

## Compulsory Licensing and Public Health during COVID-19 Pandemic

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COVID-19 pandemic continues to spread rapidly across the globe amid critical supply shortages of medical devices and medicines. The rapid spread of the virus, on the one hand, threatens supply chains and causes shortages, on the other hand, it also strengthens global solidarity.

Brands from different sectors make an effort towards helping in the fight against the pandemic. Fashion brands are manufacturing masks, luxury cosmetic brands are supporting disinfectant manufactures, the entrepreneur ecosystem swept into seeking alternative ways to support healthcare heroes who are facing the growing shortage of personal protective gear. News keeps coming from the technology industry, 3D printing of protective gears ramps up, people even have started using their personal printers for such purpose. Furthermore, pharmaceutical companies across the world are diligently working to develop vaccines and antivirals.

Not surprisingly, all these developments raise questions about compulsory licensing. Intellectual property rights, patents primarily, are protected to support and secure future inventions and developments. Because the main purpose is to support the actors who have contributed to the field to ensure continuous and stable development. Disclosing the invention to the public and making it available for others are also required for that purpose. In this sense, there is always a delicate balance between those who should use existing inventions and the inventors who need support for future inventions. In some exceptional cases, compulsory licensing mechanism comes along with patent protection, to maintain this balance.

The Agreement on Trade-Related Aspects of Intellectual Property Rights ("**TRIPS**") is one of the main sources of the World Trade Organization ("**WTO**") members regarding legislative purposes of intellectual property rights. TRIPS covers the patent protection and exceptional limitations to be imposed. Accordingly, WTO members, including Turkey, are expected to implement those into their law systems.

In Turkey, IP Law protects inventors by enabling them to patent their inventions and exercise their rights. Basically, the patent is an exclusionary right that permits the patent right holder to prevent others from making, using or selling the patented invention for a limited period. This exclusionary right is subject to exemptions, as well. Compulsory licensing mechanisms are one of the exemptions.

The exclusionary status of patent rights makes the compulsory licensing mechanisms very rare and exceptional. Since the very beginning of the patent protection in Turkey, there has been only one case for compulsory license requests which had been concluded with a settlement without a court decision.

Even though, the compulsory license may not be required as we are all together in this fight against the outbreak, the current trend on the rapid raises of the shortages indicates that this mechanism might be triggered soon.

### Compulsory Licence Proceedings in Turkey:

The IP Law sets certain conditions for granting Compulsory Licence ("**CL**") in Turkish practice and regulates the following CL request/grant proceedings respectively:

- **In case of non-use arguments:** - The courts are entitled to handle these requests.
- **In case of interdependency of the subjects of the patents** - The courts are entitled to handle these requests.
- **In cases where plant breeders cannot develop a new type of plant without infringing on a preceding patent.**
- **In cases where patent holders engage in activities that prevent, distort or restrict competition while using the patent.** - Turkish Competition Authority is entitled to handle these requests.
- **To meet requirements of the Doha Declaration** (The export of pharmaceutical products to foreign countries experiencing public health problems.) - The courts are entitled to handle these requests.
- **In the interest of public order** - Turkey's Ministry of Health and the Ministry of National Defence are entitled to request these CLs and the President decides on the granting.

## The CL Proceedings in the interest of Public Order:

The IP Law regulates that where public health or national security is at stake, at the request of the Ministry of Health and the Ministry of National Defence, the President of Turkish Republic is entitled to grant a compulsory license.

In accordance with their exclusionary nature, such rights are protected with patents and aimed to be protected as strong as possible. Due to this nature, compulsory licensing is exceptional for them.

However, at some point, this protection might upset the market balance. The non-use status of the patent or the activities of the patent holder which are not compatible with competition rules is relatively common ways of compulsory license granting mechanisms. On the other hand, the licenses granted by the President of the Turkish Republic are rarely seen in this exceptional situation. The granting mechanism - the procedural steps that need to be followed are relatively straightforward in comparison with the other compulsory license types. This is not surprising given that this license type can only be granted in cases of a national emergency and/or extreme urgency regarding public health or national security.

## Export/Import Status of the Pharmaceuticals Produced under a Compulsory Licence:

Today, we are experiencing a global outbreak, COVID-19 is a true example of "extreme urgency". Therefore, it comes as no surprise in case this mechanism is triggered in Turkey in case of need.

The compulsory license mechanism brings the questions on whether licensee will be entitled to the export and import of the pharmaceuticals that are produced under a compulsory license.

In principle, the nature of the CL does not allow the licensee the right of the exportation/importation. It is only granted for producing the generics "predominantly for the supply of the domestic market", not for export purposes. Also, the product must be produced in the market, not be imported. This principle leads to two primary consequences:

- Limiting the exportation amount when the pharmaceuticals are manufactured under the CL.,
- Effecting the countries with insufficient manufacturing capacity. These countries will face difficulties when supplying their needs.

The first exception to this principle is CL proceedings for the exportation of the pharmaceutical goods manufactured under the CL. Levels of the spread of the virus and severity vary from country to country, and each has its own weaknesses and strengths. On the other hand, each country has different level of manufacturing facilities, capacities, technologies or stocks on chemicals or active ingredients. Therefore, a country in the near future might be in need of pharmaceuticals products which it is not capable of manufacturing it. In such a case, the exportation of the products from a country where the products are being manufactured will be possible under the compulsory license.

With Doha Declaration and relevant amendments, Turkey has agreed to import the pharmaceutical products manufactured under CL only in a national emergency or other circumstances of extreme urgency, which forms the

second exception. Considering the extreme urgency of maintaining fast and uninterrupted access to these vital pharmaceutical products, in case a need arises while granting such compulsory license, the Presidency can grant the right of importation to the licensee. This authority must be limited to the need and must be granted temporarily.

In Turkey the applicable law provides the basis to act either as exporters or as importers, or as both. Regarding the COVID-19 outbreak, it is very gripping to follow the developments to see whether CL proceedings is going to be applied ever.

## References

- [https://www.wto.org/english/news\\_e/pres03\\_e/pr350\\_e.htm](https://www.wto.org/english/news_e/pres03_e/pr350_e.htm)
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