Can Pharmaceutical Companies Counter the Waiver of their Patents for COVID-19 Vaccines through Investment Treaty Arbitration?

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Since the COVID-19 outbreak, pharmaceutical companies have engaged in a highly competitive and risky vaccine race. In less than 10 months from the declaration of the global pandemic, the vaccine developed by Pfizer-BioNTech received its first regulatory approval, followed by the success stories of other companies. The swiftness of these results was praised as "unprecedented" and "nothing short of miraculous".

Despite this head start, the global process of vaccination is lagging due to multiple logistical, economic and societal obstacles, as the recurring waves of the pandemic continue to rage in many regions of the world. India and South Africa, being among the most severely affected countries, are currently leading a powerful campaign for a waiver of intellectual property protections with a view to allowing a wider access to the much-needed COVID-19 vaccines. After gaining support from more than 100 States, the campaign prompted the WTO to recommend a waiver of

obligations under various sections of the TRIPS Agreement, which would otherwise be applicable to WTO Member States. By far the most consequential is the proposed waiver of Section 5, which envisages protections for patents, including the patent-holders' right to prevent the unauthorized use of their patented technologies. Most recently, President Biden of the US threw his support behind the waiver initiative, sending the shares of the vaccine developers plummeting. Pharmaceutical companies as well as many European countries have criticized the initiative as counterproductive and disincentivizing for future research and development.

In this post, I analyze whether the pharmaceutical companies that have developed COVID-19 vaccines ("Vaccine Developers") may have an actionable claim under international investment agreements ("IIAs") against States waiving intellectual property rights over such vaccines. More specifically, I examine whether the Vaccine Developers may face jurisdictional and other threshold obstacles in pursuing their investment claims, and whether they may be entitled to compensation under the substantive standards of protection. The aim is to identify and offer a general overview of the principal legal issues, it being understood that the analysis may differ depending on the language of the applicable IIA, the circumstances of a specific case, and the final shape that the patent waiver initiative may take in different jurisdictions.

COVID-19 Patents as an Investment

A threshold jurisdictional issue that the Vaccine Developers will face in investment treaty arbitration is whether they have made an investment on the territory of the States waiving their intellectual property protections. Many IIAs expressly include intellectual property rights as a possible form of an investment. However, some developing States that currently call for the patent waiver have yet to register the patents of the Vaccine Developers. Where this is the case, the Vaccine Developers may face a jurisdictional obstacle resulting from not having an asset that exists under the law of the respondent State. As a rule, IIAs protect existing investments and rarely guarantee the right to establish an investment. Therefore, the Vaccine Developers may find it difficult to prove that the IIA applies if the respondent State has not registered the patent at issue.

Even where the State has registered the relevant patents, the Vaccine Developers may need to show that such patents meet the ordinary characteristics of an investment as established in arbitral case law. For ICSID cases in particular, this may require proof of: (i) a contribution of capital or other resources, (ii) an investment of a certain duration, and (iii) an assumption of risk. The requirement for a contribution of capital or other resources may prove particularly problematic. While the Vaccine Developers have undoubtedly invested substantial resources in the States where they developed the vaccines, they have not done so on the territory of many developing States where they merely market the vaccines. The registration of a patent without more may not therefore qualify as an investment, especially where the requirements of Article 25 of the ICSID Convention apply in addition to the definition of investment contained in the applicable IIA.

The analysis may differ if, in addition to the registered patent, the Vaccine Developer has other assets and interests in a given State. In particular, if the Vaccine Developer has an existing manufacturing plant, distribution facility or other established presence on the territory of the respondent State (such as for instance Pfizer's plants in India, or J&J's plants in China), the patent may qualify as part of the existing overall investment and may come under the protection of the applicable IIA. In such a case, even if the respondent State has refused to register the relevant patent, such refusal may itself be impugned as a possible unfair treatment of the existing investment.

Intellectual Property Exceptions

Some IIAs, such as those based on the Model US BIT, contain an exception from the States' obligation to provide compensation for expropriation in respect of the compulsory licensing of intellectual property. Some more recent IIAs also include a provision according to which limitations imposed on intellectual property rights that are consistent with the TRIPS Agreement do not constitute an expropriation (See, Article 8.12.6 CETA).

