Register of patented pharmaceutical products in Russia and “patent linkage”. New legislation under way amidst a controversial climate

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Earlier this year, the Russian Patent and Trademark Office (Rospatent) has presented to the authorities the proposed layout of the new patent protected pharmaceutical active substances register (Pharma Register). The creation of the Pharma Register was initiated by the Russian Government and aims at providing correct information on the existing patent protection of medicinal products to all stakeholders and prevent unfair practice when generics enter the market before expiry of the relevant patents. Until presently, recordals in the Pharma Register have been conceived as voluntary, and to be made on the basis of requests from the patent holders.

The head of the Rospatent Mr. Ivliev commented to the Russian press that the newly recast Pharma Register should speed up court disputes between patent owners and producers of generics and replace expensive and time-consuming expert opinions, which are often at the source of delays and inefficiencies.

As a result, the product commonly called During the presentation of the new Pharma Register on 30 June 2021 the head of the Rospatent advised that its driving principles, the information to be included therein and the procedures of recordal and challenging such recordals were discussed both with the authorities and pharma companies. He also added that the procedures and status of the Pharma Register shall be governed by specific legislation.

Companies holding patents for pharmaceutical substances in Russia

indeed often litigate with generic producers on infringement issues. Patentees understandably invest efforts in protecting their intellectual property and believe that the Pharma Register can be of help in more effectively solving infringement disputes. However, they are concerned that the Pharma Register may end up with a status as a source of general information only. In such case, the Pharma Register would be of limited use in improving the level of legal protection against premature generic entrants. For example, the information recorded in the Pharma Register does not seem per se capable of relying on as a ground for rejection of drug supply tenders in public procurement procedures, unless compliance with the data of the Pharma Register is made an express statutory requirement.

As one might expect, patient organizations argue that the Pharma Register may turn out an excessive measure that could lead to lack of or affordability of drugs. If compliance with the Pharma Register should become a mandatory requirement for all state authorities, the Ministry of Health would need to suspend the registration and issuance of marketing authorizations for generics until expiry of the relevant patents for the active substance of the drug concerned.

On 01 September 2021, at a meeting with the industry representatives the Russian Ministry of Economic Development unveiled a draft bill “On the register of patent protected pharmaceutical active substances”. Currently, this bill is at a preparatory stage before filing for consideration by the Russian State Duma (Parliament) and the text of the document is not yet available to the public.

According to the information provided by legal circles and industry representatives, who claim to have seen the draft bill, the new law will govern the process of recording, amending and removing information in the Pharma Register, its maintenance and the extraction of relevant information from the register. However, the draft bill does not seem to affect or amend any other legislation or regulatory sources of the industry and could, at this stage of elaboration, be disregarded in practice by the authorities issuing marketing authorizations for medicinal products, including generics.

The Association of International Pharmaceutical Manufactures (AIPM), an industry body, considers that the draft bill does not effectively address the existing problems caused by premature, pre-patent expiry generic entry and needs additional refinement and development.

The Association of foreign pharma producers “Pharmaceutical Innovations” (Inpharma, Bayer, Roche, Pfizer, Novartis), another originator industry body, also noted that the new legislation should address “patent linkage” also at the level of medicinal products registration and public procurement procedures.

The two associations sent to the Ministry of Economic Development a joint letter and suggested a number of relevant amendments to the draft. The Russian press reported that the owners of patent protected pharmaceuticals requested that a “patent linkage” requisite should be foreseen between patents and marketing authorization in Russia. Moreover, it was suggested that the Pharma Register requisite should be made mandatory for all players of pharmaceutical industry, become applicable to public procurement procedure, be conclusive in infringement disputes and be valid for all Eurasian Economic Union (EAEU) members.

Besides, the letter draws the attention of the authorites to the narrowness of an approach whereby only chemical substances could be an object of the new Pharma Register recordal, which should cover instead also active substances of biological nature as well as pharmaceutical compositions, combinations and derivative (secondary) medicinal products.

The new Pharma Register legislation may or may not dramatically change the current situation of the Russian pharma market. Striking a balance between the interests of patent holders, generic producers, patent protection as a

booster for research and innovation, and an expanded availability of drugs and a competitive market was never an easy task anywhere in the world, and Russia is no exception . In response to the comments of the industry, the Ministry of Economic Development declared that efforts will be made to take all proposals received from the authorities, the businesses and other stakeholders into account in the final version of the bill.

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