

## European Commission Intellectual Property Action Plan

Health Action International (HAI) and Wemos welcome the opportunity to contribute to the Intellectual Property (IP) action plan put forward by the European Commission (EC) through DG Grow.

However, this consultation should not be considered in isolation from other ongoing important initiatives, such as the European Union (EU) Pharmaceutical Strategy Review and the Pharmaceutical Incentives Review. We consider it important to pay attention to how these ongoing initiatives influence each other and that policy coherence between them is assured.

In connection to the document under examination, we do not share the assumptions concerning the overall importance given to IP rights. Moreover, we consider that the full extent of its impact on society in general, and access to medicines in particular, should have been mentioned and suggest that novel IP management initiatives in response to COVID-19 should be stressed.

Regarding the use of Supplementary Protection Certificates (SPC) on pharmaceuticals, we recall the intense discussions held on the manufacturing waiver clause, which involved a wide range of stakeholders, including the European Parliament. The text that was finally approved called on the Commission to undertake an impact evaluation of SPC on access and innovation of medicines. The possibility of granting an SPC should be contingent on a number of factors. Namely, the ability of the requesting party to demonstrate, not only prejudices due to administrative or bureaucratic delays in the approval of the original patent, but evidence that costs of R&D incurred are higher than the profit during the regular patent protection period.

Critically, instruments such as SPCs and Data Exclusivity (DE) provisions, can dissuade EU Member States from using TRIPS flexibilities, including compulsory licenses (CL) or the Bolar exemption, and thereby hinders access to medicines. This negative impact must be addressed in an eventual adjustment process, including the possibility of setting up a system of waivers and exceptions for Member States.

We agree that tools to share out IP are insufficiently explored by governments and EU institutions. We also believe that any successful response to COVID-19 must be collaborative and global; the EC should endorse and proactively support the World Health Organization (WHO) COVID-19 Technology Access Pool (C-TAP), a mechanism that will hasten the development of, and improve universal access to, an effective vaccine as well as other elements of a therapeutic response, such as diagnostics. The EU invests a substantial amount of public funding into development of COVID-19 health technologies. As such, conditions must be attached to that funding by, among other things, sharing of knowledge, data and IP with C-TAP.



We concur with the Commission on the need to improve the quality and consistency of the IP protection framework and believe that a stringent innovation threshold and examination guidelines that acknowledge genuine innovation are critical steps in such a direction.

Exploring IP protection and innovation stimulus beyond patents should be a priority of this strategy, particularly in relation to the results of public-funded research and exceptional circumstances, such as pandemics, medicines shortages or other emergencies. Patents and other IP protection arrangements on innovations that have resulted from public investments made by the EC should be made conditional to safeguard public interests and ensure a return on investment. Some examples of sustainable, non-exclusive licensing in connection to COVID-19 have been mentioned by relevant units at the EC.

Trade conditionality and IP rules can have an enormous impact on access to medicines. It is therefore encouraging that the EC is seeking to promote global fair play regarding IP observance. However, we do not believe that unilaterally pressing trade partners to prevent the use of IP management tools, specifically the use of TRIPS flexibilities, is the best strategy to achieve this goal. We would also encourage further clarification of the EC position regarding Art. 31 bis of the TRIPS agreement vis-a-vis the use of CL by EU Member States.

