



TRIPS FLEXIBILITIES AND ACCESS TO MEDICINES

A European Approach

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THE INCREASING ECONOMIC BURDEN OF PHARMACEUTICAL PROCUREMENT

Medicines are an essential element in improving our health and well-being, and affordability is critical to making universal health coverage a reality. In the European Union (EU), sky-rocketing prices of new, patented medicines are straining public health budgets and jeopardising access.

This brochure focuses on the use of intellectual property (IP) management tools to improve access to safe, effective and quality-assured medicines. The legitimate use of these tools to achieve public health goals should not be considered exceptional or limited to a specific geographical area or disease, but widespread and growing given that low-, middle, and high-income countries, alike, face increasing economic burdens linked to the procurement of pharmaceuticals. There is also growing pressure from patient groups and other stakeholders to make use of instruments, such as compulsory licences.

The TRIPS Agreement

IP rights, in general, and patents, in particular, play a critical role in the current biomedical R&D model. In the current system, innovation is rewarded with a time-limited monopoly to commercially exploit a given invention, which may include setting high prices.

Prior to the introduction of the *Trade-related Aspects of Intellectual Property (TRIPS) Agreement*, an international legal agreement negotiated in 1994 and part of the founding legal framework of the World Trade Organization, many low-, middle, and high-income countries had excluded pharmaceutical products and/or processes from national patent legislation as part of public health and industrial policies.

With the introduction of the TRIPS Agreement, the international community agreed, for the first time, a multilateral covenant to set common standards for IP protection across all technological fields. In practice, this meant that exempting certain areas or products (including food and medicines) was no longer possible for WTO Members.

Over time, what was supposed to be a common ceiling became a launch pad for extension of IP protections, with the TRIPS Agreement being used by the European Commission and EU Member States as the basis upon which to negotiate bilateral and multilateral trade agreements. These so-called ‘TRIPS-plus’ measures include steps that reduce the scope or effectiveness of provided limitations and exceptions in IP rules and regulations. Requirements, such as supplementary protection certificates (SPCs) and other forms of market exclusivity, are pushed during EU free trade negotiations to increase the level of protection for patent holders beyond the levels prescribed by the TRIPS Agreement.

TRIPS Flexibilities

TRIPS flexibilities are ‘policy spaces’ for countries to mitigate the impact of patents (i.e., the excessively high price of patented medicines due to lack of competition). Acknowledged in the original text of the TRIPS agreement—particularly

Article 30 (Exceptions) and Article 31 (Licences)—they were confirmed and given more detail and weight in the subsequent *Doha Declaration on TRIPS and Public Health* of 2001.

Alongside other IP-related tools, TRIPS flexibilities are an effective tool to promote and achieve public health goals, such as affordable access to life-saving medicines. They also include provisions for clinical data protection, which is crucial for producing and marketing generic and biosimilar medicines. The threshold protection currently in force in the EU is higher than that laid out by the TRIPS Agreement.



The Use of TRIPS Flexibilities in Europe

At a time when rising medicine prices make it more difficult for governments to guarantee the human right to health of their citizens, policy-makers must use all legal and policy tools at their disposal to protect and promote public health. European governments face challenges in the use of legal and administrative instruments that could counter the negative effects of excessive IP protection measures; however, these barriers can often be overcome.

Opportunities³: Compulsory licensing and other health oriented IP-related tools offer European governments the opportunity to protect public health where patents are an obstacle to doing so. They can also be used to guarantee fair competition and counter market abuses.

Obstacles: While patent law is essentially a national competence, there is an overarching European legal framework related to medicines

regulation that introduces additional forms of protection. Examples include:

- Regulatory test data exclusivity
- SPCs
- Market exclusivity for new products, orphan products, products for children, or new indications

These forms of non-patent exclusivity can hamper the effective use of TRIPS flexibilities and are detrimental to generic competition.

Constraints: EU regulation of clinical trial data protection—combined with the granting of market exclusivity for certain drugs and formulations—not only interferes with the effective use of compulsory licensing and other tools, but also makes it more difficult to use mechanisms, such as the Bolar Clause, to accelerate the entry of generics onto the market. This may make access to off-patent medicines more difficult.

There is no need to go beyond Article 39.3 of the TRIPS Agreement in protecting undisclosed commercial information from rival commercial use. Longer market exclusivity periods, as embodied by SPCs, have not shown a positive tangible impact on fostering innovation, but have proved harmful to access conditions.

A waiver to the exclusivity rules found in EU *Regulation on Compulsory Licensing of Patents for the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems* was enacted to implement paragraph six of the *Doha Declaration*, and is currently a permanent amendment to the TRIPS Agreement.² Certain trade agreements concluded by the EU (such as that with Peru) also refer to the possibility of exceptions.

The EU has committed itself to the achievement of the Sustainable Development Goals (SDGs). Among them, SDG3 (to ensure healthy lives and promote well-being for all), has several targets for which the use of TRIPS flexibilities is critical.

