What is permitted under the TRIPS Agreement when it comes to the scarcity of SARS-CoV-2 vaccines?

In last December we published an issue of our Legal Report concerning the legal aspects of development of vaccines against the SARS-CoV-2 virus. We wrote in it about the race of pharmaceutical concerns — at that moment back then only several weeks had passed since Moderna and Pfizer submitted first motions for emergency authorisations of their products and the optimistic news about efficiency of their vaccines had generated some major buzz. Right now, however, we have entered a completely different chapter: more vaccines are obtaining recommendations of proper authorities and a massive vaccination campaigns on an unprecedented scale are beginning, while the attention of the public shifts to other statistics: a number of vaccinated people and, closely tied to it, schedules of manufacturing and deliveries. **The problem that comes to the fore is the limited (and insecure) supply of vaccines: the manufacturing processes are falling behind the immense demand.** In every place where a vaccination campaign has begun (with a well-known exception of Israel), the objections are raised that the rollout is frustratingly slow: either in the United States, or in the European Union. The situation of developing co-

untries is particularly dramatic: according to the current predictions, the vaccine against the coronavirus will not be available in many of them before 2023.

In this issue of our Legal Report we would like to continue our analysis of this subject, attempting to find certain tools offered by intellectual/industrial property law that can provide some remedies with regard the severe problem of the scarcity of vaccines that afflicts different parts of the world to varying degrees. We come back to a matter of compulsory licences and reflect on their promises and limitations. We also address an issue of clauses that allow for suspending application of certain rules that are binding on the members of the World Trade Organization (WTO) and the reasons for and against resorting to them in that particular case.

Compulsory licenses

We have written about compulsory licenses in one of articles in our cycle "Patents Without Secrets," as well as in the aforementioned Legal Report on vaccines. Let us remind you just a few key facts about that matter. In the Polish legal system the provision of Article 82 of the Act of 30 June 2000 - Industrial Property Law **defines a compulsory license as an authorization to use an invention patented by another person, that can be granted by the Polish Patent Office (the PPO) in three enumeratively indicated cases: (1) threats to national security, (2) abuse of a patent; (3) and with regard to dependent patents.** It is non-exclusive, a person using an invention is obliged to pay a license fee a patent holder; and a decision to issue a license is made by the PPO in contentious proceedings.

Compulsory licences are regulated by the Agreement on Trade-Related Aspects of Intellectual Property of 1994 (hereinafter: TRIPS) that has been concluded within the framework of the World Trade Organization. The Agreement prescribes that where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, certain conditions must be fulfilled (Article 31). In other words, **the proper authorities of the WTO members are allowed to issue compulsory licenses as long as they do not overstep certain borders designated by law.** First of all, it must be emphasized that TRIPS requires to demonstrate 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 matter of adequate remuneration is a particularly important one: under Article 31 of TRIPS, the right holder shall be paid adequate remuneration in the cir-**

cumstances of each case, taking into account the economic value of the authorization. Other requirements refer to the limitation of a purpose (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); non-exclusivity and non-assignability of a license; as well as conditions for its expiry (authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur). Furthermore, it is provided that the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review.

Since the purpose of issuing authorizations has been mentioned, we should take note of some **special rules that apply to pharmaceutical products that are manufactured for export.** Those rules are laid out by Article 31bis that was added to TRIPS on the basis of the decision of the Ministerial Conference of 6 December 2005. The provision in question waives in certain cases the requirement that the principal purpose of an authorization should be the supply of the domestic market of a given member state. A country that is exporting a specific pharmaceutical product is entitled to obtain such an authorization and manufacture the product under a compulsory license for the supply of eligible importing states. The Annex to the TRIPS Agreement explains that the term "eligible importing Member" shall be understood as the least-developed countries, as well as those that have made a proper notification to the Council for TRIPS. In this context we should refer to the Doha Declaration whose Paragraph 6 provides grounds for a waiver of the export restriction: if a developing or least-developed country produces or imports a pharmaceutical product under a compulsory license, it is allowed to export such a product to the markets of other developing or least developed countries that are parties to the same regional trade agreement and share the same health problem.

