



Patent law protection of inventions in medicine and pharmaceutical industry

Patentna zaštita pronalazaka u oblasti medicine i farmaceutske industrije

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Key words:

patents; legalisation; medicine; pharmacy; humans; animals.

Ključne reči:

patenti; zakonodavstvo; medicina; farmacija; ljudi; životinje.

Introduction

Simply saying, inventions represent new solutions to technical problems. The word “technique” means “restraining of natural forces and controlled use of natural phenomena”¹, that is “human activity in the field of material phenomena characterized by space, time, matter and energy”². Thus, the technique is, actually, human activity to master and control nature. Once the domain of technique was confined to nonliving nature. Yet, today, it has been considered that technique also comprises the activities in the field of living beings, although the patent law protection cannot be realized in domain of those biological processes which cannot be influenced, that is, controlled in a way that their repetition under same conditions would yield the same results³.

There are two basic types of inventions: inventions of products and inventions of processes. These are the products and processes that have never been comprised in the state of the art (they have never been exposed to public in any form). The particular sorts of inventions are inventions of use. They refer to the technical instructions as for the manner of application of an already existing product, or an already known process, but for a new technical purpose⁴.

The inventions are generally protected by patent law, but not all of them. There are three groups of inventions that cannot be legally protected: the commercial application of which would be contrary to “ordre public” or morality; related to methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body; related to plant and animal varieties or essentially biological processes for the production of plants or animals.

The inventions of the products such as substances or compositions used for diagnostic, surgical and healing purposes are not excluded from patent protection. In other words, the inventions related to drugs and medical means can be registered as patents.

A patent constitutes a set of exclusive rights granted to the inventor in a sense that they prevent others to exploit the patented invention without permission – though not for an indefinite period of time, but usually for the period of 20 years. The exceptions are the inventions of human and animal drugs and medicines whose term of protection may be extended if their sale has to be previously authorized and approved by relevant government bodies.

This article is divided in three parts. The first part deals with the inventions of surgery, therapy and diagnostic methods applied to humans and animals. The second part, considers the patents for invention of products (i.e. drugs and medical means) in surgery, therapy and diagnostic to be used in surgery, methods applied on humans and animals. Finally, the third part, reviews the issue of the extended term of patent protection for inventions of drugs for humans and animals.

Exclusion of certain medical methods from patent protection

There is still widely spread opinion that granting the patent rights for inventions in the field of medicine would be inappropriate and against the general concept of health protection. Therefore, it has been decided that patent rights cannot be granted for inventions related to surgical, diagnostic and treatment procedures.

A surgical method, according to the patent law, is a method of cutting and removing a living tissue of the hu-

man or animal body. Cutting and removing of living tissue can be performed in a classical way, with knife, or by applying lasers, high-frequency electrodes, etc. Therefore, the exclusion of surgery method inventions involving cutting and removing of living tissue from patent protection refers to both invasive and non-invasive procedures. The invention of surgery methods are excluded from patent protection if maintaining life and health of treated subjects is of paramount importance for the performed intervention. Correspondingly, invention of plastic surgical methods such as transplantation of skin burnt in an explosion cannot be patent protected. On the other hand, the invention of methods such as hair cutting, wool sheering, depilation, nail trimming, horseshoeing, although involving cutting and removing of human or animal living tissue, are not excluded from patent protection.

In pursuance of the patent law, a diagnostic method is a method used to identify the health condition of an organism. A diagnostic method includes several phases: examination of health condition, data collecting, data comparison, identification of a disorder and, finally, deductive clinical decision phase. Diagnostic method invention is excluded from patent protection only if all the abovementioned phases are present. If only one of these constituent phases of the diagnostic method is missing, the entire method is not considered to be diagnostic, but only a procedure that can be used in diagnostics⁵. Additionally, the exclusion is only applied where a diagnostic method made it immediately possible to decide on a particular course of medical treatment. But if application of a diagnostic method provides only interim or preliminary results (e.g. methods of internal imaging such as magnetic resonance imaging or methods for measuring temperature), method invention is patentable.

