VEGAS LEX

WHAT IS THE FUTURE OF IP PROTECTION DURING STATE PROCUREMENT OF DRUGS?

WWW.VEGASLEX.RU

MARCH 2014

In December 2012, the auction committee of a local Ministry of Health rejected an application by a generic drug manufacturer on the basis of its infringement of the original drug manufacturer's patent. The Federal Antimonopoly Service of Russia (FAS), the court of first instance and the court of appeal all found the acts of the auction committee to be reasonable. However, on 17 February 2014 the Federal Arbitration Court for the Moscow Region[1] remanded the case to the court of first instance for a fresh proceedings, having found that the lower courts failed to examine the evidence in the case fully and thoroughly.

Background

At the end of 2012, a limited liability company supplying generic drugs (hereinafter, the Company) participated in a state procurement auction for the supply of drugs for specific social groups of Russian citizen.

A local health ministry acted as the customer (hereinafter, the Customer). The Customer's auction committee rejected the Company's application with reference to the fact that the generic drug trade name had no sale permit due to an unexpired patent on the active substance held by the original drug manufacturer (patent being valid up to April 2013).

The Company brought a claim against the Customer's committee before the FAS. The claim was by the FAS found to be unreasonable. Having disagreed with the FAS's resolution of the matter, the Company turned to the arbitration court.

FAS Opinion

During inspection, the FAS concluded that the Customer's acts were lawful. The Customer's position was founded upon information letters sent by the originator's subsidiary (hereinafter, the Originator) concerning the protection of IP rights over the relevant drug, as well as enclosing the opinion outlined in the Ruling of Presidium of the High Arbitration Court of Russia, dated 16 June 2009 No. 2578/09[2] (concerning validity of the Originator's patent). The Customer and the FAS deemed the generic drug supplier's act of applying to participate in the auction to be profit (income) seeking in contradiction of the rules enshrined in the Russian Civil Code.

Court practice

The court of first instance and court of appeal supported the FAS' opinion. The courts relied upon the fact that the Originator held exclusive rights over the drug, and suppliers under state procurement contracts should ensure that no exclusive third party rights are infringed in relation to drug supply and use.

The court of cassation found that court rulings at first instance and appeal should be recalled.

The court of cassation stated the following:

(a) the lower courts failed to examine the issue of the non-compliance of the decision issued by the FAS with part 5, section 41.9 of Law No. 94-FZ[3];

(b) the lower courts failed to assess the Company's evidence concerning the compliance of the drug supplied with auction documentation formalities;

(c) the lower courts failed to examine information on the registration of the generic drug supplied by the Company with the State Register of Drugs, though drugs are put into circulation within the Russian Federation when registered by the relevant state authority;

(d) the lower courts unreasonably neglected the Company's arguments that the Originator's patent rights should be protected by way of court or administrative procedure rather than denial of access to open auction.

The court of cassation also stated that the lower courts' reference to the circumstances previously substantiated by the Ruling of the Presidium of the High Arbitration Court of Russia dated 16 June 2009 No. 2578/09 (regarding the validity of the Originator's patent), did not provide relief from the need to substantiate the status of the original drug manufacturer. The court of cassation referred to the fact that in accordance with the Russian Arbitration Procedure Code, the facts substantiated by a final and binding court judgment regarding a previous case are not subject to re-substantiation only when both the parties involved in a case handled by the arbitration court are the same.

---

[1] See Ruling of the Federal Arbitration Court for Moscow District dated 17 February 2014 with respect to case No. A40-32698/13-17-317.

[2] In case No. 2578/09 the Presidium of the High Arbitration Court of Russia suggested an approach where manufacturing and presenting drug samples for registration not be regarded as a use of a patented invention. In this regard, the Presidium of the High Arbitration Court of Russia specified that it is not permitted to manufacture or keep a drug prior to the expiry of a patent for the purposes of selling or putting such drug into circulation.

[3] The list of grounds for refusing access to online open auctions is exhaustive and does not include infringement of third party intellectual property rights to the product.

As such, the court of cassation arrived at the conclusion that the judicial acts passed by lower courts should be recalled, remanding the case for new proceedings to be brought before the court of first instance.

What does the future have in store?

Case No. A40-32698/13-17-317 has become another corollary of the prevailing conflict of rules under the Russian Civil Code and Russia's laws on drug circulation. The Civil Code prohibits any patented drug use that is profit seeking or aimed at going into circulation. At the same time, Law No. 61-FZ "On drug circulation" states that drugs are put into civil circulation within the Russian Federation when registered by the relevant state authority.

Until recently, legal uncertainty concerning the limits of the authorized use of patented drugs seemed to have been overcome following the Ruling of the Presidium of the High Arbitration Court of Russia dated 16 June 2009 No. 2578/09. However, having enacted the Ruling dated 17 February 2014 in respect of the examined case, the Federal Arbitration Court for Moscow District has put the issue of balancing the interests of patent holders and generic manufacturers back on the agenda.

