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IP IMMUNITIES FOR DRUG MANUFACTURERS ON THE RUSSIAN MARKET

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On 23 September 2014 the Court of Appeal ruled that IP immunities may not be regarded as a valid excuse for a patent holder/trademark holder in case of abuse of dominance on the drug circulation market, inter alia in those cases where a drug manufacturer refuses to enter into a supply agreement with its distributor.[1]

BACKGROUND

In December 2013 the FAS acknowledged that a foreign drug manufacturer had abused its dominant position and therefore violated Article 10, Clause 5, Part 1 of Federal Law dated 26 July 2006 No.135-FL «On Protection of Competition» (the Competition Law). According to the FAS ruling, the foreign drug manufacturer had unreasonably refused to enter into an agreement for supplying a drug against multiocular sclerosis with a local pharmaceutical distributor. The FAS analysis showed that the drug had no analogues in Russia. Therefore, the FAS concluded that when the foreign drug manufacturer had entered Russian market through its subsidiary, it had obtained a dominant position, and was thus subject to restrictions set forth in the Competition Law.

The foreign drug manufacturer appealed the FAS decision in court. The company argued that no abuse of dominance had actually occurred because the company had acted within the framework of its IP rights, which according to Article 10, Part 4 of the Competition Law excluded application of restrictions set forth for dominant companies.

COURT RULING

The Court of First Instance discovered that the foreign drug manufacturer and the local Russian distributor had entered into a framework agreement, which inter alia obliged the local distributor to perform secondary packaging of the drugs supplied by the foreign company. To this end, the framework agreement inter alia entitled the local distributor to use the trademarks attributable to the first packaging of the drug against multiocular sclerosis.

Since the framework agreement contained provisions on the transfer of exclusive rights to use the trademark to the local distributor, the foreign drug manufacturer argued that Article 10 of the Competition Law was not applicable to its refusal to enter into the supply agreement for a particular batch of medicines.

Besides, the foreign drug manufacturer pointed out that it held a patent for an active ingredient and the manufacturing method of the drug, and therefore was entitled to unilaterally decide how to market the relevant drug and through which sources.

The Court of First Instance concluded that the drug supply had been followed by the transfer of exclusive rights to use the trademark. Therefore, the Court decided that such transfer of exclusive rights had enabled the foreign drug manufacturer to prohibit its local distributors from using the trademark and thus marketing the drug. Following this logic, the court concluded that the foreign manufacturer was not subject to restrictions of Article 10 of the Competition Law.[2]

However, on 23 September 2014 the Court of Appeal overruled the above decision of the Court of First Instance[3] and favored the earlier arguments of the FAS.[4]

In particular, the Court of Appeal stated that while deciding how to market its drugs in the Russian Federation any drug manufacturer must take into account the local rules and regulations including the restrictions set forth in the Competition Law.

The Court of Appeal concluded that the subject matter of the relevant agreement between the foreign drug manufacturer and its local distributor was supply of the drug against multiocular sclerosis. The Court decided that the use of a particular trademark in this case could not have changed the legal nature of the supply agreement. The Court also concluded that by selling the drug with the trademark on its first packaging, the foreign drug manufacturer had not actually transferred the right to use such trademark to its local distributor.

SIMILAR COURT PRACTICE

The similar logic may be found in other decisions of Russian courts.

For instance, Resolution of the Federal Arbitration Court of the Moscow Region dated 1 February 2011 No. KA-A40/17921 states that through inclusion of the

1 See at: http://kad.arbitr.ru/Card/69743520-ac8e-4d36-858b-798d47f41cce.

2 See at: http://ras.arbitr.ru/PdfDocument/6ddd7cc8-d7a7-4356-8bbf-089672d0cd87/A40-42997-2014__20140709.pdf.

3 Full text made available on 6 October 2014. See at: http://kad.arbitr.ru/PdfDocument/01faa449-c3c5-4f7d-b600-604a172d4eda/A40-42997-2014_20141006_Postanovlenie%20apelljacii.pdf.

4 However, the decision of the Court of Appeal may be further appealed in the cassation court. Therefore, further monitoring of the development of court proceedings will be necessary for the final assessment of the case.

so-called «exclusive right» of the distributor into the microcontroller unit[5] purchase agreement, the parties were not able to bypass the application of the restrictions of Article 10 of the Competition Law to their agreement.

In Resolution dated 31 March 2011 for Case No. A65-18093/2010 the Federal Arbitration Court of Povolzhsky Region found that the IP immunities were not applicable to the patent-owning manufacturer selling goods without IP transfer.

POTENTIAL RISKS: IS EXCLUSION OF IP IMMUNITIES NECESSARY?

Based on the above analysis we may conclude that antimonopoly IP immunities set forth in Article 10, Part 4 of the Competition Law may only apply to a limited number of cases (e.g. pure license agreements). However, the FAS argues that today IP immunities are being applied by courts unreasonably widely.[6] Therefore, the FAS suggests eliminating the relevant provisions from the Competition Law.

However, the above analysis reveals that the approach of the higher courts to assessment of the scope of application of IP immunities is quite consistent. Therefore, it is doubtful that total removal of IP immunities from the Competition Law might make the court practice more predictable and transparent.

On the other hand, cancelling Article 10, Part 4 of the Competition Law[7] may impair any transfer of technology as well as any refusal of a patent holder to grant a license to a local company. Such refusals might be then regarded as violation of the Competition Law and a clear pathway for compulsory licensing might be then established through the FAS and court practice without due incorporation into the Russian Civil Code.

5 Is an integral part of the protected electronic control tape to be used in cash register equipment.

6 Refer to http://www.fas.gov.ru/fas-in-press/fas-in-press_39363.html.

7 This initiative is widely discussed in relation to the so-called «fourth antimonopoly package of amendments». Refer to http://www.fas.gov.ru/fas-in-press/fas-in-press_39363.html.

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- Chambers Europe 2014
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