According to the patent law, a therapy method is a method of eliminating or alleviating a disease where the term disease is defined in the patent law as "all, even slight and passing, abnormal activities of the human body which exceeds the standard tolerance level and/or significant and not perishable deviation from standard human experience and perception"⁶ (the term disease is differently defined in the patent law, labour law or health insurance law). Therefore, the method of therapy considering the patent law does not refer to the medical treatment that is eliminating or alleviating of some ailments or problems which are not considered to be a disease (e.g. fatigue, blackheads, etc). Also, therapy methods in the sense of the patent law do not include medical treatments undertaken for cosmetic, dietary, hygienic or sanitary purposes (e.g. coloring, straightening/curling, regeneration or promoting hair growth; skin lifting, pregnancy testing, contraception, sweat removing or breath refreshing, etc)⁶. Both preventive and curative treatments fall within the meaning of "therapy" and are therefore excluded⁷.

The inventions of surgery, therapy and diagnostic methods are excluded from the patent protection only in cases when the invented method is applied to the living human or animal body. This means that the exclusion does not apply, and the patent rights could be granted for the same method if it is applied to the corpse, or on the living tissue

which is separated from the human or animal body (for example, bone marrow, blood, biopsy samples, etc.).

As for the justification of excluding the inventions of surgery, therapy and diagnostic methods from granting the patent rights, legal scholars and theoreticians have contradictory opinions and stands. Some believe that the reasons for this exclusion should be sought in a traditionally reserved stand related to awarding the patent rights for the inventions in domain of health protection, and as such, they are outdated². On the other hand, some believe that the exclusion of the inventions of surgery, therapy and diagnostic methods from patent protection is justifiable since it prevents the patent system to constrain the freedom of doctors in how they treat patients⁸. In other words, this legal solution excludes a possibility that saving a person's life by applying a particular surgical method may depend on the will of the inventor's monopolistic right over that method⁹.

Patent protection for inventions of drugs and medical means

Even when all conditions for the exclusion of surgery, therapy and diagnostic methods inventions from awarding the patent rights have been fulfilled, still the inventions of the substances and compositions applied in such methods can be protected by patents. This means that the inventions related to medical equipment, instruments and disability aids, as well as drugs can be the subject of patent protection.

Patent protection for drugs is a newer issue in our patent law history reflecting the interests of leading global pharmaceutical companies to secure profit given their enormous research and development investments. Allowing the possibility of patent protection of drugs and medical means has diminished the significance of ethical reasons for the exclusion of all inventions in the field of medicine from patent protection. This is supported by the fact that out of 56 billion dollars invested annually in medical research, less than 10% of this amount is dedicated to inventing new drugs for treating diseases affecting 90% of global population. In other words, the research and development efforts in pharmaceutical industry are mostly directed into inventing new drugs for the treatment of cardiovascular diseases, the diseases of central nervous system and diuretics¹⁰. In the period between 1975 and 1997, out of 1,223 newly patented substances or compositions for use in pharmacy, only 11 were related to the treatment of tropical diseases¹¹.

Although the industrial production of drugs started in 1896 when the first tablet press, a machine compressing powder into tablets was introduced in Germany, it has been considered that modern pharmaceutical industry started with the introduction of sulfonamide in 1935¹². The development of pharmaceutical industry has rapidly continued ever since and today this industry is among the most innovative linking chemical industry, biotechnology and medicine. Contemporary pharmaceutical industry is characterized by a large social significance, high quality standards, specially regulated conditions for drugs production and sale and large investments into research and development (sometimes over 100

million dollars need to be invested to develop a new drug)¹⁰. This was a decisive reason why the pharmaceutical industry put the pressure to obtain the patent protection of newly invented drugs securing the exclusive rights for their commercial exploitation. In this way they could ensure return to investment and profit gain that can further be reinvested into new research cycles. The opponents of the patent protection for pharmaceutical products underline the special purpose of these products – health maintenance and protection. Pointing out that pharmaceutical products assist in maintaining the functions of vital life, they believe that the inventions in this field are for public good and should be made available to entire mankind without patent restrictions. Yet, the opinion of those who advocate the awarding of patent rights for pharmaceutical products has prevailed and possibility of patent protection for these products are envisaged by the 1973 EPC and the 1995 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Patent rights awarding for inventions of drugs has contributed to further boost of this industry and its high profitability. The patented drugs are more expensive, yet it has been estimated that 65% of pharmaceutical substances would have never been developed if the drugs were not allowed patent protection¹³.