The proposal of India and South Africa

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).

Let us address shortly the legal grounds for submission of this kind of motions. Under Article IX of the Marrakesh Agreement Establishing the World Trade Organization of 1994, **it is the Ministerial Conference of the WTO that is competent to make a decision to waive an obligation imposed by a member state by the Agreement or by any**

of the multilateral trade agreements (annexes to the Agreement that comprise, i.a., the TRIPS Agreement) — however, such a decision shall, in general, be taken by three fourths of member states. A request for a waiver concerning the Marrakesh Agreement shall be submitted to the Ministerial Conference which established a time-period not exceeding 90 days: if during that time-period a consensus is not reached, a decision to grant a waiver shall be taken by 3/4 of members (Section 3(a)); whereas motions regarding the multilateral trade agreements shall be submitted initially to the Council for Trade in Goods, the Council for Trade in Services or **the Council for TRIPS**, respectively, which likewise are **bound by the time limit of 90 days and once this period lapses, shall submit a report to the Ministerial Conference** (Section 3(b)). 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 (Section 4).

In the justification of the proposal of India and South Africa we can read about "significant concerns, how [vaccines] will be made available promptly, in sufficient quantities and at affordable price to meet global demand" (paragraph 7). There is also a call for global solidarity an unhindered global sharing of technology and know-how employed for combatting COVID-19 (paragraph 11).

The scope of the provisions whose application would be suspended is very broad: the proposal concerns the whole Sections 1, 4, 5, and 7 of the Part II of the TRIPS Agreement, therefore a major part of "Standards concerning the availability, scope and use of Intellectual Property Rights" ("Copyright and Related Rights", "Industrial Designs", "Patents", "Protection of Undisclosed Information") would be suspended. India and South Africa argue that only once the widespread access to vaccination is guaranteed, the application of these rules could be resumed.

The proposal in question has been met with a sharp criticism of the United States, the United Kingdom and the European Union. Meanwhile, it has earned support of other developing countries (Kenya, Pakistan, Mozambik, and Bolivia). **Thus, the positions of the involved actors are aligned with the division between developed and developing countries** (notabene, we have witness a similar conflict in the context of the availability of medicines against HIV/AIDS, which were protected by patents in developed countries and were priced prohibitively expensive for African countries at the turn of the century). Consultations and discussions have not brought any results so far — admittedly, states have agreed that they should be continued (the next formal meeting of the Council for TRIPS is scheduled for 10 and 11 March), yet nothing suggests that anyone is considering changing their position.

Are compulsory licenses not sufficient?

At the first glance, it might seem that compulsory licensing is a means designated specifically for such challenges as a global pandemic. Countries are actually free to determine in which cases the issuance of compulsory licenses is allowed; **those are countries-members of WTO that decide which situations shall be considered to constitute a state of national emergency** (the Doha Declaration of November 2001). No matter how definitions of this term applied in national legal systems might vary, it is hard to imagine that a crisis as grave as the one caused by the spread of the SARS-CoV-2 virus would fall outside their scope. A state X could therefore grant a compulsory license to a producer Y who would manufacture a vaccine based on the patented solutions of Moderna, Pfizer or another concern, for the purposes of a vaccination campaign dedicated to the population of that state (as a side note, it is worth adding that some countries have so far approached quite liberally that freedom of determining a state of emergency, which might be illustrated by the case of Egipt issuing a compulsory license for Pfizer's Viagra).

When it comes to the concerns voiced by the proponents of the suspension of certain provisions of the TRIPS Agreement, the question should be raised: **why, when facing the scarcity of vaccines, countries do not resort more often to the institution of compulsory licenses?** What are its deficiencies causing that it is not perceived as an attractive solution to the problem of the vaccines' insufficient supply?

The governments of India and South Africa in their communication claim that intellectual property right hinder or might potentially hinder timely provisioning of medical products to the patients at affordable prices (paragraph 9). Moreover, they point out that many countries, especially developing ones, encounter institutional and legal difficulties when using flexibilities guaranteed by the TRIPS Agreement (paragraph 10). Let us reflect on some arguments that might support this thesis.

