

WTO: Leem regrets the signature of an agreement that undermines intellectual property rights and public health

The issues around the proposed waiving of Covid vaccine patents have been under discussion by the WTO since October 2020, following the submission of proposals by India and South Africa. Until the adoption earlier today of a decision that gives eligible Member States free reign to use the patents designed to protect the manufacture and distribution of Covid vaccines with no requirement to obtain authorisation to do so from the patent holder. Leem is deeply concerned about the profoundly damaging impact this decision could have on public health and pharmaceutical industry innovation.

The decision adopted today by the WTO is concerning in a number of different ways. Firstly, it envisages exemptions from fundamental principles set out in the TRIPS Agreement¹ regarding the compulsory granting to developing countries of licences for patents that are “*necessary for the production and distribution of anti-Covid vaccines*”. More specifically, it provides that products manufactured under such compulsory licensing arrangements may be exported to other developing countries with no real guarantee that this scheme will not be circumvented. A further exemption from the principle of regulatory protection for clinical trial data is also planned. These exemptions are granted for a fixed, but renewable, period of five years, and provide Member States with six months in which to decide whether to extend them beyond vaccines to include Covid diagnostics and treatments.

A counter-productive agreement in terms of public health

More than 13.9 billion doses of vaccine have been produced to date, and more than 10 billion have been administered thanks to an unprecedented collaboration between companies in industrialised and developing countries. It is clear therefore that Covid vaccine production capacity presents no barrier to access, since supply far outstrips global demand. So much so, in fact, that some producers have even ceased production due to lack of orders.

Added to which, the pricing and high level of support given by pharmaceutical companies to the COVAX initiative also ensure accessibility for all countries. To date, COVAX has distributed nearly 2 billion doses to 146 different countries.

The WTO agreement will do nothing to increase vaccination levels in low-income countries. On the contrary, undermining the intellectual property protection provided by patents puts global supplies at risk by hampering production and collaborations, at the same time as slowing the pace of research and

¹ *Agreement on Trade-Related Aspects of Intellectual Property Rights*

investment required to address current and future pandemics. And it opens the door to the diversion of raw materials and supplies from established production lines to manufacturing facilities where productivity and quality may pose problems.

A negative signal for innovation

Intellectual property has been shown to have played a fundamental role in the response to the pandemic. Pharmaceutical companies have worked tirelessly and devoted significant resources to push back the boundaries of science, develop viable solutions and secure large-scale production capacity. They have successfully done so at the same time as protecting patients by maintaining continuity of supply for other medicines. Challenging property rights in this way is a disincentive for innovation, especially in the context of Covid, for which there are 348 candidate vaccines currently in development, any of which may be needed to treat new mutations of the virus.

The pharmaceutical sector is not the only industry affected by this agreement. The decision to challenge the very principles of patents protection sends a very negative signal to all innovation-driven industries, regardless of sector.

A negative impact on international economic relations

Working within an agreed framework is what provides confidence. For innovation-driven companies, that framework is intellectual property. It is a cornerstone of international economic relations, which in the case of Covid has led to the establishment of 381 voluntary vaccine manufacturing and production partnerships around the world. *“The development of effective Covid vaccines and treatments was possible only thanks to massive investment in research and development and a favourable intellectual property framework that encouraged the rapid and voluntary formation of partnerships between the private, public and academic sectors”*, says Philippe Lamoureux, Director-General of Leem.

Leem stresses that the dramatic increase in such collaborations to meet global demand provides clear evidence of the extreme level of priority accorded by pharmaceutical companies to the absolute priority of ensuring the widest possible access to vaccines for populations around the world. It also notes that in July 2021, the WTO had identified 27 bottlenecks in vaccine production and distribution processes, the majority of which were administrative and regulatory in nature. At that time, Leem called on governments to remove trade restrictions, share doses and prepare health systems for the vaccine rollout. It is unfortunate that none of these issues have been addressed in the present agreement.

Leem further regrets that political considerations have taken precedence over the key issues of public health and innovation. *“This agreement provides no answers in terms of public health. It is ultimately a lose-lose agreement in which the WTO fails to address the many obstacles to vaccine access that it had itself identified”*, insists Philippe Lamoureux.

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