Kluwer Patent Blog

Russia Compulsory License

Neemesh Chheda (Emory University School of Law) · Monday, July 12th, 2021

Legal Basis

The legal basis for compulsory licensing in Russia flows from Articles 1360 and 1362 of the Civil Code of the Russian Federation (Civil Code). Article 1360 of the Civil Code allows the Russian Government to grant permission to the use of a patented invention in the interest of defense and national security. Such permission requires notifying the patentholder and paying him an adequate compensation.

Requirements for obtaining a Compulsory License

According to Article 1362 of the Civil Code, a compulsory license may be granted if any of the following conditions are met:

- An invention is not used or is insufficiently used by the patent holder for a long period of time; or
- A holder of a "dependent patent" cannot use the patented invention without infringing the rights of another patent holder.[1]

In either case, a company applying for a compulsory license has to try, within a reasonable period of time, to negotiate a voluntary license with the patent holder on reasonable commercial terms. Only in this situation may a compulsory license be issued, and, even then, the patent holder has a right to adequate compensation.

On November 22, 2019, the Russian Government introduced a bill amending Article 1360 providing a situation when the government may grant a compulsory license without a court proceeding despite not having explicit language for doing so:

"The Government of the Russian Federation has the right in case of emergency to provide a defense and security, a protection of life and health of the citizens to allow the use of an invention, utility model, or industrial design without the consent of the patent holder provided that he is given notification as soon as possible, and with the payment of appropriate compensation. The procedure for determining such compensation and the terms for its payment will be approved by the Government of the Russian Federation."

The bill was approved by the Parliament Committee who analyzed the bill prior to putting it for a vote before Parliament. In particular, in accordance with the Committee opinion, the law would address a patent holder's possible abuse of his dominant position on the market that could lead to

his refusal to manufacture or supply socially necessary drugs or medical devices in the territory of the Russian Federation. Such actions could endanger the life and health of Russian citizens.

According to the Committee, the "compulsory licensing" stipulated by the bill is aimed, among other things, at preventing and mitigating the effects of sanction pressure on the Russian Federation.

The amendments proposed by the bill will make it possible to compensate for the lack or shortage of foreign (innovative) patented drugs or medical devices that are necessary for the life and health of Russian citizens.

At the same time, according to the Committee opinion, the law should be applied only in exceptional cases and with a comprehensive study of specific circumstances, given the fact that the use of compulsory licenses cannot guarantee the production of high-quality, effective and safe generic drugs that are completely identical to the innovative ones. The voting on this bill is expected in 2020.

On March 3, 2020, the Russian Government introduced another bill to further amend Article 1360:

1. The Government of the Russian Federation has the right, in the cases and on the conditions provided for by an international treaty of the Russian Federation, to make a decision on the use of an invention for the production in the territory of the Russian Federation of a drug for the purpose of exporting it without the consent of the patent holder with notifying him of this as soon as possible and with the payment of appropriate compensation. The Federation's decision must contain information on the volume of production of the drug determined by the needs of the foreign state, to whose territory the drug is to be exported. The package of such a drug must have a special designation.
2. The procedure for sending the notification specified in item 1 of this article, the grounds and procedure for making a decision and determining its validity, the procedure for determining the period of validity of the decision, as well as the procedure for determining the amount of compensation and the procedure for its payment are approved by the Government of the Russian Federation in accordance with an international treaty of the Russian Federation."

This bill has been already approved by the Parliament Committee. In particular, in accordance with the Committee opinion, the bill purports to organize the production of generic drugs utilizing patents related to those drugs in Russia to provide assistance to foreign countries.

At the same time, Article 31bis of Trade Related Aspects of Intellectual Property Rights (TRIPS) grants World Trade Organization (WTO) members with insufficient capacity for the production of drugs to contact another WTO member in case of an emergency for help in providing the country with the necessary amount of drugs. Using article 31bis of TRIPS, the Russian Federation can arrange the production of drugs for delivery to foreign states at an affordable price in order to combat epidemics.

