The Debate on the Waiver of Patents for Vaccines Against SARS-CoV-2

The subject that we have already written about in our previous Legal Reports — the suspension of patent protection for vaccines against the SARS-CoV-2 virus (see: *Patent rights: an obstacle for development of a vaccine against COVID-19?* (WTS Legal Report No. 15/2020) and *What is permitted under the TRIPS Agreement when it comes to the scarcity of SARS-CoV-2 vaccines?* (WTS Legal Report No. 3/2021)) — has recently reemerged in the headlines. The matter owes its new momentum **to the statement of the White House administration about the United States' support for plans to waive patents for the available vaccines.** It is a rather radical change of mind, taking into account that so far the American position within the WTO towards such proposals remained unequivocally critical. On 5 May, Katherine Tai, the U.S. Trade Representative, announced that even though the "the administration believes strongly in intellectual property protections," in order to end the pandemic as soon as possible, it has decided to approve of their waiver with regard to vaccines against COVID-19 (see: T. Kaplan, S. G. Stolberg, R. Robbins, *Taking 'Extraordinary Measures,' Biden Backs Suspending Patents on Vaccines*, *The New York Times*). In the aftermath of this statement, a heated debate has erupted, one that touches the very purposes that IP protection is supposed to serve.

In this Legal Report we would like to gather for yo**u the most important information concerning the discussion in progress and present you the current state of play,** especially in the context of the current negotiations on the forum of the WTO. We would also like to address the popular narrative about the necessity of waiving patents for vaccines and point out some of its weak points and simplifications that it has been founded on.

The WTO regulations and the possibility of their suspension

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) signed in 1994 constitutes an annex to the Marrakesh Agreement Establishing the World Trade Organization. It establishes some minimum standards regarding the IP protection, including certain significant constraints when it comes to permissibility of limiting the rights of a patent holder. Let us remind that **on the grounds of the TRIPS Agreement, competent authorities of member states can grant compulsory licenses under some specific conditions**, among which the most important are the following:

- It must be demonstrated that **the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions** and that such efforts have not been successful within a reasonable period of time (nonetheless, this requirement might be waived in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use).
- The right holder shall be paid **adequate remuneration in the circumstances of each case**, taking into account the economic value of the authorization.
- **The scope and duration of such use shall be limited to the purpose for which it was authorized, while the principal purpose of an authorization shall be the supply of the domestic market of a given member state of the WTO** (the exception to that rule is provided in Article 31bis added pursuant to the decision of the Ministerial Conference of 6 December 2005 that introduced special rules for pharmaceutical products manufactured for exporting).
- The licence must be **non-exclusive and non-transferable**.
- Authorization of such use shall be considered on its individual merits and the legal validity of any decision relating to the authorization of such use **shall be subject to judicial review or other independent review.**

The institution of compulsory licensing, though designed specifically for situations wherein some special circumstances require “relaxation” of patent protection in order to defend some other interests, **turns out to be an imperfect remedy when it comes to the most serious problems related to the global pandemic.** As we pointed out in one of our Legal Reports dedicated to that subject, its usefulness is limited by such factors as: the requirement of adequate remuneration (its amount might exceed the financial capacity of a subject interested in obtaining it); the lengthiness and complexity of the procedure for granting of the licence; as well as a threat of retaliation of pharmaceutical concerns, but also of other, more powerful states. Even though the compulsory licenses are being mentioned as one of the possible solutions to the problem, the attitude towards them remains in general rather sceptical.

As a side note, it is worth to remark that there are some instances when states still decide to make use of flexibilities described above: the aforementioned mechanism provided by Article 31bis is currently applied by Bolivia which officially notified the WTO in May that is planning to important 15 milion doses of vaccines — it will be allowed to import them from one of around 50 eligible member states of the organisation whose domestic legal systems allow for manufacturing and exporting pharmaceuticals produced under compulsory licensing on the basis of Article 31bis.

Meanwhile, the proposal discussed right now on the forum of the WTO would involve suspending application of the rules regarding compulsory licenses altogether. The constraints presented above would be “deactivated”. According to the proposal of the South Africa and India — more about it in a moment — the waiver would extend to entire Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement, therefore a major part of "Standards concerning the availability, scope and use of Intellectual Property Rights” would be suspended ("Copyright and Related Rights", "Industrial Designs", "Patents", "Protection of Undisclosed Information”).

The procedure for adopting a waiver is defined in the Marrakesh Agreement of 1994 (Article IX). **The principal competence to make decisions in that area belongs to the Ministerial Conference.** Let us recap the most important steps of this process:

- A request for a waiver of the TRIPS agreement is submitted to the Council for TRIPS.
- The Council for TRIPS shall submit a report to the Ministerial Conference in 90 days (or to the General Council which performs the functions of the Ministerial Conference whenever the Ministerial Conference is not in session).
- The Ministerial Conference makes a decision on a waiver (the required majority: 3/4); a decision granting a waiver shall state exceptional circumstances justifying the decision, the terms and conditions governing the application of the waiver, and the date on which the waiver shall terminate.

