

# 03

## Patents and access to medicines and other health technologies

**A patent is a form of intellectual property (IP)<sup>1</sup> granted on inventions. As intellectual property rights strengthen globally, patent protections and their impact on medicines have raised serious concerns as exorbitant prices have denied access to treatment for millions across the world.**

### **The international legal framework for patent protection**

Although the laws of most countries already included patent protection, the World Trade Organization (WTO) that was created in 1995 led to a new international benchmark through its Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). All Member states must abide by this minimum standard for intellectual property (IP) protection. In the field of patents, Member states are required to grant protection for a minimum of 20 years, to any inventions in any field of technology as long as the patent fulfill the criteria of novelty, inventiveness and industrial application.

In the field of medicines, this applies to any pharmaceutical product or process. Once a patent is granted, patent holders then get exclusive rights which means they can stop generic competitors from making or importing medicines or other pharmaceutical products.

A patent is granted by a patent office (or an institute for industrial property, or an institute for intellectual property, depending on the country). This patent applies only on the territory of the country (or of the region in the case of regional agreements<sup>2</sup>) – there is no patent that applies globally.<sup>3</sup>

### **Countries that grant patents**

At present there are 164 countries that are members of the WTO. Depending on their economic development countries had different deadlines to implement the TRIPS agreement and adapt their laws: “developed” countries had until 1996, “developing” countries until 2000, “least developed countries” (LDC) had until 2006.<sup>4</sup> This transition period has been extended twice for LDC: in 2005, the TRIPS Council extended the period until 1 July 2013, and in 2013 it extended it further until 2021 – or countries cease to be in the least developed category if that happens before 2021.

For pharmaceuticals, a declaration adopted by the WTO in 2001 on TRIPS and Public Health (referred as “the Doha declaration”)<sup>5</sup> had authorized LDC not to apply protection until

1. “Intellectual property rights” is an umbrella term for various forms of intellectual property such as patents, copyright and related rights, trademarks, geographical indications, industrial designs, etc. The subjects of intellectual property are creations of the mind like a song or a poem or inventions. Through laws, these creations of the mind are protected for a certain amount of time to prevent others from using that “intellectual property” without permission or payment to the one owning it. At the origin of the establishment of these monopolies and exclusive rights was the will to ensure certain economic conditions to the inventors or authors. Nowadays, it is often the case that the ones enjoying the benefit of intellectual property rights are not the inventors or authors.

2. *Regional Patent Offices include the European Patent Office (EPO), the African Regional Intellectual Property Organisation (ARIPO) African Intellectual Property Organisation (OAPI), and the Eurasian Patent Organisation (EAPO). They centralize some or all aspects of patent applications and grant them for their member states.*

3. There is however an application process under the Patent Cooperation Treaty (PCT) through the World Intellectual Property Organization (WIPO) that facilitates the filing of patent applications in the 191 countries that are members of WIPO.

4. However many “least developing” countries already implement WTO IP standards and have not made use of the transition period – often due to advice, technical assistance or pressure from developed countries.

2016. In November 2015, the TRIPS Council further extended this transition period until 2033, or when countries cease to be in the least developed category if that happens before 2033.

Developing countries that did not grant patent protection for pharmaceutical products when TRIPS came into force had until 1st January 2005 to introduce such protection. In exchange, since 1st January 1995, they had to establish a “mailbox” system. Under this system, applications for pharmaceutical product patents could be filed and stored by the patent office which had to start assessing these applications by January 2005.

Even countries that are not WTO members often grant patents. Some that are negotiating to join the WTO have already complied with TRIPS under questionable technical assistance while some grant patents under laws that were put in place when they were colonised.

### Before TRIPS

Before the implementation of the WTO standards the duration of patent in many countries was significantly shorter. Many countries also did not provide only process patents – but not product patents. Product patents provide for protection of the active chemical product involved, whereas process patents provide protection in respect of the technology and the process or method of manufacture. Protection for process patents would not prevent the manufacture of patented products by a different process, for instance developed through reverse engineering. National legislations requiring only process patent protection have enabled manufacturers in certain countries to make generic versions of patented medicines. This is how India became the biggest producer of pharmaceutical products in the world. In France the patenting of medicines was forbidden before 1959. In Germany it was forbidden until 1967. In Switzerland, patents on processes were authorized in 1907, but patents on products only in 1977.

### Impact of patents on access to medicines

The granting of a patent is dependent on adequate disclosure of the invention. This is a key justification of the social contract on which the patent system was originally based. In exchange for the disclosure to society of an invention, the inventor then obtains exclusive rights on the market. In practice however, the exclusive rights granted on a patent translate into a monopoly on the market. Although medicines are sometimes called (or should be considered and treated as) public goods, or commons, the laws essentially treat them as product of the market.

Article 28 of the TRIPS agreement states that: *“where the subject matter of a patent is a product, to prevent third parties not having the owner’s consent from the acts of: making, offering for sale, selling, or importing for these purposes that product”.*

As a consequence a drug company that holds patents on a medicine has the right to prevent others from manufacturing it and therefore can charge an artificially high price. As they can prevent, restrict or control competition, patents can therefore have a dramatic impact on access to medicines.

In countries where people pay for drugs out of their own pockets, the high price of medicines becomes a question of life and death. In countries where patients are covered by social security system, it is now the health systems that are burdened and put at risk by the price of recent life saving treatments. A UN report from international experts recently published a report raising the alarm and making clear recommendations to government (in particular on the importance of transparency in prices, the use of international trade flexibilities, including to lift patent protection when needed (see factsheets on Compulsory licensing and on Flexibilities), and safeguards in trade agreements<sup>6</sup>.