The acts of the Customer's auction committee constitute the cornerstone of these proceedings. If the courts find that an auction committee is entitled to reject procurement applications from auction participants who have infringed an originator's rights, this will constitute a new evolutionary phase in the practice of protecting intellectual property rights in the pharmaceutical sector.

In the meantime, neither Law No. 94-FZ nor Law No. 44-FZ formally enable the Customer's committee to reject a procurement application from a participant where that participant infringes a third party's IP rights. Thus, if practice construes the rules enshrined in the laws on drug circulation in formal terms, the existing controversy could be resolved solely by amending the current regulations.

CONTACT INFORMATION:

ALEKSANDRA VASYUKHNOVA

Head of Technology and Investment group

vasukhnova@vegaslex.ru

MARIA BORZOVA

Projects manager of Pharmaceutical sector

borzova@vegaslex.ru

ANTON LAVRENTEV

Associate of Technology and Investment Group

lavrentev@vegaslex.ru

Additional information about the products and services of VEGAS LEX can be found at www.vegaslex.ru

VEGAS LEX

VEGAS LEX is one of the largest law firms headquartered in Russia, with over 100 lawyers based in Moscow, Volgograd and Krasnodar.
Since 1995 we have been providing services in every region of Russia, as well as in other countries of the world.

PRACTICE AREAS:

- Capital Markets, Securities, Listings
- Competition & Antitrust
- Compliance. Anti-bribery compliance.
- Corporate and M&A
- Dispute resolution and pretial conflict settlement. Mediation
- Environment
- Energy
- Forensics
- Innovative Projects
- International Arbitration
- International Property
- International Taxation
- Investments. Project Finance
- PPP & Infrastructure
- Real Estate, Land & Construction
- Taxation
- Regulatory and GR issues. Law-Making

KEY INDUSTRIES:

- Automotive
- Aviation
- Chemical & Petrochemical Industries
- Energy & Natural Resources
- Finance & Securities Markets
- Food Products & Agriculture
- Housing & Utilities
- Information Technology
- Infrastructure & PPP
- Insurance
- Life sciences
- Metallurgy & Mining
- Nanotechnology
- Public sector
- Real Estate & Construction
- Telecommunications

RECOMMENDATIONS & RECOGNITION:

- European Legal Experts 2013
- Best Lawyers 2012
- International Financial Law Review 2014
  - Restructuring and insolvency
  - Corporate and M&A
  - Project finance
- Chambers Europe 2013
  - PPP
  - Competition/Antitrust
  - Dispute Resolution
- PLC which lawyer? 2012
  - Competition/Antitrust
  - Insurance
- The Legal 500 EMEA 2013
  - Dispute Resolution
  - Real Estate
  - PPP
  - Corporate and M&A
  - Tax
  - Energy & Natural Resources
- Pravo.ru-300 2013
  - Competiton/Antitrust
  - Dispute resolution
  - Tax
  - Corporate/M&A
  - Real Estate
  - Energy & Natural Resources
  - Intellectual property
  - International arbitration

OUR CLIENTS:

Bank of Communications China, Belon, Brevan Howard Fund, British Airways, Fitch Design Consultants Ltd., Gazprom dobycha Astrakhan, Gazprom neft, Vnesheconombank, HOCHTIEF, Ilyushin Finance Co., Interregional Distribution Grid company of Volga, Lamnalco, MAN, Mosenergosbyt, MTD Products Inc., MTS, PhosAgro AG, R-Quadrat, RESO Holding, RusHydro, Rockwool, ROSNANO, ROSNO, Russian Funds, SITRONICS, Sun InBev, Unilever, Vitkovice Power Engineering, WABCO, WPP

COOPERATION:

Ministry of Economic Development, Ministry of Transportation of the Russian Federation, Ministry of Regional Development, Federal Antimonopoly Service, Federal Tariff Service, Federal Financial Markets Service, Committees of the State Duma and the Federation Council, Vnesheconombank, various federal agencies, PPP and Investment Commission of the Russian Union of Industrialists and Entrepreneurs, Protection Committee of the National Securities Market Association, Agency of Strategic Investments and Initiatives, IMEDA, Agency for Strategic Initiatives (ASI), etc.

MOSCOW
Tel.: +7 (495) 933 0800
Fax: +7 (495) 933 0802
vegaslex@vegaslex.ru

VOLGOGRAD
Tel.: +7 (8442) 266 312/313/314/315
Fax: +7 (8442) 266 316
volgograd@vegaslex.ru

KRASNODAR
Tel.: +7 (861) 274 7408
Fax: +7 (861) 274 7409
krasnodar@vegaslex.ru