10 Arguments Against a Waiver of Intellectual Property Rights

India and South Africa submitted a proposal to the World Trade Organization for a waiver of intellectual property rights related to the prevention, containment or treatment of Covid-19. However, this would not lead to the desired better access to vaccines.

1. Production and distribution of vaccines will not speed up

The holdups in vaccine manufacturing and global distribution are caused mainly by the shortage in raw materials, insufficient production capacity and – in the case of the mRNA and vector vaccines – highly complex manufacturing processes. It is completely unlikely that a waiver of intellectual property rights could solve these factual problems.

2. Intellectual property rights are the basis for collaborations and contracts

The development cycle of the new mRNA and vector vaccines – from the provision of the technological basis to safety studies and marketing authorisation – is tremendously multifaceted. Nevertheless, throughout the development, production and distribution of vaccines against Covid-19 cooperation has reached an unprecedented level – despite the typically fierce competition in the biopharmaceutical sector. Intellectual property rights and particularly patents are normally the basis for such cooperation; they provide assurance that contracts will be fulfilled. Even a temporary waiver of these rights may therefore have detrimental consequences for the willingness to cooperate.

3. The regulatory requirements for vaccine authorisation need to be fulfilled

To place a medicinal product on the market a marketing authorisation from the respective drug authorities is necessary. This also applies to so-called biosimilars, replica drugs with a comparable effect, whereas those are subject to even more stringent regulatory requirements compared to generic versions of small-molecule drugs. A third party does not need a marketing authorisation if this licence was successfully transferred to it by the original manufacturer. In all other cases, each new manufacturer would have to obtain its own marketing authorisation and would need to comply with safety, quality and efficacy requirements even if all related intellectual property rights – including test data exclusivity – were waived. Without the willingness of the original manufacturers to cooperate, the waiver of intellectual property rights would likely cause a delay.

4. Significantly lower prices are not to be expected

There are several reasons why a waiver of intellectual property rights will not result in a substantially lower price for biosimilar versions compared to the currently supplied products:

a. Building production facilities, especially for the new vector and mRNA vaccines, requires substantial investments, which are unlikely to be lower for biosimilars, and which is reflected in their prices.

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b. The costs of production and delivery that in some cases equal as much as half of the vaccine price can hardly be significantly reduced for biosimilars.
c. The more vaccines are available on the market the greater the pressure on prices and the tighter profit margins have to be calculated.
d. Some vaccine developers and manufacturers already offer their vaccines at cost price.

5. The TRIPS Agreement contains sufficient flexibilities to prevent negative effects of patents

Article 31 of the TRIPS Agreement allows the WTO member states under certain circumstances to provide for compulsory licences for patents. It is up to the countries to implement this option in their national laws in such a way that in case of unjustified license refusals by patentees production permits can be issued expeditiously. The available information on the measures undertaken by individual states does not suggest that the international legal framework lacks flexibility to take into account the current extraordinary circumstances.

6. Incentives for drug innovation might disappear

Adapting vaccines to mutating Covid-19 viruses may require extensive investments in the future. However, it is questionable whether the vaccine developers will be willing to do this if they were now deprived of the opportunity to amortize their previous investments based on their patents. Moreover, the already available vaccines against Covid-19 are mainly protected by basic patents that also apply in other medical fields, such as cancer therapy. In order to be allowed to manufacture vaccines, such basic patents would also have to be waived. This could cause collateral damages beyond the vaccines, because this is likely to affect investment incentives for future research and development in those areas as well.

7. Concerns regarding excessive prices do not justify a waiver of intellectual property rights

To have incentives for investments in research and development, companies must have the opportunity to generate reasonable profits from the innovations they have achieved. The question is rather how much is justified. Excessive prices for Covid-19 vaccines are not automatically caused by the patent right as such, especially when several vaccines are in competition with each other. Pricing issues should have been addressed by those governments that have funded vaccine production, in the context of corresponding agreements and by setting binding requirements in this regard.

8. Public subsidies for vaccine development require transparency

When public money is invested in drug discovery and development or in the building of production facilities, this requires transparency regarding the overall amounts invested on the one hand and the calculation related to the marketing of the resulting medicines and vaccines on the other hand. Given that such transparency cannot be expected in the case of private

companies, it is up to the financing body to oblige the recipient of its funds to disclose cost and pricing structures.

9. The scope of the waiver is not clear

The proposal states that all intellectual property rights protected under the TRIPS Agreement that are in relation to the prevention, containment or treatment of Covid-19 shall be waived. However, the clause "in relation to" can be interpreted extremely broadly. This is problematic not only with regard to the fact that state intervention must be necessary and proportionate. It would also have serious consequences for legal certainty with regard to the question of the extent to which intellectual property rights could also be waived for products that are only indirectly related to vaccines.

10. The international community has the responsibility to support developing countries more effectively

Promoting global equitable access to Covid-19-related vaccines and therapeutics is a matter of international solidarity. This objective must be unconditionally supported. Given that it cannot be achieved by the waiver of intellectual property rights, it remains a task of the international community to find alternative ways of achieving it. In order to be able to address such global challenges in the future on the basis of effective governance, a suitable international legal framework is needed. The call for an international pandemic treaty, advocated by more than 25 different countries and institutions, including Germany, is a step in the right direction. Multinational approaches such as the ACT-A or COVAX initiatives are also playing their part in managing the pandemic in certain areas. The responsibility lies with all states that are able to make a contribution. The choice to instead pursue purely national interests and support a waiver of intellectual property rights will not improve access to vaccines in developing countries within a reasonable period of time.

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