



PATENT PROTECTION ON VACCINES AND COMPULSORY LICENSING

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We can say that the most important issue on the agenda of the whole world in 2020 is the COVID-19 infection pandemic and the number of people lost due to this pandemic. Even though countries make measures including lockdown, curfew, state of emergency against the pandemic, we can only be protected from the virus with the shield of vaccines or we can only get rid of this disease if a variant occurs.

After the virus emerges and become a pandemic in particular, multiple vaccine studies were commenced all across the globe. Deep-down, many people think like "who will earn a serious income and become advantageous?" That is why several studies have been conducted all over the globe on drugs developed for use in the treatment of COVID-19 and applications have been started to be made for the patents of the developed drugs. This study is intended to shed a light on the patent production on drugs and vaccines intended for the treatment of COVID 19, and compulsory licensing ensured for the reason of public interest against potential monopoly right ownership.

General Information

Vaccine appears to be the most efficient way to destroy the coronavirus that killed more than 300 thousand people across the world. There are already more than 100 vaccine developing studies. There is another angle in these studies as well: The agenda is who will be prioritized in vaccination if vaccines are found. After the President of the USA Donald Trump declares "If I pay for the vaccine, America will have the priority", French firm Sanofi announced that the USA will have the priority. Even though Paul Hudson, CEO of Sanofi said "USA will have the biggest order right since the country takes the risk and counts on the firm", they backed down from this announcement because of the French government's reactions.

This situation leads to a vaccine war amongst countries as well as some countries take political steps to collaborate with other countries. Our country has recently declared that it will conduct vaccine studies with Russia jointly and the USA declared that they are working in cooperation with India. Even though the president of China said that they are going to share the vaccine if they manage to develop it nowadays, countries are really looking forward to be a country that developed the vaccine.

Patent is a document of which the invention holder prevents 3rd parties to produce, use, sell or violate invention-related product for a certain period of time. Countries all around the world are concerned about the fact that the COVID-19 vaccine will be restricted with a patent by some

companies or governments. So, is it possible to get a monopoly right ownership for a vaccine with a patent? In that case, can governments take a resolution for the sake the public interest? Let's find answers to these questions.

Natural microorganisms cannot be patented. Because microorganisms exist in and as a part of nature, discoveries of microorganisms are not considered as an invention (EPC [Article 52 \(2\)](#) and [IPC Article 82 \(2\)](#)). Both Turkish Patent Office and European Patent Office, do not consider this discovery as patentable. Austrian Patent Office and Swedish Patent Office agree as well. However, this rule does not apply to the microorganisms that can be created and developed in labs. In several developed countries, microorganisms created or developed by people and biological materials are allowed to be patented. Bacteria, virus, fungi, unicellular algae can be given as examples.

According to [European Patent Convention](#), if someone tries to patent an invention, the invention must fulfill three following conditions; Novelty, inventive step and industrial applicability. Let's say somebody made an invention that lets a natural microorganism have an antibiotic effect, in that case, exceptionally, the microorganism can be patented as a part of the invention. That is, if there is an invention that has a natural microorganism along with different components, it can be patented. When companies or individuals apply for patenting a vaccine, they actually apply for the created formula instead of various components that the vaccine has.

As understood from the above-detailed information, a vaccine that is a very strong drug can be protected with a patent and monopoly right ownership can be possible for it.

Although it is concerning, the authority of those to obtain a patent right can be restricted with compulsory licensing when there is an exceptional situation such as pandemic or war. Compulsory licensing is regulated under the Articles 129/1 and 132 of the TIPL (Turkish Industrial Property Law), no 6769.

Compulsory licensing might put restrictions against the patent rights holder. In compulsory licensing, when an invention is not used for a while without the will of its patent rights holder, there can be a licensing process on the grounds of correlation between patents or public interest. In extraordinary conditions such as wars, and pandemics, compulsory licensing can be made without the consent of the patent rights holder in order for the third parties to produce the products that are within the scope of the protection of the patent right.

Compulsory licensing can be both shaped in accordance with the countries' national law, and some certain principles and essentials on the compulsory licensing with the TRIPS (The Agreement on Trade-Related Aspects of Intellectual Property Rights). Countries that signed the

agreement are liable to abide by these principles and essentials. On the other hand, to help the countries having trouble getting access to drugs and remove the obstacles against the access, some regulations were conducted from the perspective of compulsory licensing.

Since compulsory licensing is granted when the public interest is needed to be secured, when the patent holder's interests and public interest are conflicted, public interest should be preferred consequently. As understood from the explanations, although a firm or organization obtains a right ownership for a vaccine, if public interest is the case, compulsory licensing is determined within the scope of public interest. It is explained in the Article 132/1 of the TIPL as follows;

"If use of the invention forming the subject of patent, increase of its use, dissemination of it in general, improvement of it for a beneficial use have a great importance by the reason of public health or national security issues or if non-use of the invention forming the subject of patent or its insufficient usage in terms of either quality or quantity shall cause serious damages in terms of the economic or technological development of the country, it shall be decided by Council of Ministers upon the proposal of the relevant ministry."

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In the light of the relevant article's second paragraph, the invention's use of which its application or subject is important in terms of public health or national security, it can be proposed by the relevant ministry in the light of the opinions of the Ministry of National Defense and Ministry of Health. The compulsory licensing process can start after a person applies to the ministry or after the administration takes steps in its own motion. In other words, a verdict of a court is not necessary for compulsory licensing on the grounds of securing public interest. Or you can simply arrange meetings with the patent holder and get a consensus. Since there is no certain obligation about who will have the compulsory licensing, a legal entity, public or natural person can apply for it.

Conclusion

The COVID-19 vaccine is allowed to be protected with a patent just like all other drugs. Since

there is a right to apply for compulsory licensing for the drugs that can be useful for the treatment of COVID-19, taking public interest into consideration, they can be removed of a single person's right ownership via licensing agreements, and gotten to the production stage.

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