PROTECTION OF INVENTIONS IN THE PHARMACEUTICAL SECTOR THROUGH SUPPLEMENTARY PROTECTION CERTIFICATE

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Abstract

The topic of health is nowadays, more than ever in the history of mankind, one that enjoys an entirely special attention. It concerns, albeit at a different level, the sick and the healthy, doctors and patients, the young and the elderly, women and men. It concerns governments and individuals, medicine and herbal medicine researchers, and beneficiaries of the research activity.

The paper below is aimed to present special issues regarding the patent for medicinal products and authorisation of placement on the European market of medicinal products.

Keywords: *health, medicinal products, research activities, supplementary protection certificate, costs, temporary monopoly, territorial monopoly, authorisation procedure.*

1. Health care policies worldwide and health care institutions in the EU

Health is a component of the standard of living that also comprises the health care, enshrined as a universal human right under art. 25 of the Universal Declaration of Human Rights[1], and in harmony with that the **World Health Organization** has stipulated in its **Constitution** that its objective is the attainment by all peoples of the highest possible level of health.

The "**Alma-Ata Declaration**" adopted in 1978 formulated the organization's disease fighting strategy. The "**Ottawa Charter**" of 1986 formulated the organization's concept on health and maintaining it through the disease fighting strategy. The organization is responsible for managing certain health risks on a worldwide basis, establishing the health research agenda, offers technical assistance to the Member States, monitors and assesses the people's health, and approaches the most complex population health challenges.

Lately, some of the WHO's actions in the health care domain have been controversial, the organization having even been accused of bioterrorism in the form of the support given to certain manufacturers of vaccines that are actually biological weapons, and of affiliation to international corporate crime syndicates. These accusations must be regarded with reservation, however they cast doubt on the overall activity of this organization and on the efficiency of its actions.

The topic of health, defined by the World Health Organization as a „***state of complete physical, mental and social well-being and not merely the absence of disease or infirmity***", or as a state that „***should ensure a physical and mental state allowing a person to become productive and useful to society***", is nowadays, more than ever in the history of mankind, one that enjoys an entirely special attention. It concerns, albeit at a different level, the sick and the healthy, doctors and patients, the young and the elderly, women and men. It concerns governments and individuals, medicine and herbal medicine researchers, and beneficiaries of the research activity.

The international cooperation in the health domain takes most complex forms. Over the past years, a special attention has been paid to the cooperation and promotion of new medical technologies and new (original, innovating, or generic) efficient medicines to be made available to the population, including the poor countries' people for whom the access to generic medicines (much cheaper than the innovator ones) is essential. In 2001, the "**Declaration on intellectual property and public health**" was adopted at the Conference in Doha, which offers an answer to the concerns expressed by the developing countries about the need for a more facile and less burdensome access to a range of essential medicines designed to fight major epidemics, at the same time offering the necessary assurances to the manufacturers of pharmaceutical products on the observance of the intellectual property rights, with a view to encouraging the furthering and development of the research activities.

The European Union has also implemented concrete actions in the public health domain, the health care concerns targeting not only the diagnosis and treatment, but also prevention. The basic principle of the health care policies of the European Union has become, „**health in all policies**", and the Lisbon Treaty has emphasized the importance of the health policy, stipulating that, „*a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities*". In its turn, the Charter of Fundamental Rights of the European Union proclaims, under art. 35 (Health care),

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[1] Adopted at 10 December 1948 by the Resolution no. 217A, in the third session of the UN General Assembly.

that „*Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national law and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities*".

From the historical viewpoint, the Community health care policy originates from the health and safety provisions, developed pursuant to the free circulation of the persons and goods within the internal market, which has made possible the coordination of the health care activities and actions. The consumption and dependence on drugs, the expansion of serious diseases like cancer, the new diseases like AIDS, the crisis caused by the bovine spongiform encephalopathy (BSE), all these represent major health issues, which in conjunction with the ever freer circulation of the patients and medical personnel within the EU have secured the public health an even more important role on the EU's agenda. Amid the crisis caused by ESB, the Directorate General or Health and Consumers of the Commission (DG-SANCO) has assumed the coordination of all the health related domains, including the medicines, albeit the main responsibility for the protection of health, and in particular of the health systems, further lies with the Member States. The strengthening of the specialized agencies like the **European Medicine Agency** (EMA) and the establishment of the **European Centre for Disease Prevention and Control (ECDC)** evidence the increased commitment of the EU to the health policy.

