Patent rights: an obstacle for development of a vaccine against COVID-19?

Recently we have been anxiously following a race of major pharmaceutical concerns: who would be the first to develop an effective vaccine against COVID-19? On 8 November Pfizer announced that their vaccine has an effectivity rate of 90%; just a week later Moderna "outbid" it, boasting 94,5% effectivity rate of their product. The dominant narrative emphasizes the common effort of the whole scientific community which is guided by a single purpose. Needless to say, everyone at our team keeps their finger crossed and hopes that a safe and effective vaccine becomes soon widely accessible.

Nonetheless, we would like to make a point that **a tension is inevitably generated between rights of patent holders and the public interest that launching of the vaccine into markets is undoubtedly supposed to serve.** We would like to examine to what extent an industrial property law, on the level of the Polish domestic legal system, but mostly on the international level, tries to strike a balance between those two distinct goods: individual and public interests. In this issue of our Legal Report we would like to raise a question about significance of compulsory licenses in this context and their adequacy with regard to the current challenges. Referring to a debate provoked by calls to treat vaccines as a global public good, we would like to share with you our reflections on a possibility of suspending patent protection on the grounds of a state of necessity. Finally, we want to

point out in which ways the *know how* protection might hamper identification of patent infringements.

mRNA vaccines

Let us begin with a brief overview of the technology we are in this case dealing with. Both pharmaceutical companies that have emerged as leaders of the peleton rely on solutions that are significantly distinct from those that the traditional vaccines are based on. They do not contain attenuated or inactive viruses (or their fragments), therefore they are not delivered to an organism with already developed antigens.

Vaccines of this kind contain a mRNA sequence that encodes proteins which are identical or similar to those of a pathogen. An organism receives in fact an instruction how to produce a vaccine: on the basis of the RNA sequence, it induces translation/synthesis of proteins which subsequently trigger an immunological response. At the same time, it is quite important which delivery methods is chosen: the available mRNA carriers include viral vectors and lipid nanoparticles.

RNA vaccines carry a great promise. Among their numerous benefits, we should mention that mRNA particles are not durable, which means that they are quite swiftly removed from an organism without posing a risk that they are permanently built into a genome of a person they are delivered to (contrarily to therapies using DNA); furthermore, they do not require insertion directly into a cell nucleus (once again, unlike DNA) — it is sufficient to deliver them into a cytoplasm where a synthesis of proteins takes place. The potential of this kind of vaccines is often mentioned in the context of cancer treatments: especially, melanotic, breast, prostate and lung cancers.

Of course **the technology that mRNA vaccines use has not arrived there overnight:** even though up to this point no treatment based on mRNA has been officially admitted into a market, as soon as in early nineties Hungarian biochemist K. Kariko was studying a possibility of applying this method to treatments of humans (interestingly, many members of the academic community displayed some degree of condescension towards her efforts, considering the area of research chosen by Kariko as cul-de-sac). A major breakthrough occurred when in cooperation with D. Weissman she invented a method of safe delivery of mRNA particles into an organism without inducing immunological response. Soon after results of their work were published, D. Rossi of Harvard founded Moderna (2005), while U. Şahin and Ö. Türeci started BioNTech (2008).

The solutions applied in the currently manufactured solutions against COVID-19, have been developed by separate teams based in different countries, often pa-

rallelly — some of those solutions do enjoy patent protection. Moderna in the most recent SEC filing submitted to the U.S. Securities and Exchange Commission clearly admits that it cannot claim with a total certainty that it is the first subject to make inventions covered by its patent claims. Actually, Moderna is already a party to patent disputes concerning the lipid nanoparticle used for mRNA delivery with Abutus Biopharma, a company which previously has shared with Moderna their inventions on the grounds of a licensing agreements.

Moving on to our analysis of legal aspects of this race for the vaccine, let us first consider what an institution of a compulsory license can offer in that field.

Compulsory licenses

In the latest entry in our cycle Patents Without Secrets we have covered a topic of compulsory licenses quite extensively. We would like to remind you that on the level of domestic law we can find the proper regulation concerning compulsory licenses in **the Act of 30 June 2000 — Intellectual Property Law (hereinafter: IPL).** According to Article 82, the term "compulsory license" shall be understood as **a permission to use an invention patented by another person**, **that can be granted by the Polish Patent Office (hereinafter: PPO) in three enumeratively indicated cases:**

1) **Threats to national security;**
2) **Abuse of a patent;**
3) **With regard to dependent patents.**

In principle, a compulsory license can be granted only once **only after an applicant demonstrates that he or she has made previously efforts in good faith to reach a licensing agreement with a patent holder**. Nevertheless, it must be emphasized that this condition **does not apply when it comes to a compulsory license that is granted to prevent or eliminate threats to national security.** Neither does it apply when an announcement that applications for such a license are accepted has been duly published (Article 82 Section 4).

