Access to COVID-19 vaccines, patent rights, and the TRIPS Agreement

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I want to really focus on the IP side of things from an international IP law perspective, so I will be talking about what I have titled: 'Access to Covid-19 Vaccines, Patent Rights, and the TRIPS Agreement'. Mainly, I want to focus on the options available under the TRIPS Agreement, including the proposed waiver that has been suggested by India and South Africa, and a number of developing countries. The key question I want to examine here is: **what role, if any, can the TRIPS Agreement play in this regard?** By the TRIPS Agreement I mean the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights, i.e. the IP Agreement in the WTO system.

As at March 2021, developed countries had already pre-purchased more than 60% of the vaccine doses that have been pledged by 2021, and they only account for a little over 10% of the global population. So, that leaves us with the problem of the equitable distribution of the existing vaccines. The developing world is still struggling to get access to the vaccines for even a fraction of their population; but of the existing vaccines, most have been purchased or pre-purchased by developed countries. The WHO's COVAX facility is seeking to vaccinate 20% of the developing countries' populations by the end of the year, but it currently (i.e. as at March 2021) only has one third of the funding it needs to do that. That is the current situation and that probably explains why a number of developing countries are pushing for the waiver or the suspension of the TRIPS Agreements for the duration of the pandemic.

Developing countries have been here before. This is not a new development for them as they have had problems with equitable access to vaccines and medicines in the past. Some of you might

know about the HIV/AIDS crisis of the 1990s and early 2000s when there was a lack of access to anti-retrovirals in developing countries. Also, around 10 years ago, with the swine flu pandemic, (i.e. the H1N1 influenza of 2009-2010), at that time, most of the global supply of vaccines was also purchased by rich countries. The question then is this: **what can we do differently this time to avoid a repeat of past problems with access to vaccines and medicines?** In other words, what can be done differently, not just for now, but also for the future?

Some of the options available in the TRIPS Agreement are: (1) compulsory licensing and (2) the national security exception. Those are the two main options that can be used in the fight against Covid-19. But a third option, which is not really in the TRIPS Agreement, although it relates to the TRIPS Agreement, is the proposal to waive certain provisions of the TRIPS Agreement for the duration of the pandemic. Those are the three main options I want to talk about. However, before discussing these three options, let me say something briefly about the TRIPS Agreement and public health. The TRIPS Agreement includes minimum standards on IP rules, including patent rights, and it contains some flexibilities that countries can use to address public health challenges, these are known as "exceptions." The exceptions under the TRIPS Agreement that states can implement include the research exception, the regulatory review exception, and compulsory licensing. The problem with these exceptions, particularly compulsory licensing, is that they are not really helpful if a country lacks domestic manufacturing capacity. I contend that if a country cannot produce vaccines and medicines locally, i.e. domestically, most of these flexibilities are not really helpful.

Starting with the first option under the TRIPS Agreement: compulsory licensing. If you look at Article 31 of the TRIPS Agreement, this provision allows WTO member states to grant licenses to third parties to produce patented medicines or vaccines. Last year, some countries invoked this option in response to Covid-19 to produce certain medicines. Canada, Germany, and Israel, changed their laws to allow compulsory licensing, in response to Covid-19. However, the problem with Article 31 is that countries can only use it predominantly to address issues within their own borders; thus, it can only be used predominantly for the supply of the domestic market. Countries cannot use it to address a problem elsewhere, outside of their domestic borders.

Due to this issue, there was an amendment to Article 31, so now we have an Article 31*bis* introduced to remedy this problem and facilitate the export of medicines produced under compulsory licenses to countries with no manufacturing capacity. The problem with this amendment to Article 31 (i.e. Article 31*bis*) is that it is very complex and very cumbersome to use, and it has only been used once by Canada and Rwanda to export generic HIV drugs from Canada to Rwanda. So far, only one country (Bolivia) has notified the WTO of its intention to use Article 31 in response to Covid-19.