The European health policy is aimed at:

(i) Offering all the Union citizens access to high quality health care;

(ii) Preventing diseases;

(iii) Fostering a healthier life style, and

(iv) Protecting citizens from health threats like pandemics.

And in order to ensure **the efficiency of its actions, the European Union has created its own instruments of action, both at regulatory and institutional levels**.

Thus, with reference to medicines, the **legislative process**, which started in 1965, **aimed at securing high standards in the pharmaceutical research and industry, harmonizing the national procedure for the grant of licenses for medicinal products, and implementing regulations on publicity, labelling and distribution**. Recent evolutions include the „***pharmaceutical package***", approved by the European Parliament (EP) in early 2011.

The community research programmes regarding the health care and public health date back to 1978, and refer not only to the main diseases, but also to aspects such as health issues influenced by age, environment and lifestyle, irradiation risks and human genome analysis. As regards the mutual assistance, the Member States have agreed to mutually assist one another in case of disasters and very serious diseases. Many such issues have come into the public eye over the past two decades, for example the bovine spongiform encephalopathy (BSE), swine flu, and more recently the H1N1 flue.

Recently (2012-2013), the European Parliament has defined its position also as regards the enactment of the legislation on the cross border health services, and the **revision of the legal framework concerning the medical devices and advanced therapies**. The European Parliament has consistently promoted and promotes coherent public health policies, also through: **notices, studies, debates, written declarations and reports**, on its own initiative, regarding multifarious aspects such as, *inter alia*: EU health care strategy; radiations; protection of patients under medical treatment or in under diagnosis process; health information and statistics; respect for life and caring for patients in terminal stages; European charter for children in hospital; health determinant factors; biotechnology research, including the transplants of cells, tissues and organs, and surrogate mothers; rare diseases; safety and self-sufficiency in supplying blood for transfusions and other medical purposes; cancer; hormones and endocrine disruptors; electromagnetic fields; drugs and their impact on health; smoking; breast cancer and in particular women's health; ionizing radiations; European health card comprising essential medical data readable by any doctor; nutrition and diets and their impact on health; ESB and its consequences, food safety and health risks; e-health and telemedicine; resistance to antibiotics; biotechnology and its medical implications; medical devices; cross border health services; Alzheimer disease and other dementia diseases; alternative medicine and herbal medicines; capacity of response to the H1N1 pandemic flue; and the advanced therapies. The (EU) Regulation no. 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) continues the previous programme. The Regulation is the result of the successful negotiations carried out in the final phases of its preparation between the Commission, Parliament and Council with regard to three main aspects: budget allocation, modes of adoption the annual work programmes, and co-financing of the joint actions designated to create incentives for improving the participation of the less prosperous Member States.

As regards the **institutional framework** required for the attainment of the health care health programmes and policies, the following have been established in the European Union:

(i) Consumers, Health and Food Executive Agency,

(ii) European Foundation for the Improvement of Living and Working Conditions,

(iii) **European Medicines Agency MA),**

(iv) European Centre for Diseases Prevention and Control,

(v) European Agency for Safety and Health at Work, and

(vi) European Food Safety Authority.

From the viewpoint of the topic discussed hereunder, particularly important are the regulations that **have instituted the supplementary protection certificate for medicinal products** and **supplementary protection certificate for plant protection products**, and the institution with special competences in the field of medicinal products, being the **European Medicines Agency (EMA).**

2. Special issues regarding the patent for medicinal products and authorisation of placement on the market of medicinal products.