5. [<http://www.who.int/medicines/areas/policy/tripshealth.pdf?ua=1>].

6. It can be accessed here: [<http://www.unsgaccessmeds.org/final-report>].

## Generic competition to reduce the prices

Competition between different producers is the most effective and sustainable way to bring down the price of a drug.

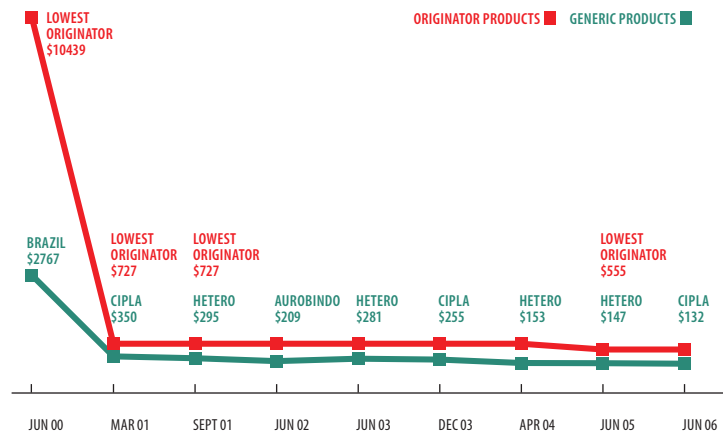
Antiretroviral treatment for HIV/AIDS provides a perfect illustration of how patents allow companies to keep the price of medicines high, and how competition can bring those prices down. At the end of the 1990s a triple combination HIV treatment, only sold by companies that hold patents, cost more than US\$ 15,000 per person per year; the best discount available was US\$ 10439. Generic production started in several countries where the medicines were not under patent, which allowed government producers (Brazil, Thailand) or private companies (India) to legally manufacture generic versions of these medicines. With competition among multiple producers, prices started to decrease significantly. The affordable generics were exported, mostly from India, to other developing countries. A 99% price reduction was possible in a few years. Today, the

most commonly used triple-drug AIDS treatment in the Global South costs less than US\$100 per patient and per year.

It is important to note that a generic medicine is the equivalent of a patented or brand name medicine which means it has the same active ingredients and the same effect in the body.<sup>7</sup> For instance, in the case of tenofovir, pharmaceutical MNC Gilead and the Indian generic company Cipla make the same medicine. But the product is sold under different names or brands by the different companies. If two medicines are the same, the same international non-proprietary name or INN should appear on the packing of the two medicines.

Researchers in the UK have recently estimated the generic price for a wide range of medicines from the Essential Medicines List of the World Health Organization (WHO). It shows that these drugs could be manufactured at very low cost, often at a fraction of the price of the brand name products and much lower than generic product when competition does not apply between several sources.<sup>8</sup>

**FIGURE 1** The fall in the price (US\$ per patient per year) of the first-line combination (stavudine [d4T], lamivudine [3TC], and nevirapine [NVP]) since 2000. Source: Médecins sans frontières.



7. Here are useful reference on generic medicines: for HIV, Waning B, Diedrichsen E, Moon S. "A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries". *J Int AIDS Soc.* 2010 Sep 14;13:35. [<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2944814>]. For PEPFAR: "The Power of Partnerships: Fourth Annual Report to Congress on PEPFAR", *Annual Report to Congress, The United States President's Emergency Plans for AIDS Relief*, 2008.

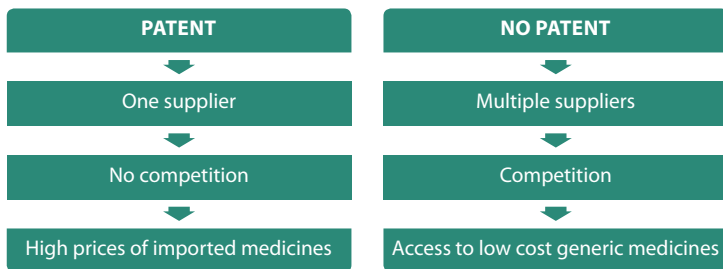
8. Hill AM, Barber MJ, Gotham D. "Estimated costs of production and potential prices for the WHO Essential Medicines List". *BMJ Glob Health* 2018. Accessible at: [<http://gh.bmj.com/content/3/1/e000571>].

### The growing price crisis

Key countries where generics are produced now grant product and process patents on medicines, in order to comply with their obligations as members of the WTO. Newer drugs are already patented in these countries including new ARVs, Hepatitis treatment, cancer treatments, etc. As a consequence production or importation of affordable generic medicines is now restricted.

Without generic competition, newer life-saving medicines will quite simply be priced out of reach for many people and kept out of reimbursement schemes. For HIV/AIDS, successful AIDS treatment programs are put at risk. For hepatitis C, new treatment (Direct Acting Antivirals) is prescribed to a limit number of people when they could cure the majority of people living with the virus. In the meantime, the global pattern of disease is changing: chronic or non-communicable diseases, such as cancer, diabetes or cardiovascular disease are rapidly increasing in the Global South, but the most efficient treatments are patented and often extremely expensive (cancer treatments often cost more than US\$ 100,000 per patient and per year).

FIGURE 2 Relation between patent protection, competition and prices of medicines



If the TRIPS agreement imposes protections also provide flexibilities to patent right that countries that use in order to produce or import generic medicines (see factsheet on Flexibilities).

However, developing and least developed countries must exercise caution in bilateral and regional trade negotiations where attempts are being made to impose stronger patent regimes and other rights (see factsheet on TRIPS+ provisions) reinforcing the capacity of pharmaceutical companies to have monopolies, impose expensive prices and prevent price control, and restrict or entirely prevent generic competition.