It should be noted that Article 31bis of TRIPS provides for serious restrictions on the production of drugs. Production of drugs using the mechanism described in Article 31bis, is a last resort, designed to solve health problems in the least developed countries.

At the same time, according to the Committee opinion, the bill needs to be improved, since the notification of the patent holder and the payment of compensation are conditions provided for by

TRIPS. At the same time, TRIPS provides for other conditions, it is unclear why only two of them are included in the bill.

It is also noted that TRIPS establishes the requirement to identify drugs by means of a special designation or labeling, but the bill specifies only a “special designation”.

Procedure for granting a Compulsory License

The jurisprudence below demonstrates that a court could grant a compulsory license to a generic (e.g.; dominating) patent, where the following conditions are met:

- The generic (e.g.; dominating) patent is protected by an additional dependent patent;
- A dependent patent constituted a significant technical achievement; and
- A dependent patent provides substantial economic advantages.

A compulsory license may be also issued due to nonuse of the patent.

Moreover, it is difficult to use the Federation’s proposed model discussed above in the current situation the world is experiencing due to COVID-19. Additionally, the current model requires a waiting period that can last 4 years.

Applicants seeking patent protection in Russia should take into account that the granting of compulsory licenses in Russia is increasingly becoming a reality. Now that Russian courts have started granting compulsory licenses to pharmaceutical companies, it should be treated as impetus for all other generic producers’ development. As discussed below in the case involving Pfizer, a compulsory license may be the basis of a counterclaim, such as in a case where a wrongdoer issued in action for patent infringement.

Appeal/Review

The appeal and review process for compulsory licensing in Russia begins after appealing a decision from a commercial court. A party may appeal to the appropriate appellate courts. From there, if the decision of the appellate court is to be appealed, it is heard by the Russian Intellectual Property court and the Economic Board of the Russian Supreme Court. The final supervision appeal—if accepted—may be considered by the Russian Supreme Court, which is entitled to review and ascertain whether there is substantial breach in law enforcement.

Jurisprudence

Natvia v. Celgene International Holdings Corporation

The Moscow City Commercial Court fulfilled a claim made by a local generic company Nativa and granted a license to use a patented drug of Celgene International Holdings Corporation in connection to the cancer drug, Lenalidomide-Nativ. The drug is used for the treatment of leprosy, tuberculosis and AIDS.

Nativa tried to contact Celgene to execute a licensing agreement to produce and sell the generic version of the original drug on the Russian market. However, Celgene failed to respond. As a result, Nativa filed a claim for a compulsory license based on the argument that it owned a dependent patent.

The Commercial Court determined that Nativa was the patentee of a dependent invention. It also determined that Nativa's product has significant economic advantages over the originator's invention due to the exclusion of certain stages from the preparation process. As a result, the court granted a non-exclusive license to Nativa on the grounds of economic development in public interest.

However, at the later stage of proceedings in the Intellectual Property Court, the parties executed a settlement agreement establishing that Nativa could not use the issued compulsory license now or in the future.

Nativa v. Sugen LLC and Pharmacia & Upjohn Company

In February 2019, the Moscow City Commercial Court granted a second compulsory license to Nativa for use of a drug named Sunitinib was protected by an Eurasian patent co-owned by Sugen LLC and Pharmacia & Upjohn Company, both of which were owned by Pfizer. Nativa argued that it owned a dependent patent that could not be exploited without infringing the patent of Sugen LLC and Pharmacia & Upjohn Company.

Sugen LLC and Pharmacia & Upjohn Company tried to appeal against the issuance of the compulsory license, but the Supreme Court of the Russian Federation also held that Nativa's actions could not be construed as an abuse of law.

Nativa vs Pfizer (Sunitinib)

Pfizer filed a patent infringement action against Nativa as a result of Nativa launching a product after participating in a state tender before expiration of the patent term. Nativa filed a counterclaim seeking a compulsory license on the basis that Nativa's sunitinib crystal form patent was dependent over Pfizer's, constituted an important technical achievement and has considerable economic significance over Pfizer`s.