A. The problem of adequate remuneration

Professor Joseph Stiglitz, an American economist and Nobel Prize laureate, did not spare strong words when he described the TRIPS Agreement as "the death warrant" for thousands of people living in the world's most destitute countries. While such rhetoric might seem perhaps excessive to some, it cannot be disputed that **the requirement to pay an adequate remuneration to a patent holder might, to put it simply, prove an insurmountable barrier for certain actors.**

Under Article 31 of the TRIPS Agreement, one of the conditions for issuing a compulsory license is the payment of adequate remuneration to the right holder. **Nonetheless, TRIPS does not mention how the term "adequate" shall be understood;** it does not offer any indication as to which criteria shall be applied for the purposes of determining the proper amount of the remuneration. It only provides that the remuneration shall reflect an economic value of an authorization. The pharmaceutical companies and the governments of developed countries are therefore in a position where they can demand high remunerations on the basis of the significant economic value of the vaccine against the coronavirus, and impose rates that would make compulsory licenses inaccessible for developing countries.

B. The problem of a complicated and lengthy procedure

Not only the condition of the adequate remuneration might turn out to be difficult to fulfill in practice for countries that decide to issue a compulsory license. **The procedure is structured in a quite convoluted fashion and it requires overcoming a number of procedural hurdles: for example, we have the requirement of a judicial revision or other independent control of the decisions, resulting in the whole process extending over time.** In a situation where any delays in starting a treatment or administering a given medication might cost a patient's health or life, this lengthiness becomes particularly problematic. We need also to remember about another feature of compulsory licenses which is their lack of flexibility: such a license allows only for manufacturing of a predetermined quantity of a particular pharmaceutical product.

After all, there is a reason why the institution of compulsory licenses is in reality relatively rarely used. For instance, when Canada made a decision on the grounds of Paragraph 6 of the Doha Declaration to export to Rwanda a generic medication for AIDS that has been produced under a compulsory license, the whole procedure turned out so time-consuming (4 years passed before the medicine could have been administered to Rwandan patients) and costly that in many commentaries experts call its reasonableness into question.

C. The threat of retaliation

A problem of potential retaliation of pharmaceutical companies is real indeed — Thailand learned about it the hard way when in 2007 it issued a compulsory license for Kaletra, a medication against HIV manufactured by Abbott. In response, the corporation announced that it would withdraw from selling some of its medications in the territory of Thailand — and, as was demonstrated by the further practice, it was an action that the protective mechanisms established in TRIPS turned out utterly defenseless against. Abbot car-

ried out its threat to a significant degree and it withdrew from Thailand its motions for market authorizations for 6 of its newly developed products.

Retaliation might come **not only from the pharmaceutical companies, but also from the more powerful countries**: the TRIPS Agreement does not protect developing countries from unilateral sanctions. In the source literature an example of the United States is often invoked in this context — the USA has adopted numerous provisions authorizing its agencies to investigate practices of other states and impose economic sanctions in response to different sorts of violations, such as failure to guarantee the sufficient level of the IP protection. The U.S. Office of Trade Representatives issues annually a report, so-called Special 301, in which it lists countries where the level of the IP protection is not considered to satisfy the requirements. With regard to those who commit the most serious violations, the trade benefits can be revoked — and a fact that a country called on the carpet complies with all the obligations that bind it under the TRIPS Agreement might be completely irrelevant in that case. **That justified concern about a potential confrontation — either with pharmaceutical companies or other countries constitutes undoubtedly a major factor that quite often discourages states from issuing compulsory licenses.** The costs in those cases would simply outweigh the benefits.

Compulsory licenses in the EU

Moving on to a closer playground, we would now like to consider the perspective of the European Union. Let us assume that the aforementioned X state that struggles with the scarcity of the vaccine against SARS-CoV-2 and wants to grant a compulsory license for the producer Y who declares readiness to produce a specified quantity of generics, is a member state of the EU — how does the membership affect its freedom to issue a license? It is worth to remark some specific challenges in that field.

