



SOVEREIGNTY: THE BEST MEDICINE AGAINST COVID-19

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Many of the drugs currently under clinical trial to treat COVID-19 are protected by patents that could render them unaffordable for a great part of the world's population. Argentina has legal instruments that could help guarantee access to these and other medical technologies. How do they work?

These instruments **are called health flexibilities and are useful to restrain monopolies generated by the current production and commercialization system around the world, based on intellectual property rights which leave the definition of "health needs" in hands of the market (because development is profit-oriented, leaving out health priorities), boost power concentration in a few companies that manage to patent their products and pause industrial development in less developed countries.**

These rules were established by States member of the World Trade Organization (WTO) during the Uruguay Round (1986-1994), in the **Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement**,^{www} subscribed by Argentina in 1994. This agreement establishes that patent holders can exclude others from producing, commercializing and importing patented products for a minimum of 20 years. The agreement also includes flexibilities so each sovereign State be free to set the most convenient method to apply the agreement's provisions, and hence protect public health, in compliance with their own legal system.

One of these flexibilities is patent opposition that can be filed when **patent applications filed by companies before patent offices do not meet the legal requirements necessary for that property right to be granted.** In fact, since this intellectual property system started to be in force, most patent applications filed by multinational pharmaceutical companies are not eligible for such patents (even when in some countries they get them anyway) , because they abuse the patent system with the sole purpose of extending and perpetuating monopolies on the drugs. Thus, **patent opposition is the instrument that Fundación GEP uses in Argentina, to contribute to the evaluation of applications and warn the National Institute of Industrial Property (INPI), the patent office, when a multinational company is attempting to obtain a patent on a relevant drug but does not meet the requirements.** This instrument proved to be key in the rejection of many patent applications that in 2017 Gilead filed for sofosbuvir, a drug that cures hepatitis C.

Fundación GEP has also filed patent oppositions for many drugs to treat HIV. It is thanks to this opposition that **in 2015 the patent application for the combination of antiretroviral lopinavir-ritonavir was rejected. This combination is currently the main treatment for patients with COVID-19.** In 2015, the laboratory that was developing the drug (Abbott/AbbVie) tried to extend the monopoly on the drug for 8 years, through an illegitimate strategy known as evergreening, which consists in filing successive patents on drug combinations known and patented. In the case of lopinavir-ritonavir, the laboratory had developed the same pill with the characteristic of being heat-stable, and intended to patent it again. Another instance in which laboratories usually appeal to file new patents on the same drugs is when they discover that such drugs can be used to treat different diseases.

“The contribution of Fundación GEP, as well as of national companies involved in production, was key in both cases. **We provided indispensable arguments so the National Institute of Industrial Property (INPI) could make the decision by which the State acquired sofosbuvir at a reduced price; ten times lower than the price initially imposed by the producer** that had a monopoly at the time. This saved more than 125,000 dollars in the first purchase of lopinavir/ritonavir, after the patent application was rejected”, recalls José María Di Bello, President of Fundación GEP, and he adds, “When we managed to contribute to stopping the abuse intended by the pharmaceutical company of extending their monopoly on lopinavir/ritonavir, we celebrated. We never imagined what it would mean today to save the life of hundreds of people infected with COVID-19. **The key is to withdraw medicines from the orbit of the WTO, since medicines are not merchandise; they are social goods that guarantee access to our right to health**”.

ARGENTINA AGAINST MONOPOLIES

Oppositions stop the granting of abusive patents. But even if patents have already been granted, the agreement includes other kind of flexibilities that support countries in limiting the exclusive rights of patent holders in cases of emergency and public health needs, to ease the access to drugs in affordable generic versions. **Such is the case of compulsory licensing, similar to licenses of non-commercial public use (or governmental use) that, as its name states, help governments use the patented product without lucrative purpose or in non-commercial activities, such as public research.** “In neither of these cases it is necessary to previously negotiate with the patent holder”, says lawyer Lorena Di Giano, Executive Director of Fundación GEP, and she explains that these licenses do not refrain patent holders, in this case pharmaceutical companies, from exploiting them while in force. “The system envisages that third parties authorized to produce and commercialize the product while the license is in force must pay reasonable royalties to the patent holder”, she specifies.

Compulsory licensing is when a government allows someone else to import, produce and commercialize the patented products. Compulsory licensing also allows governments to produce, import, and locally purchase diagnosis equipment, vaccines or patented medicines, especially when they are products that cannot be substituted (it would be the case of remdesivir).

“By issuing these licenses, governments allow the entry of competitors in the market, which undoubtedly contribute to price reduction and guarantee accessibility to everyone, regardless of their economic position, but relying on their health needs”, states Di Giano, who specializes in intellectual property, and explains that **these licenses must not be mistaken for voluntary licensing mechanism, by which transnational companies globally manipulate the medicine market, because since they are voluntary, companies can decide who will produce or commercialize the products and to whom they are destined.**

“Generally, patent holders use these mechanisms to allow the production of generic versions that can only be sold in low income countries, excluding the

rest of the countries. That is what Gilead announced this week, authorizing a few companies in India to produce remdesivir, but excluding South America from the list of countries that can buy these generic versions, depriving 440 million people of the access to treatment against the new coronavirus”, explains Di Giano.

The use of compulsory licensing was recognized by most patent laws adopted by WTO members, once TRIPS was subscribed. In fact, they have largely been used in the United States to avoid uncompetitive behavior, and have been applied to respond to public health needs, in relation with pharmaceutical products in Germany and Italy, mainly for antiretrovirals and drugs to treat HIV, but also in medicines to treat cancer, and anticoagulants, among others. Developing countries have also used these flexibilities, despite the opposition and pressure on part of governments and industries. In Latin America, for example, **Brazil used this flexibility in 2007 on antiretroviral efavirenz, and thanks to this the price was reduced in more than 60% of the price of the original version of the company owner of the patent.**

“In Argentina, these flexibilities can be issued in critical situations like the current one and to avoid uncompetitive commercial practices, or for the purpose of research, as the National Patent Law 24,481 indicates”, exemplifies Di Bello, President of Fundación GEP. “In case it is necessary, the National Executive Power can issue compulsory licenses to guarantee access to medicines, supplies and other health technologies. All they have to do is use the mechanism established by section 70 in law 27.541, which declares the health emergency; and decree 260/2020, which extends the emergency to the COVID-19 pandemic”, he adds.