In early 2020, the Supreme Court dismissed Pfizer's infringement action and granted Nativa's counterclaim requiring Pfizer to grant a non-exclusive compulsory license to Nativa. The Court laid out the terms and conditions of the license stating that Nativa as a licensee could use Pfizer's patent to manufacture, use, offer for sale, or storage of any drug containing Subitinib as an active ingredient. The royalty rate was set at 10% of net profit from sales, excluding Value Added Tax (VAT) and direct expenses incurred by the manufacturer. The royalty is to be paid annually no later than January 31st of the year following use of the patent.

These cases illustrate that the Russian Government sometimes uses the threat of issuing a Compulsory License as a negotiation tool in state affairs.

Foreign Attorneys: Vlad Ugryumov, Ruben Dzhermakyan from Gowling WLG, Kirill Filippov

****

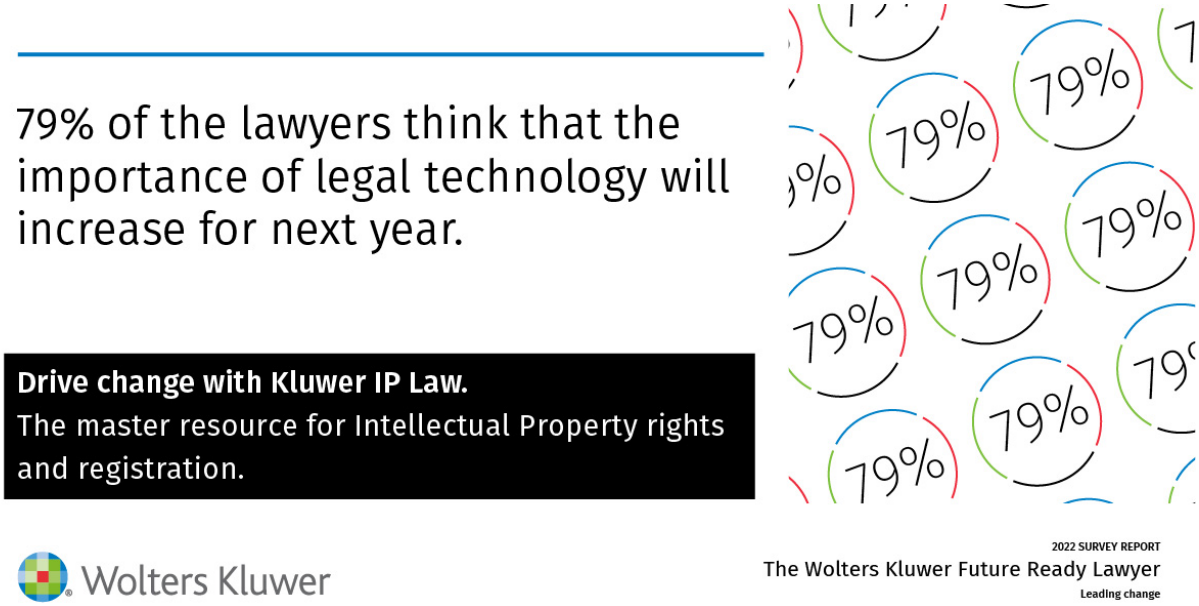
[1] Section 1362, Civil Code of the Russian Federation, *in* CIVIL CODE OF THE RUSSIAN FEDERATION 60–60, https://www.wipo.int/edocs/lexdocs/laws/en/ru/ru004en-part4.pdf (last visited Jun 16, 2020).

To make sure you do not miss out on regular updates from the Kluwer Patent Blog, please subscribe here.

Kluwer IP Law

The **2022 Future Ready Lawyer survey** showed that 79% of lawyers think that the importance of legal technology will increase for next year. With Kluwer IP Law you can navigate the increasingly global practice of IP law with specialized, local and cross-border information and tools from every preferred location. Are you, as an IP professional, ready for the future?

Learn how **Kluwer IP Law** can support you.



This entry was posted on Monday, July 12th, 2021 at 9:29 am and is filed under (Compulsory) license, Compulsory Licensing Series, Russia
You can follow any responses to this entry through the Comments (RSS) feed. Both comments and pings are currently closed.