In the Communication of the European Commission to the European institutions of 25 November 2020, entitled "Making the most of the EU's innovative potential. An intellectual property action plan to support the EU's recovery and resilience" it is highlighted that **compulsory licensing is predominantly governed by national law of each member state**, but at the same time "the Commission calls on Member States to ensure that the tools they have are as effective as possible, for instance, by putting in place fast-track procedures for issuing compulsory licenses in emergency situations". The document places strong emphasis on the need for better coordination in the area. Compulsory licensing is described as "a means of last resort and a safety, when all other efforts to make IP available have failed"; yet a potentially significant role that it has to play is still underscored. In

any event, we must remember that **those are domestic regulations of given states that provide us with the essential point of reference.**

Clearly, it does not mean that there are not any binding EU regulations pertaining to compulsory licenses. We need to refer here to **Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.** The said legal act is related directly to the mechanism established under Article 31bis of the TRIPS Agreement.

We have to be aware that **the Regulation does not establish any path for issuing compulsory licenses on the EU level.** According to Article 3, the authority that has competence to grant compulsory licenses under the Regulation is the authority competent for the granting of compulsory licenses under national patent law. Therefore, a compulsory license is issued by a specific member state and it is effective in its territory, instead of the whole EU territory. An application for a compulsory license may be submitted by any person (Article 6 Section 1) — it is a flexible solution supposed to reflect diversity among regulations adopted by the member states. It is also worth remarking that the EU cannot apply Article 31bis as an eligible importing country. Let us remind you: that mechanism is available to least developed countries and to those who made a proper notification to the Council for TRIPS. It is evident that the EU does not fulfil the former premise, however, when it comes to the latter, there is a certain room for manoeuvre. At this moment, **due to the lack of a required notification on the part of the EU, it is not allowed to import pharmaceutical products manufactured under compulsory licenses in states that are considered third parties**; nonetheless, the EU Commissioner for Trade Phil Hogan in his letter of May 2020 expressed his openness to launch a discussion regarding the change of the status of the EU.

The fundamental challenge for compulsory licensing in the EU is related to the guarantees of data exclusivity: under Article 14 Section 11 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, the data presented in the application for a market authorisation of a pharmaceutical product shall benefit from 8-year period of data protection. In fact, **as long as the data is protected, a hypothetical producer of generics has their hands tied.** It must be added that this provision does not apply to the mechanism of Article 31bis and in its case the protection would be excluded (Article 18 of Regulation No 816/2006).

An old dispute, new chapter

The proposal that the governments of India and South Africa have put forward in the light of the current pandemic crisis, constitutes an opening of a new chapter in a debate that has been going on for quite some time already: the debate on how to strike the balance between the protection of IP and securing common access to life-saving medications. The contradictory ideas about intellectual property law are clashing: on the one hand, IP law as a source of essential stimulus without which progress would not be possible, the driving force behind innovations; and on the other — one of obstacles for making vaccine against coronavirus available to all mankind. The need for certain derogations, flexible clauses is widely accepted — some serious doubts, however, arise when it comes to assessing their actual usefulness, their adequacy towards current challenges. The proponents of the waiver that India and South Africa are lobbying for **are raising objections that compulsory licensing does not offer any viable solution to the problem — because of the complicated procedural rules and the requirements concerning remunerations, as well as the threat of facing retaliatory measures, resorting to them seems more risky than profitable.** In this Legal Report we wanted to draw your attention to some of those limitations of compulsory licensing and briefly describe them.

Let us only add that in the response to the motion of India and South Africa four member states of the WTO: Australia, Canada, Chile, and Mexico, issued a communication wherein they call the Council for TRIPS to carry out a further analysis of the problems addressed. They have formulated a number of questions aiming to investigate whether there occurred in fact any cases when the IP protection hindered local manufacturing or acquiring of vaccines against COVID-19, while the issuing of compulsory licenses turned out impossible. **Regardless of whether the ongoing debate would lead to any substantial changes, it constitutes a valuable opportunity for reassessment of the tools that are currently in our possession.** We will keep you up to date about further developments of those discussions held within the WTO framework.