Legal Regulations on Trademarks and Patents in Russian Pharmaceutics

Introduction

Such IP rights as trademark or patent rights have proved to be of utmost importance in a highly competitive and fast developing pharmaceutical market. This is also true for the current market of medicines in Russia where large and small domestic and international companies compete for the attention of consumers. Good knowledge and professional exercising of opportunities offered by the legislation on trademarks and patents, as well as effective protection of IP rights, can make a considerable contribution to commercial success of pharmaceutical companies in Russia.

Outlines of Legal Regulations

Legal provisions on trademarks and patents are included primarily in the forth part of the Russian Civil Code. Article 1477 (1) defines a trademark as “a designation which individualizes goods of legal entities or of private businessmen”. Being intellectual property trademarks are protected either subject to their registration in Russia or according to international treaties (art. 1479).

The Russian Civil Code contains quite detailed provisions on the procedure of registration of trademarks (art. 1492 – 1507). The documents for registration of a new trademark shall be filed to the Russian government authority in this field: Federal Service for Intellectual Property, Patents and Trademarks (Rospatent). The examination by the experts of the submitted documents can last quite a long period of time; in current practice the whole term of registration of trademark in Rospatent can take about two years. Article 1483 gives grounds upon which Rospatent may refuse to register a trademark. Among these grounds the following ones shall be specially noted:

✓ the designation in question includes only the elements commonly used to designate certain type of goods;
✓ the designation is untrue or misleading the customers regarding the goods or the manufacturer;
✓ the designation is identical or confusingly similar to the trademarks belonging to third parties covering similar goods, either already registered or protected in Russia,
or filed for registration earlier, or to the trademarks determined as commonly known in Russia;

- the designation is identical or confusingly similar to the protected name of place of origin of the goods, to already protected company name or to commercial designation, belonging to third parties;
- the designation in question is identical to the title of scientific, literary work or of work of art, known in Russia, to the name of character or the quotation from such work, unless the rights holder of the work agreed;
- the designation in question is identical to the already existing domain name.

Foreign entities or natural persons are free to apply to Rospatent for registration of their trademarks to get protection in Russia. Alternatively, a trademark may be registered in the other country with coverage extended to Russia under the Madrid System for the International Registration of Marks.

Provided that the designation has been registered as a trademark the owner of trademark is entitled to use the trademark in any ways as well as to convey the rights to the trademark to a third party. Article 1484 (2) states that an exclusive right to a trademark can be used to individualize goods, works of services, in particular, by the following methods:

- at performing works or providing services;
- on the documents relating to putting the goods into the commercial turnover;
- on the offers relating to sale of goods, performing works or providing services, as well as in announcements, on signboards or in advertising;
- in the web including in domain names and in other means of addressing.

The basic prohibition is included into art. 1484 (3):

Without permission of the trademark owner no one is permitted to use designations similar to the trademark belonging to the owner in relation to the goods, which the registered trademark covers, or in relation to the similar goods in case a confusion results from such use.

Rights to use a trademark are normally transferred under a license agreement or under a assignment of a trademark agreement (art. 1488, 1489). Both type of agreements shall be made in a written form and are subject to registration in Rospatent to be valid (art. 1490).

Most of the patents issued in the field of pharmaceutics are invention patents. Article 1350 of the Russian Civil Code defines invention as:

A technical solution in any field related to a product (in particular, to a device, a material, a microbial strain, a plant or an animal cell culture) or to a method (a process of performing actions with a tangible object through instrumentality of material resources).

In the field of pharmaceutics the most common inventions are pharmaceutical compositions and their use for disease cure. A patent, once issued, certifies priority date of the invention, its authorship and exclusive right to use.