The second option is the national security exception. At the start of the pandemic last year, a number of scholars suggested that, given the difficulties with Article 31 and Article 31*bis*, perhaps the national security exception could be invoked in response to Covid-19. The national security exception in the TRIPS Agreement can be found in Article 73. There are a number of exceptions in Article 73, and those exceptions mirror what you find in Article XXI of the WTO's General Agreement on Tariffs and Trade (GATT) and Article XIV of the General Agreement on Trade in Services (GATS). My focus here will be on Article 73(b)(iii) of the TRIPS Agreement which permits a state to take any action for the protection of its essential security interests during the time of war or other emergency in international relations. The question then is this: does Covid-19 fall within the scope of Article 73(b)(iii)?

Historically, some countries have contended that the security exception is a self-judging and non-justiciable provision i.e. you cannot question its use before the WTO dispute settlement process. For these countries, it is up to states to decide if and when they want to invoke the exception. This has now changed with the recent panel reports in disputes involving Russia in 2019 and Saudi Arabia in 2020. The WTO dispute settlement panels have had the chance to interpret both Article XXI of GATT [in the dispute involving Russia] and Article 73 of the TRIPS Agreement [in the dispute involving Saudi Arabia]. Thus, we now have a better idea of when states can invoke this national security exception. If we look at these two cases, four factors were highlighted by the panels. These four factors, which need to be met before a country can invoke the national security exception, will now be briefly discussed.

The first factor is that there must be a war or other emergency in international relations. The way this is defined in the panel reports suggests that the focus is on armed conflict or war, but at the same time the panels talked about "heightened tension or crisis or general

instability." What is clear is that this is an objective standard. A state could argue that Covid-19, because it affects its ability to maintain law and public order within its territory, is an emergency in international relations. I would equally argue that Covid-19, being a pandemic, could meet this first factor. The second factor is that any action a country is taking in response to the emergency has to be taken while the emergency is ongoing. Thus, anything that is done right now, while the pandemic is still ongoing, I think, will meet this second factor. The third factor is that the invoking state must articulate its relevant essential security interests sufficiently to allow an assessment of whether or not there is a link between the actions taken and the protection of its essential security interests. This, however, is a subjective test. The key point here is that not every interest is an essential security interest. I believe it should not be difficult for a state to say that it must invoke this exception so as to maintain law and order within its territory during a pandemic as this would be an essential security interest. Finally, the last factor is that the actions the state takes must not be remote or unrelated to the emergency in international relations so as to make it implausible that the invoking state considers those actions to be necessary for the protection of its essential security interests arising out of the emergency. Thus, the actions must satisfy a minimum requirement of plausibility. Once again, here, I would argue that suspending the enforcement of patent rights in order to facilitate access to medicines or vaccines (as part of measures to maintain law and public order during a pandemic such as Covid-19) should satisfy this minimum requirement of plausibility. In theory, then, one can say that countries could invoke the national security exception in response to the pandemic.

The next question is this: why hasn't any country done this yet? Why hasn't any country invoked the national security exception in response to the Covid-19 pandemic? My guess is that countries have done a realistic assessment of the situation. Like the compulsory licensing option, this is only beneficial for countries with domestic manufacturing capacity. If a country does not possess domestic manufacturing capacity, invoking the national security exception to suspend the enforcement of patent rights will not really achieve much. Also, if a state can already produce medicines or vaccines locally, with or without the pandemic, that state does not really need to invoke the national security exception. So, most wealthy developed countries will not invoke it because of, among other reasons, pressure from Big Pharma and other concerns.

Furthermore, another problem with Article 73(b)(iii) is that countries cannot use it to circumvent the problems linked with Article 31*bis* of the TRIPS Agreement. As mentioned above, because of the complex and cumbersome procedure associated with its use, Article 31*bis* has only been used once. Before the panel report in the Saudi Arabia case was published, a scholar had argued that, perhaps, one could use Article 31*bis* and the security exception together to avoid the problems associated with using Article 31*bis*. According to this view, states can use Article 31*bis* and the security exception in combination to facilitate the production and export of patented medicines and vaccines to countries that lack domestic manufacturing capacity. However, if one reads the panel report in the Saudi Arabia case carefully, it is very clear that a state can only invoke the security exception to address issues within *its* own territory. So, a country cannot use the exception to export drugs or vaccines to other countries; a country cannot use it to address the problems of other countries. So, that negates the argument that you can use the national security exception to avoid the problems associated with Article 31*bis* of the TRIPS Agreement.

