

Some thoughts about barriers to access to a possible vaccine against the covid-19

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ABSTRACT

The covid-19 pandemic has caused a great impact on a global level, changing from how people behave on a daily basis to the way the world is conceived, but it has also affected the economy, the law and the international trade between nations. This article is intended to analyze the possible barriers, in each of these fields, that the future covid-19 vaccine might face either in the development, distribution and marketing stages, and how countries could be able to face and overcome them, in order to guarantee the global access, including third world countries as most Latin American countries like Colombia.

Keywords: covid-19, Vaccine, International Barriers, Intellectual Property, Access, World Trade Organization, Economy, Law, Commerce.

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REFLEXIONES SOBRE LAS BARRERAS DE LA POSIBLE VACUNA CONTRA LA COVID-19

RESUMEN

La pandemia ocasionada por el covid-19 ha causado un gran impacto a nivel mundial, cambiando desde la forma en que las personas llevan su día a día, hasta su manera de concebir el mundo, cambio que no es ajeno al mundo de la economía, el derecho y el comercio internacional entre naciones. Este artículo pretende analizar las barreras en cada uno de estos campos que podría enfrentar la vacuna contra la covid-19, tanto en su etapa de producción, distribución y comercialización como la forma en la que podría superar dichas barreras para así garantizar el acceso a nivel mundial, incluso en los países en desarrollo, como Colombia.

Palabras clave: covid-19, vacuna, barreras internacionales, propiedad intelectual, acceso, Organización Mundial del Comercio, economía, derecho, comercio.

INTRODUCTION

Due to the critical situation of covid-19, experts have been discussing future scenarios in which a vaccine is developed and how countries would guarantee access to all populations that need it³.

The pandemic is a global concern, and so is the issue of a possible production of a vaccine. Therefore, a relevant question is whether countries with insufficient or no manufacturing capacities in the pharmaceutical sector would be able to access the vaccine. Even if impoverished and developing countries can produce it, they might have issues accessing the vaccine because of legal monopolies, excessive prices, and shortages. The World Health Organization (WHO) and the World Trade Organization (WTO) partially cover those situations and may offer some solutions to overcome some of those difficulties. (WTO | The WTO and the Millennium Development Goals—Access to Medicines, n.d.)

THE PROCESS OF DEVELOPING AN EFFECTIVE VACCINE

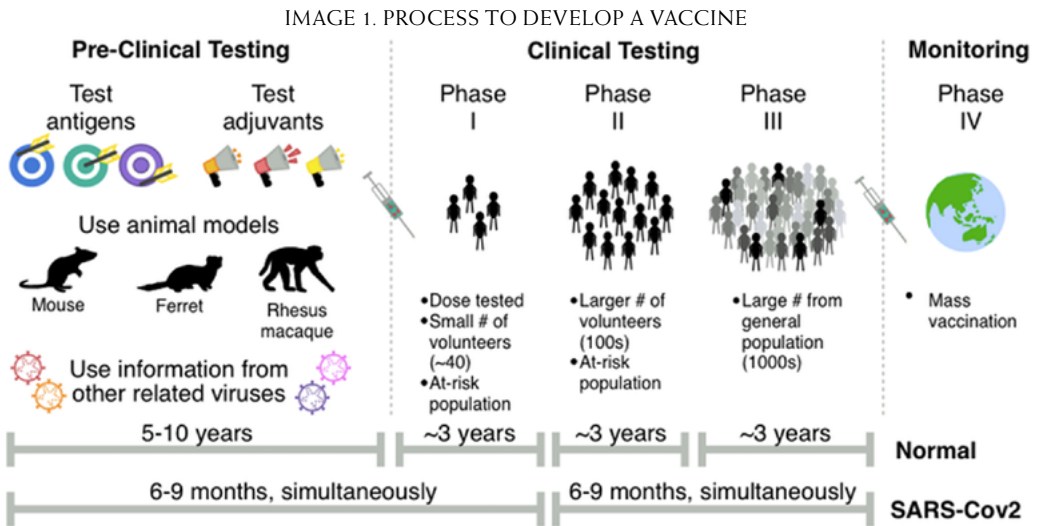
Governments of strong pharmaceutical industries have been creating expectations among people about the possibility of producing a viable vaccine in months. For

3 On May 1st, The World Trade Institute, an academic institution dedicated to the research on international trade, investment regulation and economic globalization, held a round table in which four experts, Arno Hold (AIPPI), Frederick M. Abbott (Florida State University), Ana Santos Rutschman (Saint Louis University) and Thomas Cottier (World Trade Institute, University of Bern), discussed "Intellectual property protection and access to medical technology in health emergencies". This text deals with some issues discussed then.

example, the US president stated, "We are very confident that we are going to have a vaccine [...] by the end of the year" (Wires, 2020).

However, the experience of previous pandemics has shown that developing medicines and vaccines can take from 1 up to 15 years. For instance, it took to Professor Ian Frazer took more than 15 years to develop and make available a vaccine for the Human Papillomavirus (HPV) (Quinn & Purcell, 2020). Another example is the Human Immunodeficiency Virus (HIV), whose vaccine or cure has not been found after 40 years of research.

