

The importance of patents and know-how in the pharmaceutical sector during Covid pandemic

How to match intellectual property rights with the universal right to health to guarantee to the inhabitants of least developed countries the administration of the anti-Covid vaccine

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Patents confer a monopoly regime, for a limited period of time of 20 years in order to allow the owner of the patent right to recover the investments made for the development of the patented technology. These investments are particularly huge in the pharmaceutical sector. However, thanks to the patent system, pharmaceutical companies can continue to have the resources to study and develop new and more effective compounds in the fight against diseases, old and new, dedicating huge resources to them.

Covid-19 vaccines are based on advanced research and development, know-how and trade secrets. The parties involved, the technologies, the raw materials used are many and the background of knowledge is articulated and complex. Just think of the bioreactor technology used for the production of mRNA vaccines. Patents facilitate the signing of agreements between the parties involved - often globally - for the production and distribution of vaccines in a short time: without the return guaranteed by the exclusive rights, the interest in investment and agreements would be lacking.

In 2020, some least developed countries, as India and South Africa, asked for a temporary suspension of the intellectual property rights that protect vaccines against Covid-19, triggering a heated debate also in relation to the widespread opinion that patents were the main cause of the shortage of vaccines and the delays in their distribution around the world.

These requests were unsuccessful but in 2021 the EU encouraged WTO Member States to clarify that the pandemic can be understood as a "national emergency" under Article 31 of the TRIPS agreements, for a more flexible approach to compulsory licensing. In Italy, the amendment to the so-called "Recovery Decree" which, by introducing article 70bis into the CPI, authorizes and facilitates the use of special compulsory licenses for drugs and vaccines in the event of a health emergency. How then to combine intellectual property rights with a fair and undisputed universal right of access to vaccines?

In the recent past, the topic had been addressed with particular reference to drugs for the treatment of AIDS and hepatitis. As reported in the 2014 publication of the World Health Organization¹, in the Doha conference of November 2001² a declaration was adopted which acknowledged the need to take extraordinary measures to ensure public health and universal access to treatment for particular diseases that are widespread in some of the least developed countries, while recognizing the importance of preserving the intellectual property rights. This declaration led to the introduction of a certain flexibility in the application of the rules established by the TRIPS agreements for those least developed countries without adequate production capacity in the pharmaceutical sector, facilitating both the granting of compulsory licenses and the parallel import system.

The international agreement with which the COVAX system was established in 2020 also goes in this direction. In the COVAX frame, which is an international program having as aim to ensure a fairer universal access to Covid-19 vaccines, countries with greater availability can donate certain quantities of vaccines to the least developed countries.

Moreover, this has proved to be an obligatory path also due to the complexity of the manufacturing of the anti-Covid vaccines. In addition, precisely because of this complex innovative technology the know-how issue becomes fundamental. In fact, patents contain technical descriptions capable of defining exclusive rights and cannot summarize the technical and scientific knowledge relating to a given solution.

Therefore, suspending or repealing patents would not guarantee third parties to carry out the processes in the best way. This would also be dangerous to public health, as vaccines must be manufactured in a safe way.

Therefore, before a third party would be able to produce such vaccines many months would pass, if not even years, for the technology transfer, the setting up of the production lines, and for the training of specialized personnel; activities which requires all huge economic investments.

Ultimately, regardless of the existence or not of patents, it would not be simple or immediate to produce such vaccines: the complex know-how required was developed by the patent owners against huge investments, which can be covered, thanks to the exclusive patent, to then be invested at least in part again in research and development, according to a virtuous mechanism of incentive to progress that is often summarized in the quote from Abraham Lincoln: *“The patent system added the fuel of interest to the fire of genius”*.

¹ “Access to affordable medicines for HIV/AIDS and hepatitis: the intellectual property rights context”

² Declaration on the TRIPS Agreements and public health

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