Another point to note is that least developed countries are currently exempt from providing protection for pharmaceutical patents until 2033. That is in about 12 years' time. So, they do not really need to invoke the security exception. The bottom line is this: if a state does not have domestic manufacturing capacity, it does not matter if that state invokes this exception, it is not really going to help that state. This is probably (part of the reasons) why India and South Africa, in October 2020, submitted a proposal to the WTO TRIPS Council to waive certain provisions of the TRIPS Agreement in response to the pandemic.

This proposal for a waiver is thus the third and last option that I want to discuss. What does this proposal entail? The proposal [as submitted in October 2020] requests that the provisions on copyright, industrial designs, patent rights, and undisclosed information in the TRIPS Agreement should be suspended in relation to the prevention, containment or treatment of Covid-19 until there is widespread vaccination globally and everybody in the world has acquired herd immunity to the virus. [In May 2021, the proposal was revised to limit the duration of the proposed waiver to at least 3 years]. **Essentially, this is a proposal to suspend the TRIPS Agreement for the purpose of fighting Covid-19.**

This proposal is mainly supported by developing countries and it

has been strongly opposed by developed countries. The US, UK, Australia, and the EU strongly oppose it. As at March 2021, it was not yet clear whether the US would change its position under the new administration of President Biden. Some people made representations to him asking him to support the proposal. [In May 2021, the US finally expressed its support for the waiver proposal. However, this support is limited to the production of vaccines but not therapeutics and diagnostics]. At the same time, Big Pharma has also been advocating for maintaining the status quo. It is not yet certain, then, if the proposal will be approved and [except for the recent support of the US] the debate surrounding the proposal is generally along the traditional fault lines of what you see in international IP negotiations: developing countries on one side and developed countries on the other side.

A more important question, perhaps, is: will the suspension of the TRIPS Agreement really change anything? Let us assume that the WTO members agree to suspend certain provisions of the TRIPS Agreement, would that really help developing countries? I argue that it may not, especially for those countries without domestic manufacturing capacity. In addition, even if this proposal is approved, it is unlikely that developed countries that have innovative pharmaceutical companies would implement the waiver, and the waiver will only be effective if the WTO Members (that are developed countries) implement it. I am thus quite sceptical of the utility of this proposal.

To conclude, I suspect that the solution that will unlock an equitable distribution of Covid-19 vaccines is beyond the scope of the TRIPS Agreement. I believe it will require multilateral cooperation between states, and we need to avoid things like Covid-nationalism which we see around the world today, if we really want to speed up and scale up vaccine production. Perhaps, other options like differential pricing and voluntary licensing might be useful as well. Also, partnerships between pharmaceutical companies in developed countries and producers in developing countries may be helpful. A good example of such a partnership is the one between AstraZeneca and the Serum Institute in India, collaborating together, and allowing the production of the AstraZeneca vaccine in India.

I submit that, going forward, the focus should be on developing domestic manufacturing capacity in various countries, particularly in developing countries. In order to really enable this, we need technology transfer. Without technology transfer, some of the other

options like compulsory licenses, the security exception, or even the proposed waiver, only address symptoms and not the cause of the problem of lack of access to medicines and vaccines in developing countries. In this regard, it is not really surprising that a number of developing countries are now turning to China, Russia, and India for vaccines, and they can do this because these three countries have the capacity to produce vaccines. That is why I think it is important (especially for developing countries) for the focus to be on investing in the development of substantial national or regional manufacturing capabilities. This process should begin with the fostering of technology transfer into developing countries.