- If the waiver was granted for a period of more than a year, it shall be reviewed by the Ministerial Conference not later than one year after its grant, and thereafter annually until the waiver terminates — the findings of such a review are the basis for either extension, modification or termination of the waiver.

Taking into account what has been presented above, the next question that must be posed is: at which stage of this process are we right now?

The current state of play

As we already know, **on 2 October 2020 the governments of India and South Africa, have approached the Council for TRIPS with a proposal to waive the application of certain TRIPS rules for the prevention, containment and treatment of COVID-19** (a notification IP/C/W/ 669). It is motivated by "significant concerns, how [vaccines] will be made available promptly, in sufficient quantities and at affordable price to meet global demand" (paragraph 7) and it features a call for global solidarity which is supposed to manifest in an unhindered global sharing of technology and know-how employed for combatting COVID-19 (paragraph 11).

The representatives of the WTO Member states have met several times already at the formal sessions of the Council for TRIPS with a goal to discuss the proposals presented in the submission. The negotiations rounds that have taken place so far haven't been successful in bringing any breakthrough; the next round is scheduled for 8-9 June — this time, however, it seems that the conversation will be held in completely different circumstances; **the formerly clear alignment of parties to the dispute has been shaken.** Until recently, it remained in line with the division between developed states and developing states; on one side, there were the USA, the United Kingdom, and the European Union, and on the other, such states as Kenya, Pakistan, or Bolivia. **The reversal of the Washington's position opens a new chapter in this tumultuous debate and lends a new impetus to negotiations.** It should not come as a surprise that it was met with strong and very diverse reactions.

The Director General of the WTO Ngozi Okonjo-Iweala responded with enthusiasm to the statement of the White House: she said that she warmly welcomed Washington's willingness to enter into a dialogue with proponents of the temporary suspension of the TRIPS and she emphasised that as soon as a new, updated version of the proposal is submitted by its sponsors, it should be put on the table so that negotiations could continue as soon as possible. The President of the World Health Organisation, T. Adhanom tweeted euphorically in capital letters "MONUMENTAL MOMENT IN THE FIGHT AGAINST #CO-

VID19". Even the pope Francis himself expressed his opinion on this matter saying that he is a supporter of a universal right to vaccines and the temporary suspension of intellectual property rights, adding that a "variant [of the virus] is when we put the laws of the market or of intellectual market or intellectual property over the laws of love and the health of humanity".

In Poland, opinions concurring with the new position of the White House are also prevailing: the suspension of patents has the support of the government representatives (on 7 May before an informal session of the European Council in Porto, the Prime Minister M. Morawiecki commented that he will be very vocal on that matter in order to convince the wealthiest countries to share patents and so that the production of the vaccines can radically accelerate) or of the Polish Ombudsman, Adam Bodnar (at a press conference on 12 May in presence of civil society activists he commended the European Citizens' Initiative for lifting patents).

Naturally, certain voices critical of the White House's announcement have been raised as well. They belong, among others, to the representatives of the pharmaceutical industry. It should be noted that the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) described the decision of president Biden's administration as disappointing. In an official statement issued in response to K. Tai's announcement, it is argued that suspension of patents "is the simple but the wrong answer to what is a complex problem". IFPMA claims that the waiver would cause disruption and will not help in meeting the fundamental challenges, which are the trade barriers, bottlenecks in supply chains and scarcity of raw materials and ingredients, and the lack of willingness of rich countries to start sharing doses with poor countries. At the same time, in the public opinion there can be noticed a tendency to discredit the criticism raised by pharmaceutical concerns on the grounds that they are considered to be mostly interested in increasing their revenues through sales of vaccines.

An interesting aspect of the problem is an ambiguous position of the European Union. Until now, the United States and the European states spoke in one voice on that issue, now the former find themselves in quite a difficult situation. The President of the European Commission, Ursula von der Leyen, when replying to the statement of the White House, expressed willingness to talk about the proposal of the USA (even though in one of her media appearances, she told reporters that the patent waiver will not bring in the short or the medium term a single additional dose of a vaccine). After the above-mentioned Porto summit, a communication was issued that indicated that the opposition of the EU against the waiver was not that strong anymore. Charles Michel, the President of the European Council, ensured in rather vague words: "We are ready to engage on this topic, as soon as a concrete proposal would be put on the table". Thus, the readiness to enter into dialogue was affirmed, yet the ball was put back in the American court, as Washington was called on to reveal a more precise plan. The European states are divided on that mat-

ter: whereas, for instance, Poland and Spain support the waiver of patents, Germany and France have so far conveyed mainly doubts and reservations. **The spokeswoman for the German government underscored that, "the protection of intellectual property is a source of innovation and must remain so in the future".**

Would a waiver actually contribute to an increase in the availability of vaccines?