To illustrate how complex and challenging it would be to find a vaccine for covid-19, the following image compares the average time for each step of the usual process to develop a vaccine against the time each of these steps would take to develop the vaccine for covid-19 within the 18 months. The latter is the time frame expected by governments.



Source: The conversation. (2020). Where are we at with developing a vaccine for coronavirus? [Image]. <https://theconversation.com/where-are-we-at-with-developing-a-vaccine-for-coronavirus-134784>

The standard process to research and develop a vaccine consists of three steps, a pre-clinical test, a clinical test, and mass production. A pre-clinical test involves testing antigens and adjuvants in animals, usually in rodents and monkeys. Typically, to develop a vaccine, it involves employing similar antigens and adjuvants to combat the related virus, also known as the target. An antigen is a molecule that triggers the production of an antibody and causes an immune response (Physiology, n.d.) Adjuvants may be added to an antigen to boost the immune response to produce more antibodies (ProSci Inc, n.d.).

Clinical Testing consists of a three-phase process. In Phase I, a small number of volunteers (up to forty people) from a risk population receive the trial vaccine. In Phase II, the clinical study is expanded, and vaccines are given to risk populations who have characteristics (such as age and physical health) similar to those for whom the new vaccine is intended. In Phase III, the vaccine is tested on a more significant number of people for efficacy and safety (Prevention, 2014).

Finally, the monitoring consists of mass production and vaccination, collecting and analyzing information in order to report potential adverse events that might occur after the administration of the vaccines (Prevention, 2014).

IDENTIFYING SOME BARRIERS TO ACCESS A POSSIBLE VACCINE AND SOME SOLUTIONS

Developing countries could face different types of infrastructural or technical, commercial, and legal barriers.

A technical barrier to access: The incapacity of developing a vaccine

The most significant barriers to access a possible vaccine against covid-19 are the incapacities of most developing countries to develop and manufacture it. More specifically, the capacities of countries without a research industry or lacking an advanced pharmaceutical sector. Most third world countries do not have the industry for the development of vaccines for humans.

For instance, in the 20th century, Colombia had a public institution named "Instituto Nacional de Salud" dedicated to research and develop vaccines at the national level (Dáguer, 2018), however, as a result of the entrance of private pharmaceutical multinationals, the national sector was limited to the development of medicines that have no interest for the pharmaceutical sector and procedural aspects, such as, medicines approval in accordance with the provisions of Law 100 of 1993 (Ley 100, 1993).

The creation of "Voluntary Pools" could be the most socially efficient form to develop a vaccine. Voluntary Pools are funds created by donations from citizens, companies, and governments to join investigations and jointly develop a vaccine. (Silverman, 2020) For example, the European Union (EU) suggested the Assembly of the World Health Organization (WHO), the creation of a Voluntary Pool on a global scale, with the only purpose that universities, companies, and pharmaceutical laboratories come together to find a vaccine for covid-19 (Silverman, 2020).

Issues of access to the covid-19 vaccine will depend on who is the first to develop it. Thus, initiatives such as the EU Voluntary Pool might be able to develop it, but private pharmaceutical multinationals like BioNTech and Pfizer could do it faster (Lee, 2020). If voluntary pools win the race, it is more likely that countries will take an approach of non-commercial application or exploitation with the only objective of protecting the life and health of humans.

As promising as this idea of Voluntary Pools sounds and the potential benefits it could bring, it is not feasible considering private pharmaceutical Multinationals had already made great advances in the developing process. Therefore it is highly likely the vaccine will come from these private entities and not from collective or public funds.

However, this alternative could be implemented in the mass production stage, through international organizations like Gavi with the program "Advance Market Commitment for covid-19 Vaccines (Gavi Covax AMC), a vaccine alliance which associates the private and public sectors globally in which countries like Colombia, Norway, Canada and England are part of it (Gavi, n.d.).

International barriers to trade a vaccine.

It is very unlikely that developing countries could produce the vaccine. Therefore, it would have to import facing two types of issues, the protection of local production by exporters and negotiation capacities.

According to the World Trade Organization (WTO) many countries have already banned the exportation of certain drugs and active pharmaceutical ingredients that could aid in the cure or treatment for the covid-19. For instance, the EU has imposed a licensing requirement on some medicine, provided that domestic demand is fulfilled, the US, on the other hand, has imposed export restriction in the form of quotas, Australia, India, Brazil, Mexico (WTO, n.d.-b) The prime as a protectionism mechanism to ensure access to its nationals. Export restrictions would likely be imposed on exports from producers countries.

In addition, the fact that first world countries, such as the US, have higher economic capacities and therefore more substantial negotiation power than third world countries, giving them a distinct advantage to acquire the future production of the vaccine as it has already happened the possible treatments for the covid, for instance, the redeliver (Boseley, 2020).

Nevertheless, some Latin American countries, as Brazil, have achieved agreements with private pharmaceutical Multinationals regarding the future production of the vaccine, to be able to grant access to all Latin America. However, one cannot overlook these countries will prioritize the access for its nationals first (Moura, 2020).