The connection between the people's health and the research and development activity is so close that we do not exaggerate in the least when stating that without the new medicinal products created pursuant to the research and development activities in the health domain the humankind health would be in great jeopardy. That is why it is natural the concern for this field at global, regional and national level. And the shift to the personalized medicine or precision medicine, recently announced as a political project in the US, will make the research more intense but also more costly, since this medicine will have to treat individually, with adequate medication for each patient. The personalized medicine also entails a surge in the number of medicinal products in the near future, but also the manufacture of smaller quantities thereof, therefore their prices will be increasingly higher, as the manufacturers can only eliminate the risk of not covering their investments by increasing prices.

Without examining the causes of this phenomenon, we can however say that there is an increased need for new medicinal products, that there is a permanent need in this domain of innovation, new medicines and higher efficiency, and that their manufacture and placement on the market **is conditional not only on the issue of patents**, but also on the **authorisation of their placement on the market, procedure that actually shortens the actual lifetime of a patent**.

However, certain medicinal products exist on the market that are no longer protected by a particular protection title, and these are, and have to be, bioequivalent to the original medicinal products.

The medicinal products protected by patent are also known as „***original***", „***organic***" or „***innovator***" medicinal products. These are manufactured, as a rule, by large pharmaceutical companies, which in order to achieve these products spend for research and development, and thereafter for preclinical and clinical trials, huge amounts, and even higher amounts for marketing and promotion activities. For example, if in the 70s of the last century the average price of an innovator medicine was 138 million dollars, and in the 80s was 231 million dollars, in 2007 the average cost reached 897 million dollars, and nowadays is over 1.38 billion dollars. As regards the term of achievement of a new medicine, this is 15 years on the average. In Europe, a new medicine is obtained from 5,000 through 10,000 synthesized molecules.

The high costs of achieving original active substances, researching, developing, launching in the market and maintaining these products, and the need to ensure the recovery of the investments and the manufacturers' profit also justify the concern for extending the duration of the monopoly conferred by the patent through various methods.

Pursuant to the expiry of the practical life span of the patents for inventions, which is shorter than the life span of the patent due to the lengthy procedures of authorisation of the placement on the market of the patented medicinal product, these companies lose the monopoly of exclusive manufacture rights, which allows the placement on the market of medicinal products not protected by patent, called generic medicines, whose prices is much lower.

This class of medicinal products, called **"generic"**, is actually represented by medicines equivalent to the original product, having the same quantity and quality composition of active substances and the same pharmaceutical form, the bioequivalence with the original medicinal product being proven under prior appropriate studies. The various salts, esters, ethers, isomers, mixtures of isomers or derivatives of the active substance are deemed the same as the active substance, inasmuch as they do not vary significantly as regards the safety and/or efficiency characteristics. The various pharmaceutical forms of oral administration with immediate effect are deemed as one and the same pharmaceutical form.

The generic medicine is subject to the same rules regarding the manufacture and pharmacovigilance, and has to present the same quality, efficiency and safety characteristics. The sale price thereof is, however, different from that of the original medicines, being 20% through 90% smaller than that of the original medicines, since their manufacturers do not have to recover the investments in their achievement. Due to their quality and price, generic medicines are very attractive, their low prices allowing the access to these of sick people with no income or low income, therefore they balance the health budgets of the poor economies and contribute to an increased standard of living of the consumers, stimulating the further innovation. Meanwhile, the therapeutic efficiency of these medicinal products lowers or even vanishes for reasons related to the adaptation and/or modification of the pathogenic agents of diseases, therefore without the research and development activity in the pharmaceutical industry the risks are huge. However, the research and development activity of the manufacturers of generic medicinal products is limited, their profit being generated by the fast placement on the market, and without the costs entailed by the research and development.

In other words, the original medicinal products are expensive because they entail costly research activities, and the expenses have to be recovered, while the generic medicinal products, which are much cheaper, can only be manufactured after the expiry of the term of protection of the intellectual property rights over the original medicinal products and at the expense of those. However, generic medicinal products cannot be manufactured if original medicinal products are not manufactured upstream. This does not mean that generic medicinal products are only manufactured based on original medicines.

