Barriers to generics and biosimilar competition

factsheet

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The importance of timely competition

In the Health Council Conclusions of 2016, Member States stressed "*the importance of timely availability of generics and biosimilars*". In 2017, the European Parliament Resolution on Access to Medicines also urged to ensure timely and effective generic & biosimilar competition.

In the Pharmaceutical Strategy, the European Commission highlights the importance of "*greater generic and biosimilar competition, based on the sound functioning of the single market" and is ready to work for "the removal of barriers that delay their timely entry to market and increased uptake by health systems*".

It also stresses how "*originator companies sometimes implement strategies to hinder the entry or expansion of the more affordable medicines of their generic and biosimilar competitors" and that "this lack of competition thus inhibits price savings once innovative products lose their market exclusivities*".

The barriers to timely competition of generic & biosimilar medicines

Quality of patents – Divisionals – Patent related issue

For healthcare systems to function, it is fundamental that the patent system guarantees the **highest quality of patents** and **of patent granting procedures**. The risk, otherwise, is the creation of a multitude of secondary - often 'weak' - patents ('**patent thickets**') covering one product, with the effect of keeping competitors off the market. The EC Pharma Sector Inquiry of 2009 shows that individual medicines are covered by around 100 patent families, with up to 1300 patents and/or pending applications across EU countries.

Currently, the **patent granting process at the European Patent Office (EPO) allows a misuse of divisional patent applications…**

> i.e., whereby the patent holder, after filing a "parent" patent application, files a multitude of divisional patents, with new divisionals popping up right before the previous patent is invalidated. In this way, 'weak' patents are kept alive in order to enforce them in Court and unduly delay generic/biosimilar market entry.

…and this is considered an anticompetitive practice by the Commission in its EC Pharma Sector Inquiry.

Patent linkage – Regulatory related issue

Competition is further delayed by the practice of **patent linkage**…

> i.e., whereby regulatory/market access decisions (marketing authorisations/P&R decisions/tender bids, etc.) for a generic/biosimilar product are linked to the status of patents of the reference product.

…that, despite being considered "unlawful" by the Commission in its Sector Inquiry Report of 2009, exists in several Member States where generic/biosimilar medicines are systematically delayed. The European Parliament Resolution on Access to Medicines in 2017 urged the Commission to end patent linkage to ensure immediate market entry for generic/biosimilar competitors. This would be in line with the objective of the EU Bolar 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" (European Commission Impact Assessment on the SPC manufacturing waiver).

Market or pricing or procurement related issue

Competition may also be delayed via **market strategies**…

> e.g., cases in which originators, by using their position of power on the market, change formulation or presentation (e.g. intramuscular, cutaneous/transdermal, sub-cutaneous, etc.) of a product to shift patients to the new version and reduce the accessible market for competitors, preventing head-to-head competition of similar products.

...or **pricing strategies**...

> e.g., aggressive price cuts to make the market unattractive or unprofitable for upcoming competitors, with a reduction of competition, as new entrants will struggle to penetrate the market. Reduced or absent competition result in price increases in the medium-long term.

...or **procurement policies**...

> i.e., any form of discrimination of biosimilars vs the originator, which may take the form of slots reserved for originators, with long litigation and subsequent loss of the market for the biosimilar.

Policy recommendations

Medicines for Europe urges the Commission to ensure effective competition in the pharmaceutical sector and immediate (i.e. Day-1) generic and biosimilar market entry as soon as IP protections expire. This is the only way to guarantee sustainable healthcare systems.

The European Union is encouraged to:

- Ensure **accountability of the EPO** and the **highest quality of patents**
- Immediately urge the EPO to change its internal rules to **stop the abuses of divisional patents**
- **Ban patent linkage in EU legislation** as it systematically delays timely (i.e. Day-1) competition
- Constantly **monitor the market to tackle marketing or pricing strategies or procurement policies** aimed at or with the effect of delaying generic/biosimilar entry
- Introduce a **mechanism for national authorities to systematically claim damages caused to national healthcare systems**, in compensation for overpaying due to the lack of competition caused by the conduct of dominant companies delaying off-patent entry
- Ensure **EU harmonization of the IP Enforcement Directive on damages** to be paid to companies suffering from practices delaying competition