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IP | The Waiver of Patent Protection for COVID-19 Vaccines — On Practicability and Purpose of Such Measure

Tedros Adhanom Ghebreyesus, Director-General of the World Health Organization (WHO), spoke of a "monumental moment" when referring to the U.S. government's announcement on May 5, 2021, that the U.S. would support the waiver of patent protection for COVID-19 vaccines in World Trade Organization (WTO) negotiations. On the very next day, the share prices of all manufacturers of approved COVID-19 vaccines slid by several percentage points, and the debate about a so-called patent waiver has dominated political and economic news around the world ever since. This article aims to shed light on the background of the debate.

I. What has happened so far?

As early as October 2, 2020, India and South Africa had submitted a proposal to the WTO to temporarily suspend patent rights for COVID-19 vaccines worldwide.

During the first debates in October 2020, a decision in favor of a suspension could not be reached, due to influential nations such as the UK, the EU and the USA opposing the suspension of patent protection.

While the newly announced change of direction by the U.S. was supported by the United Nations, numerous NGOs and, not least, the Pope, numerous industrialized nations, including the majority of EU states—as well as experts and industry representatives—expressed their concerns. German Chancellor Angela Merkel declared that waiving patent protection is not the solution to providing more people with vaccines.

II. Would it be possible to waive patent protection?

Even if the current discussion is a global one, a waiver of patent protection could only take place at the national level for the individual countries, considering the relevant national laws. Such waiver could be initiated by the national governments themselves or be based on a decision by an international organization such as the WTO.

Options for a waiver of patent protection under international law

The relevant legal basis for a WTO decision would be the Agreement on Trade-Related Aspects of Intellectual Property Rights (*TRIPS Agreement*), which was concluded by the members of the WTO in 1994.

In addition to a complete "waiver" of patent protection, i.e., a suspension of all regulations on industrial property rights (TRIPS II, Sec. 1, 4, 5 and 7) as envisaged in the original Indian-South African joint proposal, the TRIPS Agreement itself provides for measures to allow the use of third-party patents in certain exceptional cases.

Article 31 of the TRIPS Agreement allows member states to grant compulsory licenses to third parties for certain patents that could be used to produce patent-protected vaccines, subject to various conditions, including in the event of a national emergency. This possibility was expanded with the provision of Article 31bis, introduced in 2017. If the grant of a compulsory license is ordered by the individual member state, the licensee is thereby authorized to use the patented invention while being obliged to pay an appropriate license fee. The compulsory license can also be granted with subject or time limitations.

Practical feasibility

Although the debate has gained momentum with the announcement by the U.S. administration, the necessary consensus for a WTO decision regarding an international waiver or limitation of patent protection has not been reached so far. Given the divided opinion within the member states, this is not surprising and it is not expected that a consensus will be reached soon. For this reason, the announcement by the Biden administration is already regarded by many as a rather symbolic step.

The transposition into national law by the individual member states required after a corresponding WTO decision is likely to take additional time.

III. What would be the consequences?

Since patent rights to COVID-19 vaccines give the patent holder an exclusive right to manufacture the vaccine, one might conclude that a limitation of patent protection, whether through a waiver, compulsory license, or order of use, would lead to an increase in the supply of vaccine.

Vaccine production requires know-how and infrastructure

However, this assumption fails to recognize that an authorization to manufacture is not the same as an ability to manufacture. The latter requires a high level of knowledge, experience and technological infrastructure if the result is to be clean and safe vaccines.

The importance of manufacturing know-how applies even more regarding the mRNA technology on

which the vaccines from, e.g., BioNTech/Pfizer, Moderna and CureVac are based. For one thing, the manufacturing process is significantly more expensive and complex than that for the established vector vaccines; for another, the vaccines (apart from CureVac's vaccine candidate CVnCoV) are extremely susceptible to temperature fluctuations and mostly require a constant temperature of up to -80° Celsius.

Due to the unique challenges of manufacturing COVID-19 vaccines, it cannot be assumed that a patent release alone will result in previously inexperienced producers around the world suddenly being able to produce clean and safe vaccines.

Patents as an incentive for time-consuming and costly research and development

Another risk that a government-initiated limitation of patent protection would entail becomes clear when one considers how complex and cost-intensive the development of drugs is. Recent studies put the average development costs of a single drug at between USD $1.3–2.8 billion.

It should also be borne in mind that there is no guarantee of success during research and development of a drug, so that in a worst-case scenario the billions invested are lost. To give an example, just a few years ago the failure rate for new Alzheimer's drugs was around 99.6%.

In the face of these figures, patents provide an incentive for companies to embark on the costly and time-consuming research and development of new, breakthrough drugs.

Under German patent law, for example, the patent holder is granted an exclusive right for a period of 20 years, during which he alone is entitled to use and exploit the patented invention. For certain medicines, these 20 years can be extended by a maximum of 5 years by means of so-called Supplementary Protection Certificates("SPCs").

After the end of the protection period, imitators and generic manufacturers can often benefit from the original inventor's fundamental research work. Since their own expenditures for research and development of the formerly patent-protected drug are reduced, they can usually offer generic products at a significantly lower price.

Waiver of patent protection as a dangerous precedent

A waiver or limitation of patent protection initiated by the government could discourage pharmaceutical companies from taking on the costly research and development work required to provide critical medicines in the future, as they would have to fear that they would not be able to recoup their risky investment.

Against this background, German Chancellor Angela Merkel's rejection of the U.S. initiative should be seen as a strong signal.

After all, Germany has long been considered one of the most important patent locations in Europe. In 2017, one in three patent applications in Europe came from Germany, and Germany is also extremely popular as a location for patent infringement proceedings in Europe due to its specialized court locations in Düsseldorf, Mannheim and Munich.

IV. What are the alternatives?

As shown, a waiver or limitation of patent protection is not a suitable means of increasing the global supply of vaccines in the short term. On the contrary, a removal of patent protection entails both health risks from vaccines that are not expertly manufactured, and political risks in the form of uncertainty, which could have a lasting negative impact on the innovative strength of the pharmaceutical industry.

It is therefore more effective to support the existing companies and expand their expertly designed production capacities. An expansion of existing production is, in fact, in the interest of the pharmaceutical companies involved, which is why many of them have already entered into partnerships on their own initiative (*German-speaking readers may also like to read the commentary by our partner Dr. Ulrich Worm in Tagesspiegel Background* [1]).

Exporting vaccine doses already in stock to trouble spots would also have a direct impact. After the EU exported 34 million doses of vaccine months ago, the USA also announced its intention to export 60 million doses of AstraZeneca vaccine that it doesn't currently need.

Finally, an unequal distribution of available vaccine should be addressed by strengthening the global COVAX campaign, as well as the global vaccine initiatives Gavi and CEPI behind it.

If you are interested in this topic, you might also want to join our webinar ***'Waiving IP Rights in COVID Vaccines: Reactions from Stakeholders'*** which will take place on Wednesday, July 14, 2021, 4:00 p.m. – 5:00 p.m. EDT / 10:00 p.m. – 11:00 p.m. CEST.
During the webinar, we will discuss with industry leaders and stakeholders whether tolling vaccine manufacturers' IP rights adequately address access and distribution issues or whether there are other solutions that might help stop the spread while taking into account the interests of IP holders.
For further information and registration options please follow this link.

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[1] https://background.tagesspiegel.de/gesundheit/zwangslizenzen-fuer-impfstoffe-nicht-zielfuehrend