Position Paper

On the European Commission IP Action Plan

March 2021

Medicines for Europe welcomes the publication, on 25 November 2020, of the European Commission (EC) Intellectual Property (IP) Action Plan to support the EU's recovery and resilience.

The IP Action Plan looks at the future, focusing on IP-related matters for **Artificial Intelligence (AI)** inventions, discussion on which Medicines for Europe is ready to engage. At the same time, as stated in the plan, it is pivotal to ensure the well-functioning of the existing components of the European IP system for it to be able to produce the expected benefits and fine-tune it wherever needed.

FRAGMENTATION OF THE EUROPEAN IP FRAMEWORK

To this aim, a key priority of the IP Action Plan is to address the issue of fragmentation of the European IP framework. One of the key proposals included in the IP Action Plan is the **review of the Bolar exemption**, which results being fundamental for guaranteeing continuous supply of medicines in health emergency situations.

⇨ The **Bolar exemption** allows generic & biosimilar companies, during the IP protection of the reference product, to conduct trials and subsequent practical requirements, without considering this patent/SPC infringement, to obtain regulatory approvals and "*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*".[1]

The different transposition of the Bolar in national legislations has led to legal uncertainties as to what is allowed under Bolar, with massive disinvestments from Europe in Active Pharmaceutical Ingredients (API) development.

Seen its impact on investments for API development & production in the EU, the review of the Bolar should finally clarify all the actions allowed under Bolar, incl. API supply and administrative actions to be ready to enter the market (e.g. Marketing Authorisations, P&R listing, tender bids, etc.).

On IPR enforcement, in line with the objective to tackle fragmentation, the plan stresses the need to give effect to the EC 2017 guidance to Member States to ensure **uniform and efficient application of the conditions for granting preliminary injunctions**, including proportionality.

⇨ It is fundamental to ensure that there is a consistent EU application of the IP Enforcement Directive on ***damages for generic & biosimilar companies*** in cases of delayed off-patent competition, which in several EU Member States are very hard to obtain, discouraging competitors from entering those markets.

THE ABUSES OF DIVISIONAL PATENT APPLICATIONS

What the IP Action Plan does not directly address is the importance of **ensuring the highest quality of the European Patent Office (EPO) patent granting process and removal of the abuses of divisional patent applications**.

⇨ The ***highest quality of the patent granting process*** is vital for the credibility of the European IP system. Considering the huge societal impact of patents and their granting processes, together with

[1] European Commission Impact Assessment on the SPC manufacturing waiver, 2018, p. 15.

Rue d'Arlon 50 - 1000 Brussels - Belgium
T: +32 (0)2 736 84 11- F: +32 (0)2 736 74 38
www.medicinesforeurope.com

a clear ***political accountability of the EPO***, the EU needs to address the issue of ***abuses of the divisional patent applications at EPO*** that the EC considered anticompetitive in its Pharma Sector Inquiry Report of 2009.

Divisional patent applications are ramifications of a "parent" patent application. The EPO allows an unlimited filing of cascades of divisional patents, which are defended in EPO opposition proceedings, enforced in national courts, incl. via preliminary injunctions, and ultimately strategically withdrawn just before the EPO can decide on their validity.

This unduly prolongs the enforceable life of invalid patents, with unnecessary costly litigation and delayed generic/biosimilar entry. This practice defeats the check and balances of the system, frustrating the judicial and administrative procedures inherent in the patent system, thus prolonging the life of patents that, if reached judicial scrutiny, may not be able to stand up to it.

The EU should immediately act to stop this practice and change EPO guidelines to limit such abuses.

ORPHAN AND PAEDIATRIC MEDICINES

Medicines for Europe is also ready to support the fine-tuning of the **incentive system for orphan and paediatric medicines**, which is also a priority of the broader new pharmaceutical strategy.

⇨ Medicines for Europe supports ***orphan & paediatric incentives***, welcoming the focus of the EC on ensuring timely generic & biosimilar medicines launch (on day-1 after protections expire).

Concrete incentives to stimulate *i)* the development of generic & biosimilar versions of orphan products and *ii)* investments in off-patent paediatric medicines should be included in future EC proposals.

SUPPLEMENTARY PROTECTION CERTIFICATE

The proposal to introduce a **unitary SPC and/or a unified SPC grant mechanisms** needs careful reflection on the actual effects they would produce on the market.

⇨ Compared to the current situation, a ***unitary SPC*** would extend the geographical protection of the SPC, with serious risks for equitable access across Member States, especially those where SPCs are not registered today. These high risks can only be addressed if certain conditions are introduced in a unitary SPC proposal. On the other hand, the justification for, and benefits of, a ***unified SPC grant mechanism*** need to be clarified, since it seems to only facilitate SPC registration for SPC applicants, without addressing the actual fragmentation issues in the enforcement and litigation of SPCs. Several concrete elements and conditions should be considered in any future proposal for it to produce any benefits for patients and healthcare budgets. Medicines for Europe is willing to engage in constructive discussions to improve the IP system in Europe.

USEFUL DOCUMENTATION

* Medicines for Europe **Whitepaper**: *Anatomy of a failure to launch: a review of barriers to generic and biosimilar market entry and the use of competition law as a remedy*
* Medicines for Europe **position papers**
* Medicines for Europe **factsheets**