New developments in patent cases in pharma

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VEGAS LEX

1. Speed read

In November 2015 the Arbitration court of Moscow region rejected the originator's patent claim against the local drug manufacturer.[1]

Following the decision of the Supreme Arbitration Court in well-known Imatinibum case in 2009[2] the Arbitration court of Moscow region decided that no patent infringement may occur prior to state registration of a pharmaceutical product.

Furthermore, the court gave several potentially important interpretations of IP regulations applied to pharmaceutical products. The relevant conclusions of the court may influence the future development of IP practice in pharmaceutical sector in Russia.

2. Case study

The originator manufacturer applied to the court with the claim to prohibit a local drug manufacturer, inter alia, from producing, storing and launching into the market its allegedly generic[3] medicine as it may breach the originator's patent (valid up to September 2025). The originator's patent among other protects the method of production of pharmaceutical composition used in the originator's medicine against disseminated sclerosis.

The local drug manufacturer filed its application for registration of a follow-on/analogues medicine in 2012. As far as the original medicine and the relevant medicine of the local drug manufacturer are supposed to have the same group name glatiramer acetate the originator decided that its patent could be breached based on the following considerations.

It has come to the attention of the originator that the local drug manufacturer allegedly anticipated the issue of registration certificate for its medicine in Summer 2015 and asked the Ministry of Health (the MoH) to postpone the state purchases of the medicines having group name "glatiramer acetate" up to the Autumn 2015.

Therefore, the originator decided that there were huge risks that the local drug manufacturer may start producing and selling its follow-on/analogues medicine in 2015 (inter alia during state tenders) and applied to the court to prevent the possible violation of its patent rights[4].

The local drug manufacturer argued against the originator's claim, stating that its follow-on/analogues product was not registered by the MoH at the moment of court proceedings and, therefore, no patent violation actually occurred.[5]

The court supported the arguments of the local drug manufacturer. The court confirmed earlier findings of the Supreme Arbitration Court that the state registration of a product by itself may not be regarded as a patent violation. Furthermore, the court decided that the originator was not able to prove (e.g. through written evidence), that the local drug manufacturer actually started producing its medicine for commercial purposes or actually proposed its product for sale.

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1 Case No. A41-46966/15.

2 Resolution of the Presidium of the Supreme Arbitration Court dated 16 June 2009 No. 2578/09.

3 It is not clear from the court decision, whether the relevant medicine is being authorized as a generic medicine as far as the court prohibited access to the information contained in the registration file of a local drug manufacturer. Therefore, we will use a neutral term «follow-on/analogues product» in this alert.

4 The court actually did not decide, whether the patent of the originator was violated, as it was not clear from the proceedings whether the originator's method of production of pharmaceutical composition was actually used by the local drug manufacturer. The court did not authorize the patent expertise on formal grounds and instead based its decisions on the more general logic.

5 According to existing court practice, submission of a registration file as well as submission of samples to the MoH for registration of a medicine are not considered as patent violation as the these actions are not actually connected with marketing of the product (e.g. see the Resolution of the Presidium of the Supreme Arbitration Court dated 16 June 2009 No. 2578/09).

3. Originator's evidence basis

(a) Access to registration file of a follow-on product: refusal of the court to disclose evidence

The registration file of a medicine inter alia contains protected information (e.g. commercial secrets, know-how etc.). Therefore, as a general rule the originator has no access to registration file of a follow-on or analogues product even if originator has the reasons to believe, that its IP rights may be violated.[6]

However, in this case the court rejected the originator's claim for access to the registration file of the local drug manufacturer on the formal grounds. The court supported the arguments of the MoH that no access to confidential information may be provided to such information without the consent from its owner during the period of product registration.

(b) Patent expertise: refusal of the court to authorize an expert investigation

In order to answer the question, whether the patented invention of the originator is used in the follow-on/analogues product a specific expertise is usually necessary.

However, in this case the court rejected the originator's claim for such expertise on the formal grounds. The court stated that the relevant follow-on/analogues medicine is in the process of registration and therefore no actual "product" is being marketed at the time of court proceedings, which from the legal standpoint does not create an "object" for expert comparison.

The relevant conclusions of the court may significantly lower the ability of the originator pharmaceutical manufacturers to protect their rights and interests in the sphere of intellectual property. The originator pharmaceuticals manufacturers should consider new ways and new bases that are to be different from Imatinibum case in order to protect their rights.

4. Implications for business

This case may have a precedential importance for the industry. Today the case may be assessed as negative for originator medicines manufacturers, but positive for manufacturers of follow-on products. This situation may change, however, during appeals in the upper courts (if any). Therefore, it is necessary to monitor further developments in the relevant proceedings.

We are also not able to exclude the risks, that such controversial IP practice in pharmaceutical sector may become a trend in 2015. We note, that on 14 July 2015 the Moscow arbitration court[7] decided the patent case in favor of a local biosimilar drug manufacturer. The court concluded that a biosimilar drug manufacturer and pharmacy were not in the position to breach the originator's patent for the method of medical treatment (described in the instruction for use of the originator's medicine) as far as the biosimilar drug manufacturer and pharmacy had no license for medical services and the sale of the relevant biosimilar product could not be construed as violation of originator's patent.[8] The case was not appealed and therefore may be used as a precedent by certain market participants.[9]

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[6] Therefore, in order to obtain information regarding follow-on/analogues medicine to be able to compare its manufacturing method or other characteristic with the original product an originator will usually have to ask the court for help and disclosure of evidence.

[7] Case No. A40-32877/15.

[8] At the same time, the originator argued that the product launched by the biosimilar drug manufacturer was having the instruction for medical use, describing the patented originator's method of treatment and the sale of the biosimilar product was actually the proposal for usage of patented method of treatment. The court however, dismissed the relevant arguments and interpreted the case differently. Of note, legal instruments for protection of the patent for the method of medical treatment, with respect to court's opinion mentioned above, seems unclear due to the fact that usually drug manufacturers do not provide medical services.

[9] E.g. see an article in English at: http://finance.yahoo.com/news/russian-biotechnological-company-won-case-140000405.html.

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