The key question that should be asked, and that is almost completely absent from narratives spun by the proponents of suspension of patents, is: would in reality agreeing to the proposal that was originally submitted by India and South Africa lead to guaranteeing the common access to vaccines? The arguments invoking morality are usually difficult to refute, but those who raise them in that case seem to disregard the practical consequences of the demanded solution. In other words, though a goal is a noble one, **this is not a right way for pursuing it.**

The spokeswoman for the German government in the statement referred to above claims that **the problem of the limited supply of vaccines actually does not lie in patents: in fact, "the limiting factors in the production of vaccines are the production capacities and the high quality standards."** It is hard to disagree with that opinion — especially when we consider **the telling example of Moderna which in October of 2020 made a notorious announcement that during the pandemic it would not enforce patents for a vaccine that it owned.** So far, however, no other producers showed any interest in jumping at that opportunity; not a single company demonstrated a manufacturing capacity necessary for launching into the market a vaccine that would be based on solutions "freed" by Moderna. Nobody could achieve that overnight: such a producer would have to establish a necessary infrastructure, enlist a properly qualified staff, undergo clinical trials, obtain data, and secure a market authorisation, which takes time, as explained by Stephane Bancel, the Chief Executive at Moderna (see: C. O'donnell, M. Mishra, *Moderna sees no impact on COVID-19 vaccine from potential patent waiver*, REUTERS). It must be stressed strongly that all around the world there are relatively few factories capable of manufacturing SARS-CoV-2 vaccines on a mass scale. Moreover, it is worth to address the concerns voiced by the German Chancellor, A. Merkel, who warned that the production of vaccines by manufacturers who are not patent owners could hamper the enforcement of high quality standards (what in turn could lead to a decrease of social confidence in vaccines and slower the pace of vaccination campaigns).

Finally, we cannot forget that **a given producer who would hypothetically be interested in manufacturing a vaccine, using one of available patents, is not in the possession of a "complete manual" how to make that vaccine.** An essential elements of the manufacturing process might not be comprised in the subject matter of the patent protection at all. **This is where the know how protection enters the stage**; know how defined under the European Commission Regulation (EC) No. 772/2004 of 27 April 2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements as a package of non-patented practical information, resulting from experience and testing, which is: (i) secret, that is to say, not generally known or easily accessible, (ii) substantial, that is to say, significant and useful for the production of the contract products, and (iii) identified, that is to say, described in a sufficiently comprehensive manner so as to make it possible to verify that it fulfils the criteria of secrecy and substantiality. Let us remind you that the protection of know how is not dependant on filing of an application and conducting a proper procedure during which a disclosure of a subject matter of protection would be required. **Without the access to know how the full reconstruction of an original product would not be possible — it is yet another problem that freeing of patents fails to solve.**

It is also worthwhile to take a closer look at a fascinating paper by R. Agarwala and T. Reed: a report published by the World Bank, entitled *How to End the COVID-19 Pandemic by March 2022.* The authors argue that the achievement of herd immunity against the SARS-CoV-2 virus would be available when only about 60% of population is vaccinated, which, according to their analyses, seems feasible, taking into account the production capacity of the concerns manufacturing currently vaccines and the pace of vaccination campaigns. **The problem, in their opinion, lies somewhere else: namely in the reluctance of the concerns to start production without pre-purchase commitments of the ordering states.** The suspension of patents would not change anything here; a concrete, meaningful means that could be undertaken in order to improve the situation of developing states and least developed states, involve transferring surplus doses gathered (hoarded?) by the developed states and most of all offering them aid in purchasing vaccines on their own (such efforts are currently carried out by COVAX which is responsible for the coordination of international resources for the purpose of ensuring equal access to vaccines); it should also be remarked that from the perspective of poorer states another important initiative could be the relaxation of conditions for granting loans by the World Bank.

Above all, it seems that putting an end to export restrictions would constitute a far more meaningful step for guaranteeing an equal access to vaccines. It should be pointed out that the United States, though demanding the suspension of patents, still exercise the prerogatives based on the Defense Production Act — the statute designed for a time of war, which allows for compelling private companies to fulfil governmental contracts ahead of any other of their commitments (due to its invocation, for example, an Indian producer, the Serum Institute, cannot import from the USA syringes and needles, as it would normal-

ly do). Similar practices of imposing constraints on export are not unfamiliar also to the United Kingdom and to the EU.

The Director General of the WTO said in April that, “economic recovery from the COVID-19 pandemic means rapid, equitable access to vaccines, especially in developing and least developed countries,” while **“nobody will be safe until everyone is safe”. Delivering vaccines to states outside the club of the wealthiest, remains a priority task for the whole global community — the means for its realisation shall be adequately chosen, in the spirit of pragmatism, with knowledge of actual consequences of given solutions.** The waiver of patents seems, if not counterproductive, then at least ineffective: that is a proposal that might work well as an inspiring slogan, but not the one that, if implemented, would lead to a true increase in the availability of vaccines.

