



Freezing of foreign pharma patents in Russia? Legal uncertainty or fake news ...

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Currently, business operations in Russia keep facing hindrances introduced both by foreign sanctions and internal extraordinary legislation aimed at countering them. So far, intellectual property had not been the target of specific measures. However, certain Russian political figures and press have recently referred to intellectual property as a possible political tool.

The first IP-related hot topic was the supply of pharmaceutical products in Russia. According to information recently provided by industry experts, 48.2% of the medicines commercialized in Russia are supplied from foreign countries which imposed sanctions against Russia in the context of the Ukraine crisis. Furthermore, the chemical components utilized for pharmaceutical production in Russia are mostly imported from China, India, and the EU. Although pharma products were not directly addressed by restrictions, restrictions connected with payments and logistics created risks of under-supply, at least in the short term.

Industry sources as well as pharmacies reported a dramatic increase of demand, which was caused by prices increases coupled with a slowdown in supply chains, both actual and expected. It was reported that consumers recently purchased both general and essential medicines building up private stocks for some 2-6 months, whilst others consequently were unable to buy any.

It is against this background, that some Russian politicians argued that Russian pharma companies do have the facilities and capabilities allowing internal production of most of the medicines that are needed in the country, that the only hindrance to this solution is the existence of patents owned by foreign companies and that the suspension or termination of such patent protection would be the easiest and fastest route to achieve the goal under the present circumstances. Reference was also made to article 1360 of the Russian Civil Code, which provides for a derogation to the exclusive rights of the patentee in case of national defense and security needs, that in 2021 was expanded to the “protection of citizens’ life and health” as ground for the



non-exclusive use of a patented invention, utility model or industrial design without the consent of the rightholder. In that case, the special grant of rights, which is equivalent to a compulsory license for practical purposes, is put in place by an order of the Russian Government.

The first (and probably single) case of grant of a patent license without the consent of the patentee holder resting on that legal basis dates back to December 2020 within the extraordinary context of the Covid-19 pandemic, and was commented in two of our articles at the time (please see “Medicines for the therapy of the Covid-19 syndrome, political discretion and the bypassing of patent rights in Russia in an unprecedented legal scenario” at <https://www.lexology.com/library/detail.aspx?q=4616f1af-e652-47ad-8ff7-af39807c8b56> and “More room for the bypassing of patent rights by the Russian Government in the wake of the pandemic health emergency” at <https://www.lexology.com/library/detail.aspx?q=952e7eb4-7a65-44df-9e98-5d7e80989008>).

It is recalled that article 1360 of the Russian Civil Code is based on and remains within the scope of article 31 of the 1994 TRIPS Agreement, which allows the “use of the subject matter of a patent without the authorization of the right-holder” in the case of “a national emergency or other circumstances of extreme urgency”. This was supposed to be a rarely applicable exception from the universal rule of exclusivity of patent rights, which is one of the pillars of the intellectual property system.

As a response to recent sanctions imposed against the Russian Federation, on 08 March 2022 the Parliament adopted Law no. 46-FZ, which amended the existing legislation in different areas.

Amongst others, noteworthy are some amendments relative to intellectual property rights. Namely, article 6 of Law no. 46-FZ amended the Law “On circulation of medicinal products” and allowed a special registration procedure of amendments to the drug master file of

a pharmaceutical product in case of inventory shortages due to foreign sanctions. The special procedure shall be set in detail by the Russian Government.

More importantly, article 18 of the same Law no. 46-FZ grants to the Russian Government special powers for year 2022, including the power to define a list of goods (product groups), which fall outside the scope of certain provisions of the Civil Code on the protection of intellectual property rights utilized in such products. The new rules allow the Government to suspend the provisions of IP law for certain goods. The text of the law does not set any additional conditions for exercising that power; as a result, the choice of the product groups affected and of the rights that could be suspended fall within the full discretion of the Government. The extremely broad wording provides for an open mandate to the Government and creates a high level of legal uncertainty for all rightholders in Russia, at least for 2022.


To the best of our knowledge, there are no other legislative proposals under way aimed at introducing a general suspension or expropriation of patent rights in the pharma sector in Russia. One cannot, though, deny that there are tools available in the legal system, allowing the Government to bypass patent rights based on the catch-all justification of ensuring state defense and security and protecting citizens' life and health, including the patents of foreign pharmaceutical companies, which was already tested in 2021, as well as on new extensive powers to suspend any IP rights. It is, therefore, not unconceivable that these legal mechanisms - in substance, a compulsory license under article 1360 of the Civil Code or a suspension of IP rights under new Law no. 46-FZ - could be resorted to for purposes of international economic policy, in practice as de facto countersanctions. However, there is no serious indication that this is going to happen, and the intellectual property system in Russia is at present in all respects working as usual, including as concerns foreign rightholders in the pharma sector.



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