3. Medicine patenting, actual lifetime of the medicinal product patent and consequences of its short lifetime

The protection through patent of medicinal products is recent. In France, it was only through a decree of 30 May 1960 that the solution of the French lawmaker of 1844 was invalidated, and the patenting of medicines was admitted, a "special patent for medicine" being crated. The rationale of exclusion stems from the interpretation given to the condition of industrial applicability, and the fact that medicinal products can be found in nature, and these are actually discoveries, the case of penicillin being maybe the best example. Nowadays, however, in truth, pharmacy is considered an industry, and medicines, manufactured.

What is a medicinal product? In a simple definition, the medicinal product is a substance used to prevent, cure, alleviate or treat disease or, in a wider definition, a medication is a substance or a composition which contains curative or preventive properties with regard to humans or animal illnesses for the purpose of medical diagnostic or to restore, to correct or to modify organic functions. According to another definition, a medicine is a preparation used to prevent, diagnose, treat a disease, trauma, or to restore, correct or modify organic functions.

Art. 1 (a) of the Regulation no. 469/2009 defines the medicinal product as "*any* ***substance or combination of substances*** *presented for treating or preventing disease in human beings or animals and* ***any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals***".

Generally, medicines are classified into indispensable, secondary or adjuvant, comfort and placebo type. The general basic law of the medicinal product, which does not take exception, is that medication acts on the functions of the body, modifying them in a positive (stimulatory) or negative (inhibitory) way.

Medicinal products have been prepared for a long time solely based on plants (e.g., alkaloids like digitalin or morphine), animals (e.g., vaccines) or minerals (e.g., aluminium). Nowadays, medicines are manufactured by the pharmaceutical industry, which offers a higher accuracy and safety of use. In parallel, the pharmacy proposes more and more synthetic products, which copy more or less truthfully natural substances, or are entirely original.

A medicinal product contains one or more active ingredients. Generally, the essential active ingredient gives its name to the medicinal product. Each essential active ingredient is identified in three different ways from the scientific, legal or commercial viewpoint. The scientific denomination is the exact chemical name of the active ingredient. It is typically less used due to its complexity. The international common denomination (DCI) corresponds to the generic name of the active ingredient in medicine. The commercial name is given by the pharmaceutical laboratories, which create new medicines by modifying the molecular structures of the original substances to increase their therapeutic efficiency and reduce secondary effects. One and the same active ingredient may be marketed as medicinal product by two different laboratories, two commercial names may correspond to the same substance, possibly with different presentations and/or doses.

In this domain, patents may also refer to a product or a procedure. No patents are granted for treatment methods, however the products, substances, compositions used in treatments are not excluded from patenting.

Generally, the **medicinal product has an active substance, a molecule** and **other parts that make the active substance therapeutically usable**, conferring the pharmaceutical form of the medicine, the types of claims encountered in practice in respect of innovator and patentable medicinal products being as follows:

- Product claim, where the claimed substance is new and the result of an inventive activity. The protection granted by the product invention covers all the types of manufacture and use of the substance, even those not related to the pharmaceutical domain;
- Claim to scope as the „first medical indication", where the claimed substance is technically known but the invention reveals for the first time a medical use thereof;
- Claim to scope as „a second or other medical indication", possible where the substance is also known as medicinal product but the invention consists in a new use in the medical field, in which case in order to be patentable it should also not be obvious;
- Claim to use for „a second or other medical indication", possible where the use of a substance already known as medicinal product is new and inventive for the treatment of another affection;
- Claim to a medicinal product preparation process, where the process in itself is new and includes an inventive activity, and not the substance.

Significant for the examined topic are the first four types of claim, which put up for discussion the active ingredient or combination of active ingredients, the only ones susceptible to supplementary protection.

At the same time, the Regulation provides for in art. 1 (c) that the basic patent (which must exist for a supplementary protection certificate to be granted) may also protect „***a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate***".