In our country, in spite of big resistance of the pharmaceutical industry in former Yugoslavia, patent rights were granted to the inventors of pharmaceutical products under the 1990 Law amending and modifying the former federal 1981 Law on the protection of inventions, technical improvements and distinctive signs¹⁴. However, in order to allow the national pharmaceutical industry to adjust to the new strategic orientation of technological development, granting of patent rights for drug inventions was delayed until December 31, 1992. Despite the advantages offered by this law, our pharmaceutical industry continued to produce mostly generic medical products¹⁵ that cannot be patented. These are the drugs and medicines which contain the same active ingredient as the original medical products, thus having the same effect as the original drugs. However, since the original drug is the subject of patent protection, a generic drug is launched to the market after the expiration of the original drug's patent. Generic drugs are, therefore, cheaper although their quality, efficacy and safety should not lag behind those of the original drugs. From the abovementioned, it can be concluded that since generic medical drugs do not represent newly invented products, they cannot be the subject of patent protection¹⁶.

Curative substances can be obtained from natural sources by applying isolation or purification methods or in a biosynthetic way, that is they can be produced according to previously defined structure of pharmacologically active molecule or designed according to genomics and goals to be attained by these medicines¹³. So far several million compounds have been isolated, synthesized and tested for the purpose of obtaining new drugs¹⁰. Yet, in modern pharmacology, there is a decreasing number of drugs which are based on a completely new chemical compound, but rather on a new formula, composition, production process or application of the already known active pharmaceutical ingredi-

ents (API)^{17, 13}. The latter (a new application of known API) means the possibility of obtaining further purpose-related patent protection for the second and any further more specific use of an API in surgery, therapy and diagnostic method since according to article 54 (4) EPC the new use of such substances and compositions for any such method is not comprised in the state of art. It is a significant digression from the corner stone rule of patent law that patents can be granted for inventions upon which the requirement of absolute novelty is fulfilled. This is the result of the fact that during the development of pharmaceutical industry, focus has been placed on the product formulation to secure the optimal exploitation of a curative substance (quantity, composition and form) for treatment and therapeutic purposes¹². The patent law theory advocates the thesis that the substance itself cannot be the subject of patent protection. Nowadays, it is not difficult to synthesize a new compound, but it is difficult and extremely expensive to find a medical application for such a new compound¹⁴. Sometimes it is necessary to synthesize hundreds, even thousands of new compounds to create a new drug¹⁰. Therefore, the invention of the substance itself for the purpose of a drug creation is of a secondary importance, which is not the case with other products. Moreover, in case that the invented substances and not its application was patented, this would be threaten and hinder further enhancement of chemical and pharmaceutical industries¹⁴. On the other side, a patent protection of the application of the invented curative substance is quite justifiable. Therefore, it can be said that patent law allows the protection of the invented substance or composition in its technical form, to be applied during surgery, therapy or diagnostic methods under the condition that these curative substances are applied for new purposes which have never been indicated before¹⁸.

The extension of the patent protection term for the inventions of human and animal drugs

Human or animal drug is a product which is found on the market in a certain dosage, pharmaceutical form and package containing the substance or a combination of substances which have been proven to be effective in treatment, cure or prevention of disease in humans, or animals, that is the substance or a combination of substances which can be used in humans and animals either for the purpose of establishing diagnosis or for the purpose of restoring, improving or changing a physiological function in humans or animals by means of pharmacological, immunological or metabolic effects of that drug¹⁹. Patent rights awarded for drug invention fall in domain of property rights, that is, private rights. However, given the general purpose of drugs, this field reflects strong public interest. It is of public interest that substances and compositions declared as drugs are safe for human and animals' health. Obtaining the patent protection for a certain pharmaceutical product means that that product is new, having an inventive step and can be applied in industry. However, granting patent rights for a newly invented drug is not a guarantee that this new, inventive substance or composition, applicable in industry, could not adversely affect one's

health. Since this kind of testing is not performed during the patent administrative procedures, it is necessary to evaluate that the invented human or animal drug (or plant protection product) is "safe for humans, animals and plants before it is launched for sale"²⁰. Only after it has been confirmed that the invented product does not represent health hazard, the inventor, that is the holder of patent rights for this drug, is allowed to start its production and sale. In our country the Medicines and Medical Devices Agency of Serbia is the final authority charged for issuing permissions to put of solely quality, safe and efficacious medicinal products and medical devices to market.

