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Russia: First “public security” compulsory license

Boris Malakhov (Lidings) · Thursday, March 4th, 2021



At the beginning of the year, the Russian Government granted the first compulsory license on a series of Big Pharma’s patents.

For the first time ever, “public security” clause has been evoked.

According to the [Decree 3718-r](#), Pharmasintez JSC, a Russian generic company, has been granted a 1-year compulsory license to use Gilead’s patents protecting Remdesivir subject to a “fair compensation”.^[1]

Pharmasintez JSC filed a request for a compulsory license to the Government after a few unsuccessful attempts to [enter into a license agreement with Gilead](#) voluntarily.

The Decree is based on art. 1360 of the Russian Civil Code which entitles the Government to grant a compulsory license “in the interests of public security” without a patent holder’s consent subject to its notification and “a fair compensation”.

According to the [Russian Federal Antimonopoly Service](#), such compulsory licenses are designed to eliminate discrimination in relation to Russian manufacturers by global pharmaceutical companies, which is, however, strongly criticized by the professional community.

The Decree has triggered the mechanism of art. 1360 of the Russian Civil Code for the first time.

But a compulsory license has not been first ever made: previously, compulsory licenses for dependent patents (art. 1362 of the Russian Civil Code) were granted to Nativa LLC, a Russian generic company, based on the court decisions (particularly, as a result of the [dispute against Celgene on Lenalidomid](#)^[2]).

The Russian Parliament currently works under the [draft law 842633-7](#), which

significantly simplifies the mechanism of compulsory licenses in the pharmaceutical industry. It is expected to expand the scope of Article 1360 of the Civil Code, under which compulsory licenses will be allowed “in the interest of life and health protection”. In a nutshell, for almost any drug the Government finds interesting to localize.

It is evident that the Decree is another step towards consistent restriction of patent rights in the sphere of Life Sciences in Russia clearly aimed to support national generic business.

[1] The criteria of “fair compensation” have not been established so far. According to [social media](#), compensation is unlikely to exceed 1-1.5% of total revenue.

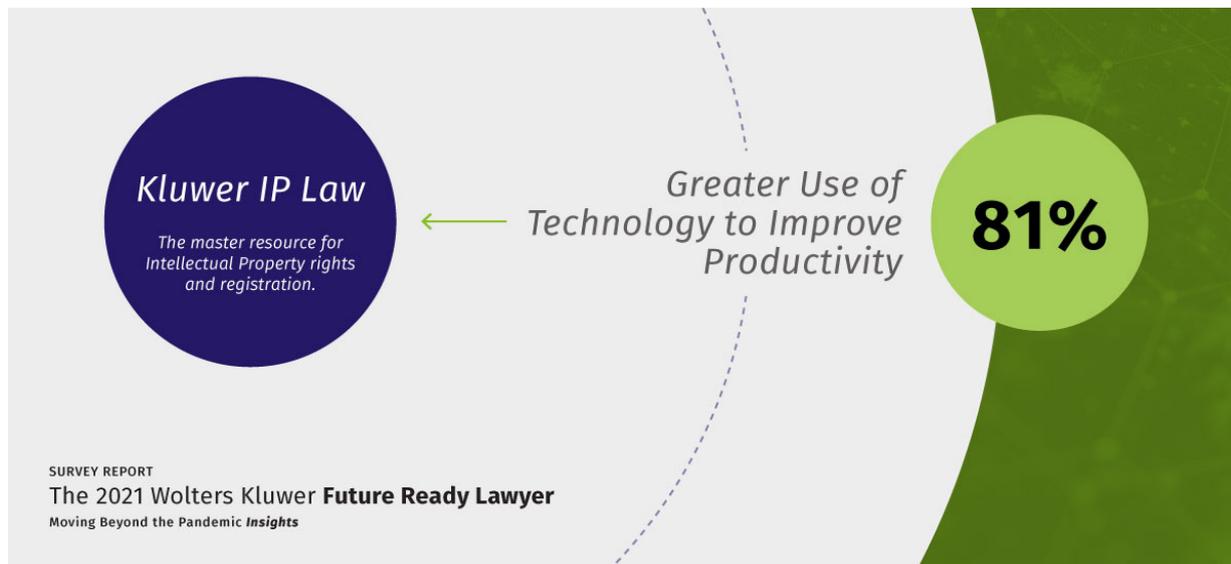
[2] By the way, in the said case royalty under the compulsory license was calculated as 30% of the revenue side of the price using the following formula: revenue of the generic drug reduced by the amount of VAT and direct costs.

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