The existence of legal barriers: legal monopolies

Another barrier to access, if at any time there is a vaccine, patent, "an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem" (WIPO, n.d.).

When a pharmaceutical firm develops a vaccine, it files for patent to capture much of the economic benefit for itself, in order to recover the resources that it had invested during the vaccine development. Therefore, if anyone seeks to use a patent-protected vaccine, it has to obtain permission from the inventing firm, normally paying a royalty.

Arguably, the patent system gives the pharmaceutical company a greater incentive to engage in research and develop a possible vaccine.

During this pandemic, countries may refuse to grant the patent under a public health situation according to article 27.2 of the TRIPS Agreement of the WTO (WTO, 1995), that allows countries to exclude from patentability inventions if its use is contrary to ordre public or morality. The use of this exception is subject to the condition that the commercial exploitation of the invention must also be prevented, and this prevention must be necessary for the protection of ordre public or morality (Article 27.2). In this case, public order would be derived from the need for protection to the life and health of humans.

Notwithstanding, this solution is not well received as it directly affects the intellectual property rights and the economic interests of private pharmaceutical multinationals.

In the same manner, within the patentability exclusion, China's president in a press announcement stated that in the event the cure is developed in his country, it will be declared as a public good and thus help the developing countries to access the vaccine (Wheaton, 2020).

If countries do not exclude patentability and private companies develop a vaccine or treatment, patents could become a higher barrier to the public. Then, to access those treatments, countries may grant patents under a compulsory license allowing other companies to produce the patented vaccine without the consent of the patent owner. (WTO, n.d.-a) According to Article 31 of the TRIPS Agreement (WTO, 1995), countries are allowed to produce low-cost generic medicines to be produced and exported under a compulsory license exclusively to serve the needs of countries that cannot manufacture vaccines themselves.

In the case the vaccine production is not feasible, an alternative with less economic impact would be the parallel imports, which has been accepted by the WTO in the framework of the agreement on trade-related aspects of intellectual property rights. It would consist in the purchase of the vaccine from a country that has a compulsory license at a lower price.

Nevertheless, the first countries to produce this vaccine will prefer to guarantee access to this vaccine to its population rather than to sell it to other countries; this problem would make this alternative less attainable.

VIABILITY OF THE SOLUTIONS IN THE COLOMBIAN CONTEXT

On the covid-19 pandemic, Colombia could be found in three situations: the first, in the case the government decides to intervene in developing the vaccine; the second, if a private pharmaceutical Multinationals and the third, supposing the government intends to produce the vaccine locally.

In the first situation, a possible solution in the developing stage considering the lack of economic and technological capacity in the pharmaceutical industry in third

world countries, like Colombia, the most suitable solution would be a voluntary pooling. Costa Rica's government has suggested to the WHO the creation of a voluntary pool (Review, 2020) in the same way as the EU has; this voluntary pool would allow a collaborative investigation and development between countries.

In this framework, Colombia could contribute with research from experts in different fields of the best universities of this country, such as the University of Los Andes, the Javeriana University and the National University of Colombia. This is not an odd proposal as in the 90s, Colombian immunologist and researcher Manuel Elkin Patarroyo, sponsored with public and private funds and goods, worked with a team of 153 researchers from Colombia, Mozambique and Tanzania in the development of the vaccine for the malaria disease, this example indicates that, despite the scarce pharmaceutical industry in Colombia, a global scale contribution can be made (Enciso, 2016).

Regarding the second situation, there are two solutions:

- (i) Temporally exceptions to patentability, under Article 27 of the TRIPS Agreement on behalf of public order countries (WTO, 1995) could allow domestic industries to produce generic medicines. As a matter of fact, in Colombia a group of people including members of Congress, scholars, journalists, organizations, and leaders suggested a proposal similar to that of Germany, which consist in granting compulsory licenses and the temporary suspension of patents, paying the due royalties to the owner, by the expedition of a Decree (Rojas, 2020).
- (ii) Compulsory licenses, under the TRIPS agreement countries, could confer licensing contracts for the exploitation of the patent, in return for economic compensation, to be able to mass-produce. An alternative to this second solution are free licenses, and private entities could grant free licenses so that all countries could mass-produce.

Concerning the third situation, even though in Colombia there is not a national industry that produces vaccines for humans, there is one for animals, as Vetcol company, which may, due to the unusual and extreme situation, produce the future covid-19 vaccine at a national level (Contexto Ganadero, 2019).

CONCLUSION

In conclusion, covid-19 pandemic has allowed experts all around the world to propose solutions to old problems like access to essential medicines. When a vaccine is produced, it would have to face access barriers. The zero barriers are the impossibility to research and mass production in countries without a vaccine research industry or not having an advanced pharmaceutical sector.

Another barrier to access is intellectual property (IP) rights. Some solutions that could apply to third world countries, like Colombia that may reduce the inability for people to access the vaccine, could be that countries and companies engage with voluntary pools for the development, the exclusion of patentability, and compulsory licenses. These, as a manner to balance the rights of citizens to access a possible vaccine to protect their lives and health, the right of States to exclude IP rights or allow compulsory licenses, and the right of the owner of the innovative vaccine to explode its invention.

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