Under art. 1363 the term of exclusive rights granted by an invention patent is twenty years from the date of priority. In the field of pharmaceutics this patent term can be extended for the period not exceeding five years in case it took more than five years to get the first government permission to use the medicine.
The examination of patent application by Rospatent consists of two stages: (a) formal examination and (b) substantive examination. The formal examination generally takes from two to four months from the application date, in includes examination from the perspective of compliance of the filed documents to the legal requirements. The substantive examination can be completed in eighteen months from the date of application. The patent is granted if the substantive examination reveals that the method or the product, as described in the application, is new, and it can be used in industry, and has an inventive level (art. 1350). These criteria are considered for the date of the application.

Foreign legal entities or natural persons can apply for Russian patent by filing direct application to Rospatent or by using PCT procedure. It is worth noting that foreign applicants to Rospatent must be represented by Russian patent attorneys (art. 1247 (2) of the Civil Code).

A patent owner is entitled to use the patented product or method in any ways or license such use to any third party. According to art. 1369 a license agreement should be made in writing and registered by Rospatent to be valid.

Economic Importance of Trademark and Patents in Russian Pharmaceutics

It is undoubtedly that trademarks have a huge economic importance for the pharmaceutical market. Main functions of trademarks are here the same as in any other sector. Trademarks make possible for the consumers to identify easily both the product they need and its manufacturer, and to be confident in the quality of the product. On the other hand, by using a trademark a manufacturer makes the product more recognizable that results in sales growth. It is no less important that a trademark opens up wide opportunities for advertising and market promotion.

Special importance of trademarks in pharmaceutics relate to psychological factors. Name of any medicine, once registered as a trademark, becomes a big force on the market. Consumers usually purchase drugs very carefully: successful treatment requires exactly defined medications and dosages, and wrongly selected medicine is hazardous for health. A very small proportion of ordinary consumers can say they know the compositions of or differences between the medicines used for similar purposes. Thus, for the most people trademarks (names of medical products) have become the only way to be sure that they are making a right choice in a drugstore. Products bearing widely known trademarks even if their full analogues on the market exist nonetheless occupy the lion’s share: the consumers pay greater attention to a trademark put on a medicine rather than to a composition or to a price.

Pharmaceutical companies all over the world invest significant resources into researches of new pharmaceutics and medical care and treatment methods. Patents are one of the most important tool for recovering the moneys spent. Within the patent term (in Russia it is twenty years from the date of the application) the patent owner, or his or her licensees, if any, are the only legal manufacturers, sellers, importers of the patented product or the method. This gives huge preferences to the patent owner on the market.

Liability for infringement

Russian legislation provides for three types of liability for infringement of intellectual rights: civil, criminal and administrative liability.

i. Civil liability
Primary rules on civil liability for illegal use of a trademark are set forth in art. 1515 of the Civil Code:

- Goods, labels, packages on which a trademark or a designation confusingly similar to a trademark has been illegally placed are counterfeit;
- A trademark owner is entitled to claim withdrawal of counterfeit goods, labels and packages of goods (on which an illegally used trademark or a confusingly similar designation is placed) from the market, destruction of them at the expense of the infringer;
- A trademark owner is entitled to claim damages or a compensation from ten thousand to five million rubles (exact amount of compensation shall be determined by court), or in the amount of double value of the goods on which the trademark has been illegally placed, or in the amount of double fee for use of the trademark to be determined on the basis of a fee charged in similar circumstances.

Civil liability for infringement of patent is set forth in art. 1406 of the Civil Code. Such liability is mostly limited to recovering damages.

ii. Criminal liability

Criminal liability for illegal use of trademarks is provided for by art. 180 of the Russian Criminal Code:

- In case the illegal use has been repeated or has caused substantial damage it is fined in the amount up to two hundred thousand rubles, or in the amount of the wage or salary, or any other income of the convicted person for a period up to eighteen months, or punished by compulsory works for the term from one hundred eighty to two hundred forty hours, or by corrective labors for a term of up to two years;
- Illegal use of special marking (® or ™) in respect to a trademark not registered in the Russian Federation, if repeated or caused substantial damage, is fined in the amount of up to one hundred twenty thousand rubles, or in the amount of the wage or salary, or any other income of the convicted person for a period of up to one year, or is punishable by compulsory works for a term from one hundred twenty to one hundred eighty hours, or by corrective labors for a term of up to one year;
- The actions specified above committed by a group or by an organized group shall be punishable by imprisonment for a term of up to six years with or without a fine in the amount of five hundred thousand rubles or at the rate of the wage or other earnings of the convicted person for a period up to three years.