Similarly to any other domain, the product newly obtained through a creative activity and susceptible of industrial application is protected by patent, the **pharmaceutical product** designated for marketing being difficult, impossible even, to protect by secrecy, the modern techniques allowing the reproduction without much difficulty of the medicinal products.

The patent is that protection title conferring its holder a **temporary and territorial monopoly**[2]: of **exclusive exploitation**, being to manufacture and market the product and prohibit third parties from performing any act of use without his consent on the **territory** in which the protection title is effective, over the period of validity of the patent.

As regards the **term of the exclusive monopoly conferred by the patent**, this is twenty years from the regular filing date (art. 33 of the Romanian patent law, which is consistent with the regulations of other law systems, the community law and the international conventions).

The exploitation monopoly is territorially limited, in principle, since the patent is effective where the law is effective, the protection outside the borders being able to the obtained either based on a patent requested in the country where the applicant has an interest, or through a patent obtained in accordance with the Washington Treaty of 1970 (PCT), or through an European patent.

Mention should be made that the Community law also limits the **effects of the territoriality** of the national patents in the EU. The Treaty on the Functioning of the European Union enshrines the principle of free circulation of goods, which contradicts the territorial nature of the monopoly related to the national patent. In order to eliminate the contradiction between the two legal orders, the Community case law referring to the analysis of art. 30 of the TFEU has evidenced a specific object of the patent right, and a principle of the right exhaustion Community-wide, thus restricting the exercise of right in the name of the free circulation, but preserving the existence thereof. The specific object of the right conferred by the patent, that the Treaty does not want to affect, is to ensure its holder, in order to compensate the creative effort of the inventor, the exclusive right to use the invention for the purposes of manufacturing and putting into circulation for the first time the industrial products, either directly or through the grant of licenses, and the right to challenge any counterfeiting, infringements of his right. However, once a product covered by patent is put into circulation for the first time in an European Union country, with the holder's consent, the latter can no longer oppose to the product circulation in other Member States by calling forth parallel patent rights (valid in those countries).

Another exception from the exploitation monopoly is, with reference to medicinal products, the so-called **Bolar provision**[3], an exception meant to favour the placement on the market of generic medicinal products immediately after the expiry of the protection conferred by patent and supplementary certificate of the original medicinal product. In accordance with this provision of exception, the **manufacturers of generic medicinal products may commence the preparations for the authorisation of the placement on the market of a generic medicinal product prior to the expiry of the period of protection of the original product, and file the authorisation documentation so that the generic medicinal product can be placed on the market immediately after the original product is no longer protected by patent and supplementary protection certificate**.

Obtaining a patent for a medicinal product is possible solely provided that the **claimed active substance benefits from novelty**, in other words the substance is not known either in the medicine or other domain, therefore is different from the known substances due to its technical characteristics, such as a new formulation, dosage or synergistic combination. The new medicinal product will be patented provided that it also meets the other two conditions imposed by the law, being: the inventive activity (the patent should be granted for ingenious achievements involving an intellectual effort that has to be rewarded) and industrial applicability (that includes besides uses the redundancy of achievement of the medicinal product).

The placement on the market of innovator medicinal products, protected by patent, is however also conditional upon **obtaining the marketing authorisation for medicinal products**, which requires studies, tests, verifications and authorisation formalities, the procedure taking a long time (up to 12 -15 years), which makes the actual lifetime of a medicinal product patent much shorter.

This means that the term of protection of the new achievement through patent is not equal to the actual lifetime of the patent, the latter one being significantly shorter in the case of the medicinal products. However, this short actual lifetime makes the activity of research and development, and of achievement of new innovator medicine unattractive, since the relevant investments cannot be recovered in such a short time. The solution to this problem is to extend the term of

[2] The territorial limitation of the right of exclusive exploitation is, in the EU, contrary to the principle of free circulation of goods (commodities).

[3] The name comes from the case Roche Products vs. Bolar Pharmaceutical examined by the US Federal Tribunal in 1984 regarding the manufacture of generic medicinal products, Bolar being the manufacturer thereof.

protection through the supplementary protection certificate.

