Patent Waiving Is Not the Solution to Enhance Access.

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Q: Patent waiving for COVID-19 vaccines has been touted as a way to increase access to those jabs. How would such a measure impact global vaccination campaigns?

A: Patents are not responsible for the crisis or issues related to the mismanagement of health system. It is easy to say that patents are barriers but this is incorrect. The technology developed to create COVID-19 vaccines is very complex and is recognized through legal protection. Patent protection should not be used as the argument to blame lack of access, neither for COVID-19 vaccines nor for any other medical development. If anything, patents help innovation reach the market and foment further medical developments.

For the COVID-19 vaccine, it is worth noting that the global demand is unprecedented, which alone is likely to cause delays in vaccine delivery. Production processes for these vaccines must be performed in specialized infrastructure with controlled environments for their manufacture, storage and distribution. Therefore, a strong and continuous supply chain and expert workforce are necessary across this entire operation.

Patent waiving will not solve any of the supply chain requirements or challenges in the manufacturing of the vaccine. Pharmaceutical innovation, protected by patents, is developing these unique solutions to a global crisis in record time. New drugs and new vaccines are not created spontaneously, it derives from the virtuous circle of innovation fueled by the patent system Industrial property protection is a significant incentive for the pharmaceutical industry. Without this mechanism, COVID-19 vaccines could have taken up years ears to be developed. Vaccines are the result of many joint ventures and collaborations between two or more pharmaceuticals that

combined technology and science to reach this goal faster. Without patent protection, investment on vaccines technology would have been out of the question.

To eliminate the limitations of manufacturing it is necessary for countries to invest in it. International mechanisms like COVAX could enhance vaccine production, without compromising innovation and efficacy.

Q: How should Mexican regulations respond to new technologies?

A: Legal certainty for all players is fundamental. The laws should be clear regarding the IP protection scope and market rules for the introduction of new products, among other areas. If companies feel there is uncertainty regarding the protection of their products, then investment and innovation will sink.

Q: How can the sector create a consolidated purchasing scheme that does not compromise the national health system or the Mexican economy?

A: The official reason behind the implementation of UNOPS' acquisition mechanism was to avoid corruption and promote transparency, which everyone in the industry agreed to. Corruption in Mexico has proven to be a cancer for progress but there are better and clearer ways to eradicate it. However, this measure does not tackle any other acquisition process. Corruption in Mexico is multisectoral; thus, it is curious that this strict change on acquisition mechanisms was only for medicines.

Regardless, it is now necessary to establish clear working frameworks that will prevent medicine shortages. To do so, it is key to have in-depth knowledge of the Mexican market, health system and its stakeholders to build effective strategies. Otherwise, the project will most likely fail. UNOPS' acquisition mechanism showcases a fundamental lack of understanding of the market, which created other problems that threaten the Mexican population.

Q: How will the new Federal Law for the Protection of Industrial Property impact the innovative medicine sector?

A: In general terms and with few exceptions, the new IP Law is positive for innovation. Regarding topics related with the pharma industry, the Bolar exemption has always existed. First it was an exemption to the law for the experimental use of a patent product and it was added to the Law for the Protection of Industrial Property, specifically for conducting tests for the approval process. This is a system of equity between the one who has the IP and the rest of the public. In the life sciences field, this exemption gains more relevance as it involves life-saving technology.

What happened in November, aside from the already-established protection rules for commercial purposes was a change in the time frame. In the past, experimental processes could begin three years prior to a chemical compound patent expiration, or eight years before in the case of a biological compound. These times have been

eliminated. Therefore, processes can be carried out at any time. This is positive as long as manufacturers do not abuse the opportunity and begin the process for commercial purposes early.