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# Forced License and Legal Regulation

The impact of coronavirus infection on all spheres of life, and especially on the economies of many countries drawn particular attention of states to the issue of forced licensing of the intellectual deliverables in the health sector. Any object of industrial property (invention, utility model, or industrial design), whether it be the military industry, space industry, technology sector, pharmaceuticals, agriculture, or consumer goods, etc., is usually protected by a patent from unauthorised use. The patent holder has the exclusive right to prohibit other persons from commercialising the patented object without his/her permit in the territory of the country/region, where the patent is valid. It is the patent holder, who decides when, to whom, why, for how long, to what extent, on what financial or other commercial terms the right (license) to use the industrial property object would be granted. Such licenses issued by a patentee are voluntary.

However, there are cases when right holders misuse their exclusive right, whereby hindering the development of a competitive environment, equal access of consumers to goods and services, improvement of the patented object for further technological progress in the development of the state. In those cases, international provisions and national laws provide for a *forced* licensing mechanism, when a competent authority or court binds a patent holder to grant a license for the patented object to a third party. By issuing a forced license, the patent holder executes not own will, but the order of the competent authority or court to grant a third party a permit to manufacture, use, sell or import an invention or use a process protected by the patent in certain circumstances.

## Basic International Acts

The international regulatory legal act related to forced licensing of industrial property objects include, inter alia, the **Paris Convention for the Protection of Industrial Property** dated 20 March 1883 (hereinafter - the 'Paris Convention') and the **Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)** dated 15 April 1994 (hereinafter - the 'TRIPS Agreement').

Article 5A of the **Paris Convention** provides for more general provisions on a forced license to use patents, referring to national law. Pursuant to the Paris Convention, the main purpose to issue a forced license is the prevention of misuse of exclusive rights by the right holder, for instance, abuse of a dominant position in the market, lack of capacity to meet market needs (e.g., with food and medicines), non-use of the patent, impeding the technological progress. The UK national law, for instance, specifies that the state authority on competition protection (antitrust authority) can apply to the relevant authority for forced licensing, if an undesirable monopolistic situation or anticompetitive practice is observed on the part of the patent holder that is detrimental to the public interest.

The Paris Convention is silent as to the issue of a forced license in case of the need to ensure national security or public health. In other words, the Paris Convention aims more at restricting the patent owner from the non-use of the patent. The later international act - the TRIPS Agreement, detailed the conditions for granting a forced license.

The Paris Convention provides for an important condition that a forced license must be issued after four years from the date of the patent application or three years from the date of the patent issue, whichever expires first. This period is considered sufficient for the patent holder to arrange the process for the invention use individually or through issuing a voluntary license. The Paris Convention establishes that the competent authority shall refuse to issue a forced license if the patent holder justifies his/her failure to act for valid reasons. Such reasons may be legal, economic or technical obstacles to the patent use in the country.

Forced licensing is described in more detail in the **TRIPS Agreement**. While empowering the national legislation to impose restrictions on the exclusive rights of a patent holder (Article 30 of the TRIPS Agreement), the TRIPS Agreement, however,

requires that the legitimate interests of the right holder be not infringed upon when restrictions are introduced.

Article 31 of the TRIPS Agreement provides for the cases when local legislation allows commercial or non-commercial use of an invention without the voluntary consent of the patent holder. Article 31(b), however, distinguishes two scenarios:

- ▶ if the right holder failed to agree on reasonable commercial terms with the person interested in using the license and trying to obtain the license, or
- ▶ in conditions of extreme necessity and/or state of emergency or non-commercial use by the state; in these cases, the patent holder must be notified of the patent use immediately or as soon as possible.

Although this invention may be used without the consent of the patent owner, the TRIPS Agreement nevertheless sets limits on such forced use (Article 31(c)) that are limited to the achievement of the purpose of such a forced patent use. For instance, this issue could be more relevant in the face of a pandemic, when an emergency regime was introduced in many countries in order to reduce the COVID-19 infection. If the patented COVID-19 vaccine was available in the spring and summer of 2020, many states would have localised the production under conditions of the non-commercial patent use and in the event of the national emergency. With such a non-commercial use, the licensee has no goal of benefiting from the patented invention. In this case, the public and state interests in the security and health protection are pursued. Upon reaching a certain level of the herd immunity, the forced license would be terminated.

