



Médecins Sans Frontières feedback on the European Commission’s roadmap for an Intellectual Property Action Plan

The European Commission (EC) roadmap for an intellectual property (IP) action plan lays out the need for a well-calibrated and balanced IP policy, yet it fails to recognise that granting more exclusive rights does not necessarily lead to more innovationⁱ but unambiguously discourages it.ⁱⁱ

MSF has witnessed first-hand how monopolies granted to pharmaceutical corporations result in high prices negatively impacting patient access in different countries.ⁱⁱⁱ

Patents can be a barrier for the development of new medical tools^{iv} showcased by IP disputes against Moderna^v and Inovio^{vi} stalling the development of much-needed COVID-19 vaccine candidates. Overly general language concerning the scope of the inventions in patent claims obstructs research efforts for medical tools.^{vii} The European Patent Office (EPO) has granted such broad patents despite their unmerited legal and scientific basis.^{viii}

Prolonged market monopolies on medical tools through patent evergreening undermine the fiscal sustainability of national healthcare systems. Unacceptably, the EC has not delivered a study on the impact of Supplementary Protection Certificates (SPCs) on access to medicines requested by the EC Council.^{ix} Our analysis shows that SPCs upset the balance between commercial and public interests. Pharmaceutical companies do not need SPCs to recoup investments on research and development (R&D) as claimed. SPCs consistently prolong market exclusivity and delay the availability of affordable generic medicines in Europe, potentially causing unnecessary suffering or death for patients. This calls for a more fundamental review rather than a consolidation of the SPC system in Europe.^x

Even in case of a health emergency, European Union (EU) law fails to provide safeguards to waive data exclusivity and market protections to allow effective use of compulsory licensing.^{xi} EU member states also declared themselves not eligible as importers for TRIPS Article 31*bis* hampering effective use of compulsory licensing.^{xii}

The COVID-19 pandemic highlights how IP and other exclusivities are an impediment to accessing treatments, diagnostics and vaccines. A growing number of countries, including EU member states, are prepared to overcome monopoly control over medical tools to address the pandemic, an effort that should be supported by the EC.

MSF strongly supports **mandatory open sharing of technologies for COVID-19 related health technologies, knowledge and data**,^{xiii} to boost the R&D of new medical tools, and expand and diversify production and supply capacities by enabling multiple manufacturers to produce. However, IP is a key challenge to this end. MSF produced a briefing document on overcoming IP monopolies to enable the sharing of COVID-19 technologies, knowledge and data.^{xiv}

Stringent IP enforcement measures and insufficient safeguards threaten or delay the availability of treatments and vaccines. Recommendations for law and policy reform need to be incorporated into the IP action plan to address the pandemic and beyond, such as:

- introduce a waiver for data exclusivity to ensure effective compulsory licensing in the EU^{xv} and encourage the EU member states to restate the eligibility for import under Article 31*bis* of the TRIPS Agreement
- raise the bar on patent quality at EPO to counter the granting of unmerited patents
- stop the proliferation of secondary patents and evergreening practices
- end the imposition of the EU's Intellectual Property Rights (IPR) system to trading partners and developing countries
- commission an independent study of the impact of the SPC system on access to medicines as part of a legislative review of the SPC system
- map EU IP and legal barriers to the global sharing of COVID-19 technologies, knowledge and data; and develop a roadmap to enable a global right to use and produce essential COVID-19 technologies

ⁱ Qian, Yi, *Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection, 1978-2002*. Review of Economics and Statistics, Vol. 89, No. 3, 2007. Available at SSRN: <https://ssrn.com/abstract=1024829>

ⁱⁱ Moser P. *Patents and Innovation in Economic History*. Social Science Research Network: January 2016. Available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2712428

ⁱⁱⁱ MSF Access, *Hepatitis C - Not even close*, 2017. Available at: <https://www.msfacecess.org/hepatitis-c-not-even-close>

^{iv} European Commission, *Communication from the Commission. Executive Summary of the Pharmaceutical Sector Inquiry Report*, 2009. Available at : https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf

^v Third World Network, *TWN Info Service on Intellectual Property Issues (Aug20/01)*, 03 August 2020. Available at: https://www.twn.my/title2/intellectual_property/info.service/2020/ip200801.htm

^{vi} Third World Network, *TWN Info Service on Intellectual Property Issues (Jul20/04)*, 16 July 2020. Available at: https://www.twn.my/title2/intellectual_property/info.service/2020/ip200704.htm

^{vii} MSF Access Campaign, *A Fair Shot For Vaccine Affordability*, 2017. Available at: <https://www.msfacecess.org/fair-shot-vaccine-affordability>

^{viii} MSF Access Campaign, *Lethal monopolies - How pharma games the patent system to maximise profits*, 2020. Available at: <https://www.msfacecess.org/lethal-monopolies-how-pharma-games-patent-system-maximise-profits>

^{ix} Council of the EU, *Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States*. Press release, 17 June 2016. Available at:

<https://www.consilium.europa.eu/en/press/press-releases/2016/06/17/epsco-conclusions-balance-pharmaceutical-system/>

^x Hu, Y., Eynikel, D., Boulet, P. *et al.* Supplementary protection certificates and their impact on access to medicines in Europe: case studies of sofosbuvir, trastuzumab and imatinib. *J of Pharm Policy and Practice* **13**, 1 (2020). Available at: <https://doi.org/10.1186/s40545-019-0198-6>

^{xi} Letter from the EC to European Generic Medicines Association on the subject of ‘Tamiflu application and data exclusivity in an emergency compulsory license situation’, 2006. Available at: <http://www.cptech.org/ip/health/dataexcl/ec-de-tamiflu.pdf>

^{xii} KEI, *Open letter asking 37 WTO Members to declare themselves eligible to import medicines manufactured under compulsory license in another country, under 31bis of TRIPS Agreement*. 07 April 2020. Available at <https://www.keionline.org/32707>

^{xiii} MSF Access Campaign, *Position Paper Mandatory open sharing of technologies for COVID-19 to ensure equitable access for all*, 2020. Available at: <https://www.msfacecess.org/msf-access-campaign-position-paper-sharing-technologies-covid-19-ensure-equitable-access-all>

^{xiv} MSF Access Campaign, *Overcoming intellectual property monopolies in the COVID-19 pandemic*, 2020. Available at: <https://www.msfacecess.org/overcoming-intellectual-property-monopolies-covid-19-pandemic>

^{xv} ‘t Hoen *et al* *Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation*. In *Journal of Pharmaceutical Policy and Practice* (2017) 10:19 Available at: <https://doi.org/10.1186/s40545-017-0107-9>