PUBLIC HEALTH-RELATED TRIPS FLEXIBILITIES AND OTHER IP-RELATED TOOLS¹

FLEXIBILITY	TRIPS ARTICLE	DESCRIPTION
Parallel imports	6	Goods legitimately placed on another market may be imported without permission of the rights holder, as long as the patent holder's rights have expired.
Patentability criteria	27	World Trade Organization members may develop their own criteria for novelty, inventive step, and industrial application.
General exceptions (including research exception or 'Bolar clause')	30	<p>World Trade Organization members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent holder.</p> <p>The Regulatory Review Exception also permits the use of a patented invention before the patent expires for the purpose of obtaining marketing approval of a generic product for commercialisation once the patent expires.</p>
Compulsory licensing	31	A non-voluntary licence may be granted by a duly authorised administrative, quasi-judicial, or judicial body to a third party to use a patented invention without the consent of the patent holder, subject to the payment of adequate remuneration dependent on the circumstances of each case.
Compulsory licensing for export purposes	31bis	Additional protocol for WTO members that do not have pharmaceutical manufacturing capabilities.
Government use	31	A government authority may decide to use a patent without the consent of the patent holder for public, non-commercial purposes, subject to the payment of adequate remuneration in the circumstances of each case.
Competition-related provisions	8 31(k) 40	Members may adopt appropriate measures to prevent or remedy anti-competitive practices relating to IP. These include compulsory licences issued on the basis of anti-competitive conduct and control of anti-competitive licensing.

COMPULSORY LICENCES

A Global Perspective

Since 2001, compulsory licensing of medicines has been used 34 times in 24 countries. Meanwhile, there have been 51 instances of government use of patents by 35 countries, with a peak between 2004 and 2008.

Between 2011 and 2016, there were approximately 100 instances of compulsory or government use of these tools, with 81 being implemented. While most were used to accelerate access to antiretrovirals (ARVs), a growing number of countries are turning to the use of TRIPS flexibilities to facilitate access to treatments for non-communicable diseases, such as cancers and cardiovascular diseases.

Although originally focused on HIV, 23 out of 85 compulsory licence and government use instances have concerned non-HIV medicines. This includes seven licences or uses for cancer medicines between 2008 and 2014, of which five were granted.⁵

WHAT POLICY-MAKERS CAN DO TO IMPROVE ACCESS TO MEDICINES

Using TRIPS Flexibilities

National authorities must make use of all available tools and instruments that secure and improve access to medicines, especially those that would ensure the financial sustainability of health systems by promoting competition in the pharmaceutical market. By taking the tried and tested step of implementing the flexibilities described above, governments have the ability to protect the human right to health of their citizens. Considering that this has worked for ARVs, there is no legal reason why it should not work with other life-saving medicines.

Within the context of the EU, Member States have the power to instruct the European Commission to abstain from including TRIPS+ and other clauses that might erode the possibility of using TRIPS flexibilities. These measures are not only harmful to public health goals of EU trade partners, but are an obstacle to future revision of the EU IP protection framework.

NATIONAL EXAMPLES^{4,5}

- Between 1969 and 1992, Canada issued 613 compulsory licences for importation and/or local production of medicines as part of cost/containment measures.
- The United States Human and Health Services (HHS), facing the threat of bioterrorism, used the possibility of issuing a compulsory licence on Cipro if its patent holder, Bayer, did not lower its offering price. (It did.)
- Brazil achieved a 72.5% reduction in the price of ARVs through import substitution from 1996 to 2000.
- Thailand issued a compulsory licence on ARVs in 2006 and, in 2008, a compulsory licence on anti-cancer medicines, letrozole, docetaxel, erlotinib, and imatinib.
- A German court issued a compulsory licence for the ARV, Raltegravir, in 2016, citing “public interest of patients and health risks associated with the potential non-availability of the drug”.
- In September, 2017, Malaysia issued a compulsory licence (for government use) of sofosbuvir for the treatment of hepatitis C.
- Civil society in Switzerland, Romania and Colombia, among others, have conducted campaigns demanding the enactment of compulsory licences for a variety of medicines.

The European Parliament must also demand that the European Commission and Council explicitly support the inclusion of TRIPS flexibilities in operational paragraphs of WHO resolutions and other documents relevant to the *Global Health and Agenda 2030*.

Implementing Other IP-related Tools

The use of TRIPS flexibilities is not the only IP-related intervention at the disposal of national authorities for the fulfillment of a public health agenda that promotes access to medicines. Other measures can be taken at different stages of the R&D production-procurement continuum, and typically involve different government departments and institutions.

For example, health products resulting from public-funded research (at universities or government-funded laboratories) must be made available in the most affordable way. Licensing agreements can be the best option to exploit a given invention while also ensuring affordability.

Patents should only be granted when promoting genuine innovation. Patent opposition is a legitimate precaution to avoid granting monopoly rights to undeserving products. Secondary patents for marginal incremental innovations may have a detrimental effect on the access to innovation and hinder future activities by effectively blocking access to knowledge.

But equitable and affordable access to medicines does not depend on IP alone: Manufacturing practices, supply conditions, efficacy and safety also play a role. Therefore, in addition to, and in combination with, our work to promote public health-oriented approaches to IP in the EU, Health Action International:

- Advocates for the rational use of medicines.
- Builds awareness and support among policy-makers about alternative models of biomedical R&D to replace the current profit-driven and patent-centred system.
- Promotes increased cooperation among EU Member States on HTA, as well as more transparent joint medicine price negotiations and procurement.

About Health Action International

Health Action International is a non-profit organisation that conducts research and advocacy to advance policies that enable access to medicines and rational medicine use for all people around the world. We pursue advocacy from the patient level up to the highest levels of government through our 'official relations' status with the World Health Organization (WHO) and respected relationship with the EU and the EMA. To safeguard our objectivity and integrity, we are resolutely independent of the pharmaceutical industry and protect ourselves from all other conflicts of interest.

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