Setting up the condition that a human or animal drug needs an authorization issued by a relevant government body before being put into production or sold means that obtaining the patent rights for that product is not enough and that it cannot be commercially exploited before completing the authorization procedure. Sometime this means that, in addition to obtaining a necessary production license, the entire administrative procedure for a new drug to be approved may last for several years. Since the term of patent protection nevertheless elapses, it can expire even before the inventor has gained any profit from the patented drug. This can adversely affect the possibility of profit return on investment and discourage future investment and research efforts in this field. In order to compensate the inventors and the holders of patent rights for this loss of time in the term of patent protection for human and animal drugs, which are the subject of mandatory approval by a relevant state agency, they are entitled to an additional legal protection in the form of a Supplementary Protection Certificate.

The supplementary protection certificate is a *sui generis* industrial property right. The legal powers of supplementary protection certificate and patent are equal, but supplementary protection certificate is not granted for all inventions but only for inventions of drugs for humans and animals and plant protection products such as insecticides and herbicides for which to be put to commercial circulation a prior official authorization has to be secured. Since there are some kinds of these products which do not require a prior regulatory approval (galenic medicines, traditional herbal medicines, active substances used in drug production, etc), the inventions of such products cannot be the subject of additional legal protection by the supplementary protection certificate.

The supplementary protection certificate as a patent law institute was first introduced in the US patent law in 1984, in Japanese patent law in 1987, while in EU it was recognized following the adoption of the Regulation No. 1762/92 by the Council of EU on June 18, 1992. Since originally this Regulation referred only to pharmaceutical products, the Council of EU adopted a new Regulation No. 1610/96 on June 23, 1996 extending the possibility of granting the supplementary protection certificate for inventions of plant protection products¹⁵. In the Republic of Serbia it was first time laid down by the 1994 Patent Act. According to Serbian law, in order to grant the supplementary protection certificate, it is necessary to fulfill the following preconditions: human or animal drug or plant protection product is covered by a valid patent; there

is a valid authorization issued for that product; human or animal drug or plant protection product has never been the subject of a supplementary protection certificate; patent application is submitted after January 1993; first official authorization to put the product into market is issued after January 2005.

The procedures for granting the supplementary protection certificate (as well as for the termination of these rights) are guided by the same provisions for granting the patents. In order to be granted by a supplementary protection certificate, the original inventor, that is the holder of the patent rights for the relevant human or animal drug (or the plant protection product) or his successor in title, needs to file the application within six months from the date of receiving the marketing permission for that product. If this permission was issued before granting the patent rights, then the application has to be filed within 6 months from the date of the official publication of the patent rights. Application includes: a written request for granting the certificate; the data on the person/organization submitting the request (name and address); the data on the legal representative (name and address); the number of the original patent and the full name of the invention; the number and date of issue of the first marketing authorization or the note stating that the product has already been the subject of a supplementary protection certificate; a copy of the marketing authorization issued by a relevant government body; if such a marketing authorization is not the first one, then the proof of the product's identity, the information on the procedures conducted for its granting, and the official journal in which the information on the marketing authorization was published.

The data submitted in the application for granting the supplementary protection certificate are filed in the Register of supplementary protection certificates and published in the Intellectual Property Journal within six months from the application date. This means that within these six months the application has to be formally evaluated, which includes the following checking: that the application was submitted in the required form and contains all required information; that the application was submitted within legally prescribed time frame; that all the required documents were enclosed; that the patent was still valid in time of submitting the application for the supplementary protection certificate.

Having confirmed that application for the supplementary protection certificate has been formally and technically valid, the reviewers proceed with the evaluation of its content to determine: that all the preconditions prescribed by substantial law (valid on the date of the application submission) have been met for granting the supplementary protection certificate; that the product for which the supplementary protection certificate has been filed is patent protected; that the marketing authorization has been issued in an adequate manner; that the product has not been the subject of a supplementary protection certificate.

