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Russian Patent Office Attempts to Fight against Evergreening in Pharma

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I. Foreword

After long discussions on addressing the evergreening problem in Russian pharma, the Ministry of Economic Development signed an act on amending the Rules for drafting, filing and examining documents for the state registration of inventions and the Requirements imposed on the documents of patent applications. The act came in force on December 15, 2018. The new provisions apply restrictions to applications that involve compositions in general, and pharmaceutical compositions in particular.

II. Secondary inventions

Generally speaking, patents for secondary inventions are granted for follow on alterations of an invention protected by a primary patent, which in pharma field usually relates to an active ingredient. Such alterations include different physical forms, pharmaceutical formulations, dosage regimes, new medical uses, etc. Although patenting of secondary inventions as such is a legitimate procedure, which is meant to protect incremental improvements of an invention, these incremental «improvements» sometimes contain marginal inventiveness and are patented by companies solely to extend monopoly on certain drugs in order to recoup large investments spent on their R&D. Such strategic extension of patent protection is commonly known as «evergreening».

In fact, the majority of patents in pharmaceutical field are granted for secondary inventions. The study on European patents and patent applications related to 219 top-selling INN's (nearly 40,000 cases) that were granted by European patent offices, or were pending, over the period of 2000-2007 showed that about 87% of the cases involved secondary inventions [1]. The prevalence of secondary patents was also reported with respect to developing countries: in India between 2009 and 2016 the largest share of pharmaceutical patents (72%) was granted for follow-on inventions [2]. As full screening of all pharmaceutical patents issued in a certain jurisdiction requires a significant amount of efforts, such studies are scarce. However, the ones which are out there do outline the abovementioned trend (see, for example, the results of an extensive research carried out in Chile - [3]). According to the experts from Skolkovo Innovation Center, Russia is no exception to this: secondary patents may account for more than 70% of the national pharma patent base [4].

III. Ways to approach secondary inventions

Opinions on secondary patenting and ways to approach it vary across jurisdictions. On the one hand, if manufacturers of branded drugs are free to pursue the evergreening strategy, the ability of patients to have affordable drugs becomes limited as the extension of patent protection delays the market entry of generics. On the other hand, if secondary patenting is highly constrained, pharmaceutical companies may be discouraged to invest money into R&D of new lifesaving treatments in the first place.

[1] European Commission (2009) Pharmaceutical Sector Inquiry – Final Report.

[2] Ali, F., Rajagopal, S., Raman, V.S. & John, R. (2018) Pharmaceutical Patent Grants in India: How our safeguards against evergreening have failed, and why the system must be reformed. White Paper Published by AccessIBSA and the Shuttleworth Foundation.

[3] Abud Sittler, M.J., Helmers, C. & Hall, B. (2015) Study on pharmaceutical patents in Chile. CDIP WIPO.

[4] Krechetova, A. & Baulin, A. (2017) The first billion in a long line. «Biokad» won a case against Genentech on an evergreen patent. Forbes. Retrieved from https://www.forbes.ru/tehnologii/351783-pervyy-milliard-v-dlinnom-ryadu-biokad-vyigrala-spor-u-genentech-po-vechnozelenomu.

Needless to say that it is very difficult to sustain the balance of interests in this question. In order to keep this balance the U.S. patent system uses litigation instruments to filter out secondary patents that involve trivial inventions [5]. Contrary to this post factum approach, developing countries often choose to adopt preemptive measures to filter out some secondary inventions at the stage of examination [6], which is believed to make the balance of interests somewhat biased towards generic producers and patients.

As a matter of fact, due to the high dependence on generic production many of developing countries did not allow patenting of pharma products at all prior to becoming the members of the World Trade Organization (WTO). Obliged to recognize patent protection for pharmaceuticals under the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), some of these countries tried to find ways to limit secondary patenting by using flexibilities of the Agreement. This was done in India, Brazil and Argentina. These three jurisdictions adopted different measures to pursue the same goal [5].

In short, India denied protection of new forms, new properties or new uses of known substances, unless these new modifications of a primary invention demonstrate enhanced efficacy. Brazil arranged a dual examination, where pharmaceutical patent applications are to be approved by the Brazilian Patent Office and the Brazilian Health Regulatory Agency. And Argentina simply banned most forms of pharmaceutical secondary inventions.