A compulsory license is **non-exclusive** (Article 82) and a person using an invention on its basis should pay **a license fee** to a patent holder (Article 84). **A decision to grant a compulsory license is made by the Polish Patent Office in contentious proceedings** (Article 255 Section 1(6-6[1])).

This time let us focus mostly on the international regulation — this is international law that generates stimuli which guided the Polish legislator in regulating the issue of

compulsory licenses in the fashion that has been described above: the key legal document in this area would be the **Agreement on Trade-Related Aspects of Intellectual Property Rights of 1994 (hereinafter: TRIPS**), an agreement made between all the members of the World Trade Organization (hereinafter: WTO). Under Article 31 of the Agreement, 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, the following provisions shall be respected:

- authorization of such use shall be considered on its individual merits;
- such use may **only be permitted if, prior to such use, 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** (a waiver of this requirement is possible in situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use);
- the scope and duration of such use shall be limited to the purpose for which it was authorized;
- such use shall be **non-exclusive**;
- such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- any such use shall be **authorized predominantly for the supply of the domestic market of the Member authorizing such use**;
- 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. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
- the right holder shall be paid **adequate remuneration in the circumstances of each case**, taking into account the economic value of the authorization;
- **the legal validity of any decision relating to the authorization of such use shall be subject to judicial review** or other independent review by a distinct higher authority in that Member;
- any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

Furthermore, where an authorization permits an exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the TRIPS Agreement provides the following additional conditions:

- the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
- the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent;
- the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

It is worth noticing that the TRIPS Agreement, **besides exhaustive listing of limitations, does not designate in which situations the grant of compulsory license is actually permissible; this matter is left to domestic regulations of specific states.** According to the Doha Ministerial Declaration adopted in November 2001, each Member of the WTO is free to determine the grounds for granting compulsory licences, and to determine what constitutes a national emergency.

On the basis of the decision of the Ministerial Conference of 6 December 2005, Article 31bis has been added to the TRIPS Agreement, introducing special rules dedicated for pharmaceutical products that are manufactured for export. Article 31(f) provides that the main goal of compulsory licenses should be to supply of the domestic market of the Member authorizing such use; meanwhile Article 31bis — as a *lex specialis* — waives this requirement in a specific case: under this rule, to put it briefly, **the country A unable to manufacture on its own given pharmaceuticals can import them from the country B where a compulsory license that allows to start the manufacture is granted.** All WTO Members are eligible to export medicines using this mechanism; as for importing, the least developed countries are entitled to it right away, without having to meet any additional criteria, while other countries are required to notify their intention first.

Vaccine against COVID-19 as a global public good

To summarize the regulations of domestic and international law discussed above, we need to emphasize that **the institution of a compulsory license is subordinated to numerous limitations that safeguard the position of a patent holder: namely, we should underscore the right to remuneration, the legal standing to demand the judicial review of a decision to grant a compulsory license and, above all, restrictive premisses for issuance of such a license,** which can take place only after the efforts of the proposed user to obtain voluntary authorization turned out unfruitful. On the other hand, a compulsory license opens the door for an action serving the common interest —

which in the current situation might demand the use of specific, patent-protected solutions for development of a COVID-19 vaccine. Compulsory licenses, applied in designated legal frame, as a matter of fact do permit to reconcile individual and public goods that remain in the state of conflict.

The governments of India and South Africa however has put forward a proposition to suspend the application of some of the guarantees of intellectual property stemming from the TRIPS Agreement. The discussion on this subject took place on the forum of the WTO in October and did not bring any decisive results; no such a decision has been made. This initiative emerges **in the context of the ongoing debate whether the vaccine should be treated as a global public good in face of the current pandemic crisis.**

Global public goods are defined as goods which are non-rivalrous and non-excludable. Commonly three categories of global public goods are distinguished: natural global public goods (e.g. biodiversity, clean air); global public goods produced by humans (e.g. scientific knowledge, cultural heritage) and global public goods resulting from international policies (such as peace, health and security).

A call to guarantee a free and universal access to the vaccine to all mankind has been signed so far by 155 prominent persons, including 25 Nobel Prize laureates — it can be found at https://vaccinecommongood.org. On 4 June 2020, at the opening of a summit of the Global Vaccine Alliance (Gavi) Antonio Guterres, the UN Secretary General, expressed his conviction that a future vaccine against COVID-19 should be a vaccine "for people," accessible to everyone. In the WHO resolution of 19 May 2020 it is unambiguously declared that common vaccination against COVID-19 should be treated as a global public good and access to vaccines should be equal for everyone. The rhetoric "all aboard!" echoes in the establishment of the collaborative platform ACT (*The Access to COVID-19 Tools*) that was supposed to connect governments, scientists, business, civil society and philanthropists in order to enable them to exchange information and share resources.