As clear from the above, criminal liability for illegal use of a trademark applies when such illegal use has been done repeatedly or caused substantial damage. Repeated use should be understood as use of one trademark in respect of several (two or more) objects when an intent to perform both can be proved separately. Substantial damage, that is more than two hundred fifty thousand rubles, usually relates to loss of profits of a trademark owner due to unpaid use of this trademark, or to deterioration of the economic position of the trademark owner: business reputation and market share can be undermined if the counterfeit goods are of bad quality.

In criminal procedure only those foreign trademark owners can be admitted who are covered by Paris Convention 1883 or, in accordance with the principle of reciprocity, who are citizens or legal entities of the countries which provide legal protection to Russian trademark holders.
Criminal liability for **patent** infringement is set forth in art. 147 of the Criminal Code:

- Illegal use of invention, utility model or industrial design, or their unauthorized disclosure prior to official publication, conversion of authorship or forcing to co-authorship, if these actions caused substantial damages, is fined in the amount of the wage or salary, or any other income of the convicted person for a period up to eighteen months, or punished by compulsory works for the term from one hundred eighty to two hundred forty hours, or by corrective labors for a term of up to two years;
- The actions specified above committed by a group or by an organized group is fined in the amount of the wage or salary, or any other income of the convicted person for a period from one to two years, or punished by confinement from four to six months, or by imprisonment for a term of up to six years.

iii. Administrative liability

Under art. 14.10. of the Code on Administrative Offences illegal use of another person's **trademark** or a confusingly similar designation lead to confiscation of the counterfeit goods and a) for citizens: imposition of a fine in the amount from one thousand five hundred to two thousand rubles; b) for officials: a fine in the amount from ten thousand to twenty thousand rubles; c) for legal entities: a fine in the amount from thirty thousand to forty thousand rubles.

Under art. 7.12 (2) of the Code on Administrative Offences illegal use of **invention, utility model** or **industrial design**, their unauthorized disclosure prior to official publication, authorship conversion or forcing to co-authorship lead to a) for citizens: imposition of a fine in the amount from one thousand five hundred to two thousand rubles; b) for officials: a fine in the amount from ten thousand to twenty thousand rubles; c) for legal entities: a fine in the amount from thirty thousand to forty thousand rubles.

In current practice in the field of pharmaceutics the majority anti-counterfeit and patent infringement cases are administrative cases because the procedure is relatively efficient. In criminal cases it is difficult to establish strict evidences of the sustained damages and of a repeated illegal use. In civil cases a complicating factor is that the trademark owner has to collect all necessary evidences supporting the claim himself or herself; unlike in administrative or criminal cases, in civil litigations assistance from law enforcement agencies is not available.

**Conclusion**

Despite certain legal uncertainty and sweeping legislative reforms in Russia which are inherent in the current period of transition to a free economy, some stable legal devices exist and can be used to promote company’s business and ensure its growth. With regards pharmaceutical market, it is advisable to pay attention to efficient use of the company’s trademarks and patents. The company which has sought and received protection in Russia for its trademarks and patents, which is also pursuing a legally correct and reasonable policy in licensing and distributing, which is actively protecting its trademark and patents against infringers, can get certain market advantages over its less considerate and careful competitors. Effective exercising of the available legal opportunities and devices as well as strict compliance with the domestic regulations are strong factors for commercial success on the market. Russian pharmaceutical market, despite all its peculiar features, does not seem to be an exception.