

INTELLECTUAL PROPERTY ACTION PLAN

ECL A2M TF Feedback to Roadmap submitted on 29 July 2020

More info here: <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12510-Intellectual-property-action-plan>

The patent system and additional mechanisms (e.g., supplementary protection certificate - SPC) protect medicines from generic competition and incentivise companies to do research and development. In the EU, a new medicine is protected from competition by for 13 years on average. In this period, the absence of competition keeps the price at a high level and companies can gain high profit margins which recover their R&D costs. This further allows them to continue investing in R&D and discover new treatments.

Although this system undeniably stimulates R&D by companies, it also has disadvantages. Growing competition, particularly related to increased availability of generics and biosimilars, significantly contributes to savings in medicine's budget, allowing for both greater availability of off-patent medicines, but also greater investments in innovative treatment options. Patents and incentives such as data exclusivity can slow down research. Researchers and companies who intend to patent an invention are not inclined to share information about their work. But sharing early research results gives an impetus to further research.

ECL Recommends to:

1. Fund pilot studies to find alternative ways to incentivise and award medicines development and ensure R&D models result in affordable products. Research should not be driven by the chase after IP but rather by societal return where valuable solutions for patients are awarded. There is little evidence analysing alternative models which are designed to bring innovative medicines at reduced and affordable prices. This uncertainty should lead to a cautious approach, particularly regarding initiatives such as delinkage, which are highly disruptive and require legal change and/or substantial change in the practice of medicine development.
2. Conduct continuous review of the European IP system (including the application of patent protection, SPC and R&D incentives) to ensure an effective stimulus for further innovation, particularly in areas of high unmet medical need, while avoiding the current affordability issues and excessive pricing spiral caused by anti-competitive practices (including pay-for-delay deals and misuse of patent protection and incentives).
3. Ensure the right balance between awarding IP incentives in orphan medicine development, particularly where there exist no treatment alternatives, and preventing unintended effects on affordability (e.g., by revoking market exclusivity when a medicine has generated sufficient return on investment; or evaluating the benefit-risk ratio of extended market and data exclusivity).
4. Enforce compulsory licences for products in case of public health emergencies (including covid-19 pandemic). If European patents with unitary effects can be granted, granting European compulsory licences must also be enabled. The EU should be able to invoke this right in public health crises, including when unavailability or limited availability of medicine/vaccine occurs, e.g., due to excessive prices or manufacturing issues.