So far not a single pharmaceutical company has joined the ACT. On their side, they are voicing a sharp criticism of such an approach that one-sidedly treats the protection of intellectual property as a barrier when it comes to developing and perfecting new solutions. Quite often one can come across opinions that it is in reality the other way around**: it is the IP protection that provides the necessary stimuli, the essential incentive to conduct research and enter into collaboration with other subjects with a purpose of getting improved results.** If we wanted all those entities developing and manufacturing COVID-19 vaccines to relinquish rights to their own achievements and to transfer all their knowledge and work into a common pool of solutions, certainly we would have to expect a chilling effect. This act of making their results totally public-owned would lead to hampering

the progress.

The positions presented by the pharmaceutical companies in the ongoing debates do not seem entirely coherent. We should remake that **a few among them have pledged to voluntarily give up some of their IP rights:** for instance Moderna announced that it would not enforce its patent rights and it will offer licenses to other manufactures developing their own products serving in COVID-19 treatments (though trade secrets will not be disclosed); admittedly, this strategy does not stand in its way of fighting legal battles against Arbutus Biopharma. Similar pledge has not been made by Pfizer, even though it has published an urgent call for cooperation and sharing of results transcending any possible divisions.

We could wonder if the current situation could translate in the legal realm into a certain sort of a state of necessity wherein it would be possible to suspend enforcement of patent rights and to loosen requirements for the grant of compulsory licenses. **At this moment it seems that it would be more a figure of speech than an actual legal concept that would allow us to exclude responsibility for infringements of rights protected under patents.** The conditions for the grant of compulsory licenses prescribed by the TRIPS Agreement remain in force; and there are no available paths that would circumvent those rules. The state apparatus of Members of the WTO are not free to cease patent enforcement; otherwise, they would incur responsibility on the forum of the organization.

Know-how: the infringements that we miss out on

It is also worth to mention another problem which — as we might reasonably expect — could occur quite often in practice: **many times we will not find out about acts of infringements.** We argued that compulsory licenses serve to safeguard the interest of a patent holder and at the same time permit to take steps required by the public interest. Even so, we would deal sometimes with situations when a compulsory license is not granted at all; a given party developing a vaccine would apply (even inadvertently) solutions that are already protected on the grounds of an application filed previously by an independent inventor. The proper patent office will not notice any faults while preparing its report on the state of art because what is derived from the work of predecessor is not disclosed at all, but enjoys protection under different rules.

The holder of the patent might only surmise that a newly patented invention is based on their own, theoretically protected, solutions. **The fact that infringement did in fact occur would not always be evident and proving it might be particularly difficult, if not entirely impossible — this is where the protection of know-how enters the stage.**

A useful definition of know-how can be found in 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; according to Article 1(1), this term means 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 fulfilfs the criteria of secrecy and substantiality;

Contrarily to patents, the protection of know-how is not dependent on filing an application and carrying out a special procedure during which a disclosure of a subject matter under protection would be required. Know-how would encompass technological secrets just like patents, yet this concept shall be understood more broadly. Moreover, the protection would be exempt from time limits to its duration.

The concepts of know-how are common for different countries and their specific regulations bear a strong resemblance to each other. For instance, in the Polish law know-how is protected on the grounds of the Act of 16 April 1993 on combatting unfair competition: it falls within the scope of a trade secret which Article 11 Section 2 defines as **technical, technological and organisational information belonging to an enterprise or other information of economic significance which as a whole or in their specific combination or in the set of their elements are not commonly known to persons usually dealing with this kind of information, or not easy accessible to such persons,** provided that a subject entitled to use or dispose such information undertook, with due diligence, measures to keep the information secret. The act of unfair competition is disclosing, using or acquiring of someone else's information constituting a trade secret (Article 11 Section 1); it is a criminal offense punishable by fine, restriction of freedom, or deprivation of liberty up to 2 years (Article 23).

It is not that difficult to imagine a situation where a given pharmaceutical company is successful in its efforts to obtain a patent for its vaccine, without disclosing all aspects of its invention, but certain aspects — derived from other inventors not on the grounds of a compulsory license — keeping to itself as know-how. In consequence a patent holder is not eligible to ask for a judicial verification of such an invention. A race for vaccine has turned out to pose a certain risk that such practices might occur.

Summary

The goal of this article was to juxtapose institutions specific to industrial property law with challenges caused by the COVID-19 pandemic. Naturally, a full, comprehensive analysis of the issues that have been mentioned would require a much lengthier study. We do not attempt to make any general statements or present any definite conclusions; we consciously leave this subject somewhat open. What we wanted to achieve was to paint a rather more general pictures of rules that create the applicable framework: compulsory licenses, protection of know-how, a category of global public goods, and pinpoint certain doubts that might arise when it comes to adequacy of terms and norms from our current toolkit to the pandemic. We encourage you to consider this article an invitation to engage in a discussion on whether the IP law has in fact a capacity to strike a balance between private and public interest, or whether these extreme circumstances have weakened or strained its potential.