IV. Russia chooses its way

On October 1, 2018, the Ministry of Economic Development of Russia issued an act on amending the Guidelines for drafting, filing and examining documents for the state registration of inventions (clauses 70 and 76) and the Requirements imposed on the documents of patent applications (clauses 39.3 and 53.14) to address the problem of evergreening. The amendments are effective as of December 15, 2018. The introduced changes did not come as a surprise. The Russian Patent Office has talked about adopting anti-evergreening measures before, referring to India and the Eurasian Patent Organization (EAPO) as models to follow. In the end, the amendments were drafted almost repeating the provisions of the EAPO. In accordance with the new amendments, a composition cannot be described by:

- information that is not directly related to the composition (for example, conditions and regimes of use of the composition in a process or a method);
- a quantitative parameter (measured or calculated) that defines one or more characteristics of the composition (for example, lamination strength, cracking resistance, pharmacokinetic profile, etc), if this parameter is used as an essential feature in an independent claim;
- a technical result achieved by production or use of the composition.

The introduced provisions also restrict patenting of pharmaceutical compositions: now pharma compositions cannot be described by features related to methods of treatment (e.g., dosage regime, administration schedule of the compositions or drugs based on the compositions). The above features if included in the claims will not be considered in the assessment of the compliance of invention with the novelty and inventive step criteria. The introduced measures are motivated by the fact that some properties that patentees claim to be novel are often known from the drug's registration file, which is kept confidential.

[5] Sampat, B.N., Shadlen, K.C. (2017) Secondary Pharmaceutical Patenting: A Global Perspective. Research Policy. 46(3), 693-707.

[6] Sampat, B.N., Shadlen, K.C. (2015) TRIPS implementation and secondary pharmaceutical patenting in Brazil and India. Studies in Comparative International Development. 50(2), 228-257.

V. Whom does it affect?

Even though the primary goal of the new provisions is to constrain originators' attempts of evergreening, in certain cases these provisions may, in fact, work for originators' benefit. This is because there are some highly proactive generic producers in Russian pharma market, which manage to obtain secondary patents that are dependent on primary patents of originator producers. They use these secondary patents to legitimize early market entry of generics by obtaining compulsory licenses for the primary patents. Lately this practice has been extensively used by a generic producer called Nativa, which over the past few years became infamous for having patent disputes with the largest originator companies including Novartis, Bayer, Bristol-Myers Squibb, etc. In six of the disputes Nativa claimed for the grant of a compulsory license on the grounds of having a patent for a dependent, i.e. secondary, invention.

To give you a short overview of one of the cases: back in 2016 Nativa filed a patent application for a modification of lenalidomide – an active substance originally protected by a patent owned by Celgene, and did manage to get a patent for this secondary invention. In 2018 Nativa used this patent to claim for the grant of a compulsory license for the Celgene's primary patent. However, at the cassation instance the case was settled with no license granted due to the cancellation of the Nativa's patent by the Russian Patent Office as a result of a nullity action filed by Celgene. The Nativa's patent protected a crystalline form of lenalidomide defined in the independent claim by a particular d-space pattern and a particular differential scanning calorimetry plot. The nullity action contested inventive step of said form compared to the Celgene's patent and some other prior art. Having considered the argumentation, the Patent Office agreed that the modified form patented by Nativa did not have any unexpected beneficial effect compared to the crystalline forms of lenalidomide known from the prior art, and, thus, was not inventive. Such approach to the analysis of inventive step is rather unusual for the Russian Patent Office, and may potentially serve as another barrier against questionable secondary inventions, in addition to the introduced amendments.

VI. Conclusions

How effectively the amendments introduced in Russia will fight evergreening, and trivial secondary inventions in general, is hard to predict. This is especially in light of recent studies on the effects of similar measures undertaken in other countries. Although the use of anti-evergreening provisions appears to be on the rise in India [7], a large share of granted patents there still falls within the scope of these provisions, which suggests that patentees do find ways to bypass them [2]. Moreover, the provisions of the Indian patent law originally designed to fight against marginal secondary inventions, instead are often invoked against primary inventions [7]. Some issues with implementation of anti-evergreening measures were also reported from Brazil [5]. Whether the recent amendments to the Russian examination guidelines will have their intended impact is something to monitor in the coming years.

[7] Sampat, B.N., Shadlen, K.C. (2018) Indian pharmaceutical patent prosecution: The changing role of Section 3 (d). PloS one. 13(4)