In addition to *achieving the objectives* of the forced use of a patent, the patent holder is protected by other conditions for the issue of a forced license provided for in Article 31 of the TRIPS Agreement, they are:

- ▶ the patent holder is not limited in the right to license the invention to any other person on a commercial basis (Article 31(d));
- ▶ There are some restrictions for the transfer (assignment) of a forced license (Article 31(f));
- ▶ a forced license is used primarily to meet the needs of the domestic market (Article 31(f)) of the country that decided on the forced license;
- ▶ the patent owner is entitled to the appropriate remuneration (Article 31(h));
- ▶ the judicial or other competent authorities of the state can review both the legality of the decision to issue a forced license, and the decision to give remuneration under the forced license (Article 31(i)(j)).

The TRIPS Agreement is only a guideline for the member states, since it leaves the definition of the license conditions and the time for negotiations with the right holder to the discretion of national legislation. The TRIPS Agreement does not contain definitions of 'emergency' or 'extreme necessity', which would allow skipping the negotiations stage. However, the TRIPS Agreement strictly requires to comply with the terms of Articles 30 and 31 and prevent unreasonable infringement of the legitimate interests of the right holder.

The Doha Declaration on the TRIPS Agreement and Public Health (hereinafter - the 'Declaration') provides for specific options for member states of the World Trade Organisation (WTO) to meet public health needs, also referred to as 'flexible means'. Article 5(b) of the Declaration specifically emphasises that, in accordance with TRIPS Agreement, WTO member states can independently determine situations and conditions for issuing forced licenses.

The Declaration also states that each member has the right to determine what constitutes a national emergency or other circumstance of extreme necessity. In this case, it is understood that public health crises, including those related to HIV/AIDS, tuberculosis, malaria and other epidemics, may represent a national emergency or other circumstance of extreme necessity.

## Laws of the Republic of Kazakhstan

There is no special regulatory legal act in the Republic of Kazakhstan governing the procedure for issuing a forced license. The possibility of issuing a forced license is provided for by Article 11 of the Patent Law of the Republic of Kazakhstan dated 16 July 1999, No. 427-I (hereinafter - the 'Patent Law'), which provisions mainly duplicate the provisions of the Paris Convention and the TRIPS Agreement.

The issue of a forced license in Kazakhstan is addressed by the court in the course of action proceedings. Pursuant to Article 11 of the Patent Law, *the court*, by its decision, forces a patent owner to issue a license to a third party, if the following conditions are simultaneously met:

- ▶ Non-use by the patent holder of the patented object (which means that the patent holder does not use the industrial property object continuously for three years preceding the appeal to the court);
- ▶ Refusal by the patent holder to license this third party on acceptable commercial terms.

At the same time, a potential licensee must prove in the court that the patent holder refused to enter into a license agreement, while the patent holder must prove that the invention non-use is due to valid reasons. Otherwise, the court would grant the license specifying the limits of use, size, timing and procedure for payments.

The Patent Law also provides for the following cases for granting a forced license:

- ▶ the need to ensure national security or public health protection;
- ▶ misuse by the patent holder of the exclusive rights, facilitating or not preventing the abuse of such exclusive rights by another person with his/her consent (e.g., unreasonable overpricing or deliberate non-use of the patent).

Please note, any forced license must be issued primarily to meet the needs of the internal market of the Republic of Kazakhstan. An exceptions is the cases when such a license is claimed for a medicine or the process of its manufacturing for export to the territory, where there are no or insufficient production facilities, in accordance with international treaties ratified by the Republic of Kazakhstan. This typically refers to developing countries, where population do not have access to medicines, which has been a topic of debate in the World Trade Organization.

As for the remuneration to the right holder in case of forced licensing, Kazakh legislation says nothing on the minimum payments. However, the remuneration provisions are contained in Article 31(h) of the TRIPS Agreement, one of the prerequisites for the issue of a forced license is that the patent holder must get sufficient, in the specific circumstances, remuneration to take into account the economic value of the licenses.

As noted above, the Patent Law duplicates provisions of the Paris Convention and TRIPS Agreement on forced licenses and does not contain a more detailed mechanism, procedure and conditions to grant them. Article 4 of the Patent Law only indicates that the competent authority develops and approves the rules for registration of forced licenses with the relevant state registers. Thus, there is no relevant regulation regulating the detailed mechanism and procedure for granting a forced license.

Currently, the country is considering the 'Development Concept in the Area of Intellectual Property in the Republic of Kazakhstan for 2021 - 2025', which pays attention to the development of the mechanism and regulation of forced licenses. The concept involves the development and implementation at the legislative level of provisions on the issue of forced licenses, especially in the area of healthcare. In particular, it is suggested to amend the current Patent Law, as well as consider the forced licensing mechanism based on decision of the Government, while the current Patent Law establishes the judicial procedure for issuing compulsory licenses. Those responsible for the Concept implementation in 2022 are the Ministry of Justice and the Ministry of Health.

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