However, mention should be made of, and is essential to emphasize, the **absolute independence of the patent from the marketing authorisation for medicinal products**. This means that where any medicinal product may be marketed solely provided that it has been authorized for placement on the market, the medicinal product does not necessarily has to be patented. For example, generic medicinal products are not covered by patent, however in order to be patented their prior authorisation is compulsory. And where there is an existing patent for a medicinal product but subsequently such patent is cancelled or revoked, the marketing authorisation does not have to be withdrawn, the same as the withdrawal of the marketing authorisation will not affect the validity of the medicinal product subject to the withdrawn authorisation.

4. Medicinal product marketing authorisation

The patent for a **new medicinal product** is a protection title for the **patented medicinal product**, and confers its holder an exclusive exploitation right over twenty years from the regular filing date. In order for the medicinal product to be placed in the market, the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (which has replaced the Directive 65/65/EEC) has instituted the **obligation to obtain an authorisation prior to marketing** in all the Member States of the European Union. With reference to medicinal products for veterinary use, the code was adopted by the Directive 2001/82.

The procedure is lengthy both for the applicant (holder of the patent) and in terms of the formalities to be performed by the latter and of those in charge of the authorities issuing the authorisation. It is a procedure whereby and in the course of which the national authority or, as the case may be, the European one verifies, in order to approve the placement on the market of a medicinal product, its safety, efficiency and quality. The studies indicate that this procedure involves filling out about 1,850,000 pages of over 4,000 files measuring 230 meters in height and 500 kilometres in length, and lasting sometimes up to 12 - 15 years.

The medicinal product marketing authorisation can be obtained on the basis of a centralized procedure, in respect of the whole territory of the European Union, by the European Medicines Agency (EMA), or of a domestic procedure, by the National Agency for Medicines and Medical Devices. The similar body in the US is the US Food and Drug Administration (FDA).

5. Domestic authorisation procedure

In our law, the marketing authorisation for (original or generic) medicinal products is regulated by the Law no. 95/2006 on the health reform, updated in 2013, which transposes the Directive 2001/83/EC, Chapter 3 (Marketing authorisation), Section I (Marketing authorisation for medicinal products). No medicinal product may be placed on the market in Romania without a marketing authorisation (MA) issued by the National Agency for Medicines and Medical Devices, in accordance with the provisions of this law, or an authorisation issued according to the centralized procedure.

Medicinal products that have to be authorized by the European Medicines Agency under the centralized procedure are excluded from the grant of this marketing authorisation. The issued authorisations may enjoy mutual recognition in other Member States of the European Union. As of 1 January 1998, the mutual recognition procedure is compulsory in respect of the medicinal products that are to be marketed in another Member State than the one where the medicinal product has been first authorized. The procedure of mutual recognition of the marketing authorisation has been introduced by the Council Directive 93/39/EEC, in accordance with the provisions of Directives 65/65/EEC and 73/319/EEC.

6. Centralized procedure of marketing authorisation for medicinal products in the EU

The creation of a single market for medicinal products as well has been a concern of the Communities ever since the establishment thereof[4]. In order to attain the relevant objectives, the centralized procedure of marketing authorisation for medicinal products has been instituted, and the body(ies) in charge of the verification of the conditions established by the Community rules, and of the grant of the authorisation has(ve) been nominated, being the European Commission, the technical procedures being carried out through the European Medicines Agency (EMA) based in London.

The procedure of centralized authorisation of marketing for new medicinal products is currently regulated by the Regulation (EC) no. 726/2004 of the European Parliament and of the Council of Europe 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. EMA

[4] Directive 65/65/EEC was the first Community legal enactment concerning the pharmaceutical products. This regulated the regime of the marketing authorizations for medicinal products and data exclusivity. Other legal enactments regulated the pharmacovigilance – Council Directive 75/319, labeling and packaging of medicinal products - Directive 92/27/EEC, while the Council Regulation 1768/1992 created the supplementary protection certificate for medicinal products.

verifies and monitors the safety, efficiency and quality characteristics of the medicinal products for both human and veterinary use.

