related to procurement

A system linking the procurement of generic medicines to any patent (incl. irrelevant secondary patents), regardless of their validity or invalidity, will inevitably delay access to generic medicines. Very often, indeed, it is very complicated, especially for procurement agencies, to verify whether a patent is actually relevant for the generic entry. This is particularly the case for secondary patents, which do not cover the product substance, but other less significant aspects.

In several countries, the existence of a patent/SPC prevents companies from participating in tenders. However, tenders cover supply periods that very often either start after or go beyond the expiry of the patent/SPC, preventing generic and biosimilar medicines from entering the market immediately after the exclusivity period. Indeed, in a number of EU countries submitting a tender bid before the expiry of a patent or SPC (even if the supply period falls entirely after such expiry) is deemed an act of infringement. For this reason, while in Italy a P&R patent linkage remains in place, in the case of tenders for biological products, the legislation foresees that tenders are reopened once patents/Supplementary Protection Certificates (SPC) expire, in order to avoid delay in biosimilars entry.

An attempt of introducing a procurement patent linkage system has been made at international level. The WIPO, in collaboration with IFPMA (the international association of originator companies), launched a database called Pat-INFORMED. The database claims to be "an online tool designed to help procurement agencies better understand the global patent status of medicines." Notably the information in the Pat-INFORMED platform can be accessed from the WIPO website, while all the patent details (both substance patents and secondary patents) are uploaded directly by originator companies who are the patent/ SPC holders, without any justification or verification by WIPO. No safeguards or rules whatsoever have been introduced to avoid abuse of such a system. That way, incorrect information can easily be uploaded to the database, and outdated information may not be revised or removed in a timely manner. There is a risk that, in contravention to EU law, national authorities will use this information in competition tenders and delay generic and biosimilar entry into the market. Furthermore,

since the platform is accessible at global level, potentially any national authority could use it to apply this type of patent linkage and eventually create barriers to fair competition on the market.

The effects

A delay of generic entry means delayed competition on the market, which translates in delayed access to generic and biosimilar medicines. For this reason, patent linkage mechanisms are considered *unlawful* in Europe. The impact on prices due to delayed generic entry is significant, and bears negative effects on the overall sustainability of the healthcare systems of EU Member States.

The Final Report on the Sector Inquiry identified a series of originator tactics of particular relevance in terms of competition, such as patent filing strategies of originator companies aimed at delaying competition. It is therefore crucial that no additional tool to delay competition in the market is introduced and that the Commission rather continues to aim at stimulating competition.

Patent linkage related to marketing authorisations or P&R inevitably leads to generic delay and an increase in the amount of patent litigation commenced by originator companies. In fact, when a generic is potentially ready to launch and to start delivering savings to healthcare systems across Europe, the benefits to the originator in trying to delay generic launch are substantial and this is at the expense of national health authorities.

The link between patent linkage mechanisms and increase of patent litigation is undeniable.[12] Countries that have introduced similar patent linkage systems have also experienced a vast increase in the amount of patent litigation. An increase in patent litigation is strongly detrimental to the aim of increasing access to medicines. It increases litigation costs for pharmaceutical companies, which poses a particular burden for small to medium sized companies, reducing their ability to introduce generic medicines in the market. The Sector Inquiry also took into account the total costs of patent litigations in the EU between the years 2000 and 2007, which was estimated to exceed € 420 million for that limited period.[13]

Moreover, the average duration of a case of patent litigation in the EU is 2.8 years just to a first instance decision, in some EU countries it even reaches over 6 years.[14] Patent linkage provides an additional tool to delaying marketing of generic medicines. As the Final Report of the sector inquiry stresses

> *"the inquiry's findings show […] that litigation can also be an efficient means of creating obstacles for generic companies, in particular for smaller ones. In certain instances originator companies may consider litigation not so much on its merits, but rather as a signal to deter generic entrants*.[15]"

The effect of patent linkage is a delay in generic entry to the detriment of access to cost-efficient medicines for patients. These effects have been recognised in other countries where patent linkage forms are in place (e.g. US,

[12] Ravikant Bhardwaj, K.D. Raju, M. Padmavati, The impact of patent linkage on marketing of generic drugs, Journal of Intellectual Property Rights 18, 316-322, 2013. http://nopr.niscair.res.in/bitstream/123456789/20282/1/JIPR%2018(4)%20316-322.pdf

[13] Final Report of the sector inquiry on pharmaceuticals, p.238.

[14] Final Report of the sector inquiry on pharmaceuticals, p.228.

[15] Final Report of the sector inquiry on pharmaceuticals, p.238.

Singapore, etc.).[16] Any notification system, also widely proposed by some stakeholders, would have exactly the same effect.

4. The situation in EU Member States

The table below lists cases in EU Member States where patent linkage is in place or there has been a risk of its introduction, as well as relevant decisions of competent national authorities, if existent.

