

## How to increase access to medicines at the Crossroads of Public Health, Intellectual Property and Trade

The global nature of the pharmaceutical industry and its supply chains entails the huge importance of international trade for the well-functioning of public health systems. Indeed, not only bilateral, but also plurilateral and multilateral trade talks represent a great opportunity for the pharmaceutical industry and national health systems to remain resilient, especially - but not only - when health emergencies occur. Continuity to supply of medicines worldwide is vital and Covid-19 has been a clear example of the importance of such an international cooperation to tackle the vulnerabilities of the pharmaceutical industry's global supply chains, particularly in the areas of raw materials, manufacturing, transportation, and logistics.

International trade, in fact, contributes to shaping national or regional norms in the interest of an unrestricted import and export of products between different regions of the world. However, free trade agreements (FTAs) - and trade talks more generally - have been focusing mainly, on the one hand, on removing tariff and non-tariff barriers, but on the other hand on committing to a sophistication of rules for the protection of intellectual property (IP) rights.

### **The switch of focus in FTAs**

However, recent bilateral negotiations (e.g. trade talks between [EU and US](#), [EU and Canada](#), or [US, Mexico and Canada](#)) have shown that better outcomes for patients and health systems can be achieved by softening the focus on IP right related measures and strengthening regulatory cooperation initiatives. This aims at reducing unnecessary burdensome regulatory procedures and optimising the use of resources for industry and regulatory authorities, by for instance adopting mutual recognition agreements, regulatory reliance, or by reducing the need for unnecessary - and therefore unethical - duplicative clinical studies in different regions of the world for the same product. In parallel, negotiations to strengthen the resilience of the pharmaceutical supply chain seems to be of utmost importance to keep trade going but also to allow the industry to immediately react when emergencies occur.

### **Balancing IP and competition**

While it is becoming rather clear to all stakeholders that efforts should be put on harmonisation or convergence of regulatory requirements and practices to stimulate availability of medicines into the markets, what does not seem to be under the radar of trade negotiators is the need to balance out the existing rules on the protection of IP rights in order to ensure timely and healthy competition on the markets. An additional potential issue related to IP is the way FTAs are implemented at national level after the FTA is adopted. The introduction of novel IP mechanisms, if unbalanced, can result in systemic delays to patient access to generic and biosimilar medicines.

The study on "[Promoting Access to Medical Technologies and Innovation](#)" that results from the ongoing [trilateral cooperation](#) between World Health Organisation (WHO), World Trade Organisation (WTO) and World Intellectual Property Organisation (WIPO) stresses the importance of competition law and policies. It makes reference to the strategies used by patent holders to extend as much as possible exclusivities by delaying generic and biosimilar medicines market entry and the role that competition law, enforcement and policies play to correct these practices and effectively stimulate innovation.

In several regions of the world, especially those with more sophisticated IP systems, governments are considering corrective measures to limit the effects of IP rights misuses. To this end, a significant [cooperation between the Food and Drug Administration \(FDA\) and the Patent and Trademarks Office \(USPTO\)](#) has recently

started in the United States to tackle abuses of divisional patents<sup>1</sup> and evergreening<sup>2</sup>. In Europe, a review of the legislation on pharmaceuticals and competition investigations are addressing the different layers of protection.

### Where are we heading?

The credibility of those IP systems that provide the strongest protection is therefore at stake. However, surprisingly, in parallel there is a continuous attempt to strengthen IP protections (e.g. via patent extensions, patent linkages, etc.) even in countries whose healthcare systems would not be able to sustain it. A [study](#) on the impact of 8 IP-centered trade agreements has shown that they contributed to \$622 billion in lost savings.

Keeping in mind that a balanced IP system requires well-functioning granting and enforcement procedures embedding the right guardrails and safeguards for the sake of timely patient access and long-term sustainability of healthcare systems, a question remains unanswered: when will we see competition policies become driving pillars of trade negotiations?

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<sup>1</sup> Divisional patent applications are those deriving from an earlier patent application (the "parent"), which the applicant splits into a sequence of divisional applications each claiming a single element of the same claimed invention. Divisional applications, themselves, can give rise to further multiple divisional applications, without any limitation. Each divisional patent lasts until the expiry date of the parent patent, but is subject to new examination procedures and, if granted, new opposition periods independently from the outcome of the parent application.

<sup>2</sup> "Evergreening" is a term used to refer to strategies by which pharmaceutical companies extend the lifetime of their patents to maximise revenues from them.