Having been confirmed that all the preconditions prescribed by substantial law have been met for granting the supplementary protection certificate, a formal decision on accepting the application and granting the supplementary

protection certificate is issued and the data from the granted certificate are published in the Official Journal of the Intellectual Property Office. The holder of the supplementary protection certificate is entitled to supplementary protection of the patent rights for the period which is equal to the period that has lapsed from the date of submitting the patent application to the date of receiving the first approval for product marketing, less five years (even such a shortened period of certificate duration cannot exceed five years from the date of granting the supplementary protection certificate). Since this certificate is valid from the date of the expiring of basic patent rights, it means that the entire patent protection period for inventions of human and animal drugs and products for plant protection can be extended to 25 years.

Granting the supplementary protection certificate favors the interests of pharmaceutical companies which produce original drugs and medicines. In order to decrease negative consequences of introducing the institution of the supplementary protection certificate in the domestic pharmaceutical industry which mostly produces generic drugs and medicines, the application of the legal provisions related to the supplementary protection certificate was postponed July 1, 2013.

Legal considerations

In conformity in classical patent law doctrine, the inventions related to drugs are not appropriate for patent protection. These products are vital for the preservation of basic life functions and therefore, their inventions have been considered as public good which means that the consumption of the good by one individual cannot be exclusive and patent protected, thus reducing availability of the good for consumption by others. The remainders of these traditional patent law theories can be still found in modern patent law provisions related to the exclusion of surgery, therapy and diagnostic methods inventions performed on living people and animals from patent protection. Although one may consider that exclusion from patentability of inventions of surgery, therapy and diagnostic methods is senseless since inventions of substances, compositions and other products used in those medical methods are patentable, this legal solution still may be deemed as justified. There are more reasons for that. The most important is that the legal status of pharmaceutical companies and doctors is very different. Pharmaceutical companies are business operators which produce and sell goods on the market and at the same time compete with other pharmaceutical companies in attracting customers. They have to innovate to survive. Investments in R&D are tremendous and patent protection is necessary to ensure return of invested capital creating monopolistic market position. Doctors are employed or self-employed high educated pro-

fessionals who devoted themselves to help people. They are not business operators and do not do business to obtain profit but do their job enjoying personal satisfaction, kudos and respect²¹. For mentioned they do not need legally guaranteed market monopoly but conditions to improve their practice and competencies. In contrary doctors would long time ago form a lobby strong enough to procure patentability of inventions of medical methods. There is one more important *rationale pro* exclusion. On the one hand, completely different from the pharmaceutical companies who deal with interposers (drug stores) that is pure commercial activity, doctors perform some kind of public service²² applying their professional knowledge directly on patients at the time of urgency. On the other hand, patent protection of drugs, medicines and other products used in medical procedures is not of an absolute character. Immediate and individual preparation of medicine in the pharmacy by virtue of presented prescription is excluded from the legal effect of patent. Surgery, diagnostic and therapy are naturally immediate and individual treatment and such exclusionary situation is constantly present in doctors' activity. The fact of emergency also makes acquisition of license uncertain. From the same reason, in the case of patent abuse, acquisition of compulsory license is impossible because the legal procedure for that lasts too long. There are more other argumentation in favor of existing legal solution²³, especially the possibility of moral dilemmas appearing (save life and risk trial or left patient to die).

One may accept exclusion for inventions of surgery, therapy and diagnostic methods performed on the human body but not on animals. Out of any discussion regarding the animals' position in nutrition chain and its meaning for human health, looking strict legally, existing legal solution is in compliance with the ratio of the 2009 Act on Animal Well-being and overall trends in legal protection of animals.

Conclusion

Although the introduction of patent protection for drugs, medical means and other products used in medical methods brought in a mess and confusion in the basis of the classical patent law theory, the exception from the patentability of methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body still may be deemed justified.

As for the patent protection of drugs, we could discern two specific characteristics of patent law. The first is related to the possibility to grant patent rights for the new medical application (use) of already known product, and the other is related to the introduction of the supplementary protection certificate which allows the extension of the protection term for up to five years.

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Received on September 11, 2011.

Revised on December 13, 2011.

Accepted on December 15, 2011.