The patent waiver initiative may at least partly fall under such exceptions, should they be present in the applicable IIA. However, the exceptions usually apply to the expropriation provision only, and would therefore leave it open for the Vaccine Developers to invoke other standards of protection, such as fair and equitable

treatment (“FET”).

Right to Regulate

States may argue that, given the exceptional circumstances and the legitimate purpose of protecting public health, the waiver of patent protection constitutes a non-compensable exercise of their sovereign right to regulate. While the aims pursued by the patent waiver initiative may be criticized from a policy perspective, they are likely to meet the criteria for a legitimate public purpose under the FET and expropriation standards, since investment treaty tribunals do not as a rule second-guess the regulators’ policy judgments.

However, having a legitimate public purpose would not necessarily render a measure non-compensable, especially if it deprives the investor of its acquired property rights. The jurisprudence of investment treaty tribunals is not settled on the criteria that distinguish the non-compensable exercise of the right to regulate from compensable expropriation. While the provisions on the right-to-regulate contained in recent IIAs clarify certain questions (See, Annex 8-A CETA), they do not offer a clear test to distinguish between non-compensable regulation and regulatory expropriation. That said, a review of the case law shows that measures that eliminate the investor’s property rights may be exempt from the requirement of compensation in circumstances that fall within two broad groups:

- First, the obligation to compensate does not apply to generally accepted measures of police powers (such as criminal and tax sanctions, or revocation of licenses and concessions) that enforce existing rules against the investor’s own wrongdoings.
- Second, no compensation may be required for regulatory measures that abate threats that the investor’s activities pose to public health, environment or public order, such as production or commercialization of harmful substances.

The patent waiver initiative does not appear to fall under either of these two categories. It does not seem designed to sanction the Vaccine Developers for their own wrongdoing. Nor does it appear to abate a threat to public health that emanates from the conduct of the Vaccine Developers. Thus, while States may have a sovereign right to waive the patents in order to tackle the pandemic, there

appears to be no obvious justification that would allow them to do so without compensating the Vaccine Developers for their waived property interests.

Substantive Standards and Compensation

The two main substantive standards of protection that are likely to apply to the patent waiver initiative are expropriation and FET.

Patents are an intellectual property interest. The waiver initiative implies the interference with one of the major attributes of that proprietary interest, *i.e.* the patent-holders' right to exclude others from unauthorized use of their technology. If the waiver, even if temporary, results in a substantial diminution of the value of the patent, it will likely qualify as an indirect expropriation and, depending on the formulation of the applicable IIA, will call for compensation in the amount of the fair market value of the patent. If the waiving States were to offer compensation falling short of this standard, the Vaccine Developers could seek to recover full compensation under the governing IIAs. In this respect, it is worth mentioning that some States have partly financed the development of the vaccines with multiple conditions that affect their free marketability. This factor may be relevant at least to the quantification of the value of the relevant patents.

If the diminution of the value of the patent is not substantial, e.g. because it retains a considerable portion of its value after the waiver is lifted, the Vaccine Developer may seek to recover its loss under the FET standard. In particular, it may argue that the waiver constitutes an interference with its legitimate expectations, in which case it will likely need to demonstrate that it received specific assurances of stability of the legal framework from the State. It may also argue that the patent waiver is a disproportionate measure, not warranted by the pursued goal. In either case, however, the prospect of recovering the loss is less certain than under the expropriation standard.

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Overall, the patent waiver initiative may give rise to claims under the expropriation standard, and to a lesser degree, under the FET standard. However, the success of such claims may depend on whether the Vaccine Developer is able to demonstrate that it has made an investment on the territory of the waiving State in addition to

the registered patent. Moreover, the compulsory patent licensing exceptions contained in some IIAs may (partly) exempt the States from liability. In turn, the States may find it difficult to demonstrate that the proposed waiver of the intellectual property rights, while justified in light of the public health objective that it pursues, constitutes a non-compensable measure.

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