Country	Relevant Authority Decision
Czech Republic: The Court was requested to clarify whether price and reimbursement negotiations with the national authority can constitute patent infringement.	The High Court in Prague stated that marketing authorisation holders cannot be challenged for taking *"any necessary preliminary steps to enter the market before the envisaged expiry of SPC"*. (31.10.2017, No. 3 Cmo 146/2017)
Germany: A pharmacy can calculate and claim reimbursement from public health insurances only if a product has been included to the price list of the privately held IFA (Informationsstelle fur Arzneispezialitäten), which is published monthly/bi-monthly/quarterly, even sometimes only a day before patent expiration. According to its current practice, IFA does not list a generic product if a patent holder has filed an objection against the act of listing the price in the IFA's list.	Generic companies need to obtain injunctive legal remedy from civil courts on the basis of competition law in order to challenge the IFA's practice of non-price listing. However, the general practice of not allowing the listing remains present and raises legal uncertainty. Furthermore, IFA is the only institution in Germany to give the drug the number it needs (the PPN) in order for it to get sold in a pharmacy, or to get the serial number. The agency has a specific weight on the market entry of a drug and the patent holders' practice of injuncting IFA is a very effective tool to delay market access for generic medicines.
France: <u>Marketing Authorisation approval:</u> The Medicine Act obligations for generics and biosimilars applicants to inform *(i)* the innovator if MA grant is expected during patent protection (Art L5121-10, al. 1 CSP and L5121-10-2 CSP) and *(ii)* the FR regulatory authorities about the existing patent rights protecting formulations, indications and dosages of the product (L5121-10, al. 4 CSP) <u>Price & Reimbursement:</u> In the context of the agreement between the FR price authority (CEPS) and the FR association of pharmaceutical companies (LEEM): • Innovator companies can declare to the CEPS the IP rights they own in relation to each reference product;	

[16] Ravikant Bhardwaj, K.D. Raju, M. Padmavati, The impact of patent linkage on marketing of generic drugs, Journal of Intellectual Property Rights 18, 316-322, 2013.

• a generic cannot be listed in the official list of reimbursed products more than 6 months prior to the expiry date of the IP rights declared by the innovator for the reference product, unless the generic company has informed the CEPS that it believes it will not infringe such rights; • if IP rights have been declared and will still be in force within such timeframe, the CEPS, before approving the price of a generic product, requests a statement from the applicant that the specific product will not infringe any such IP rights declared by the innovator; • the CEPS then immediately inform the innovator of the response provided by the generic company;	
Italy: Patent linkage has been already in place for several years (Article 11 of the so-called "Balduzzi Decree", converted into Law no. 189/2012), even if the European Commission and the AGCM (Italian Antitrust authority) condemned the Italian legislator on different occasions.	The Italian Competition Authority (AGCM) has urged several times Italian Authorities to open up competition in the pharmaceutical market: "*The sector is still characterized by a discipline that closes the market and protects incumbent firms; it would be appropriate to undertake a process of liberalization less ambiguous and more decisive" (report submitted under the law October 10, 1990, No. 287 by AGCM to the Italian Parliament in May 15, 2009).*
The Netherlands: The country presents the same issue as Germany as regards listing products in the G-Standaard, the Dutch medicines database, which is assessed to be an infringement**.**	
Poland: Under the reimbursement act art. 25(3) the applicant for reimbursement needs to confirm availability of its product on the market before filing the application. Due to such obligation there is no possibility to enter the Polish market with reimbursed biosimilar/generic product on the Day 1 after the expiry of a constraining SPC/patent or a regulatory protection.	
Portugal: A generics Marketing Authorisation Application allows the patent holder to start litigation. Previously, via arbitration, which would not even consider the actual validity of the patent. As a result, as described in the "*8th Report on the Monitoring of Patent Settlements"* [17], 55 cases of patent settlement	The Portuguese Government refers in the preamble of the Decree-Law No. 110/2018 that considering: «*(…) the circumstances that led to the approval of Law No. 62/2011 and the mandatory arbitration system established therein are no longer present and the conditions necessary for revisiting this matter are now*

[17] http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report8_en.pdf

were registered in Portugal in 2016, versus less than 20 cases in Germany or Italy. Currently, the MA patent linkage is still in place, however the system of mandatory arbitration involving patent holders and generic companies originally established by Law no. 62/2011 has been recently amended (Decree-Law No. 110/2018). Accordingly, (**a**) the mandatory arbitration system applicable to disputes arising from the enforcement of IPR, including preliminary injunctions, has been revoked; (**b**) the disputes concerning patent exclusive rights and generic medicines that Law No. 62/2011 has promoted must now be brought before the Portuguese Intellectual Property Court; and (**c**) said disputes may however still be subject to voluntary arbitration, whether or not institutionalized, under both parties agreement.	*met, the government opts to revoke the mandatory arbitration regime formerly established, leaving to the parties the possibility to recourse to an arbitration on a voluntary basis or to the competent court.*». There is a provision in Decree-Law No. 110/2018 that foresees a statistical analysis by the Government in 1 year «*(…) related to the functioning of the intellectual property court specifically in the context of disputes arising from the enforcement of intellectual property rights related to reference medicines*.».
Romania: Proposal on pricing methodology in Romania, which would include a conditionality of the generic price approval on the patent expiration of the reference product.	No patent linkage has been introduced so far in Romania due to the government's assessment of the European Commission's position on patent linkage.

5. Conclusions

As strongly confirmed by the European Commission, any form of patent linkage is against EU law and produces anti-competitive effects.

Patent linkage significantly delays market entry of generic and biosimilar competitors, has a negative impact on patient access, and results in additional costs to be sustained by national healthcare systems, by the generic industry and ultimately by citizens.

National authorities should comply with EU law and immediately remove any form of patent linkage as well as refrain from introducing it in the future.