As regards its scope of application, the Regulation no. 726/2004 provides for that no medicinal product appearing in the annex thereto may be placed on the market within the Community without a prior authorisation granted by the Commission, which acts in this regard and performs its verification duties through the European Medicines Agency (EMA).

In order to obtain an authorisation, the applicant has to make available to EMA comprehensive data pertaining to the characteristics, safety and efficiency of the medicinal product, in accordance with art. 8.3 of the Directive 2001/83/EC of the European Parliament and of the Council, amended by the Directive 2002/82/EC of 27 January 2003.

EMA has established **two Scientific Committees** (for medicinal products of human use and for medicinal products of veterinary use) and one **(Scientific) Paediatric Committee**, responsible for preparing the notices regarding the medicinal products falling within their ambit of competence, the notices of these committees underlying the authorisation to be issued by the European Commission.

The committees have to present their notices within 210 days from receiving the relevant request, and for these purposes may perform tests on the medicinal product, raw materials or intermediary products, or may perform inspections at the medicinal product manufacturing plant. Each authorisation proposal has to be taken into consideration by the Committee on the basis of the **scientific criteria** regarding the quality, safety and efficacy of the respective medicine. These three criteria allow the assessment of the risk-benefit ratio in respect of any medicinal product. The Committee first verifies the compliance with the conditions of issue of a marketing authorisation. If the authorisation conditions are deemed not complied with, the applicant will be informed thereof, and may submit to EMA within fifteen days a notice re-examination application.

On the basis of the (positive) notice of the EMA Committee, the European Commission prepares a draft decision regarding the application for medicinal product authorisation. The final decision is made pursuant to a procedure of consultation of the EU Member States. If the draft decision of the European Commission is not consistent with the EMA notice, the Commission will attach to its draft decision an annex explaining the reasons of the divergent opinion, which will be submitted to the Member States and the applicant.

The marketing authorisation will be **rejected** if the:

- Applicant has not properly and sufficiently demonstrated the quality, safety and efficacy of the medicinal product;
- Information is inaccurate.

The Commission may impose on an applicant, at EMA's recommendation, the obligation to perform: a post-authorisation safety study and/or a post-authorisation efficacy study.

The authorisation issued by the Commission is valid in all the Member States of the European Union for 5 years, and can be renewed upon request. Once renewed the marketing authorisation will be valid for indefinite term, unless the Commission opts for a new period of validity of five years.

Generic medicinal products are also subject to the authorisation procedure, however in their case, when the active substance is equivalent to a previously authorized medicinal product, the results of the preclinical tests are no longer required. This procedure of authorisation of the generic medicinal products is known as the „**abridged procedure**", since while the new medicinal products require the submission of preclinical tests providing data about the product safety, efficacy and quality, article 10 of Directive 2001/83 sets forth that the manufacturers of generic medicinal products may use and rely on the data and results already obtained by the original manufacturer. With reference to the **generic medicinal products** of the medicinal products of reference authorized by the EU, these can be subject to a decentralized authorisation procedure provided that the Europe-wide harmonization is maintained.

With reference to the medicinal products for **veterinary use**, these follow the rules applicable to the medicinal for human use, subject to the specific adaptations.

The refusal to issue a marketing authorisation in the centralized procedure shall be deemed a prohibition to market the medicinal product on the whole territory of the EU.

Any marketing authorisation for a medicinal product not followed by the actual marketing thereof for three consecutive years becomes invalid.

After its placement on the market, in order to ensure the people's protection by preventing, detecting and assessing the adverse reactions of the medicinal products for human use, inasmuch as the safety profile of the medicine cannot be fully known except after its marketing, the supervision of medicinal products (pharmacovigilance) is instituted. In respect of the medicinal products manufactured in the EU, the authorities responsible for pharmacovigilance are the relevant authorities of the Member States that have issued the authorisation. With reference to the medicinal products imported from a third country, the responsible relevant authorities are the issuers of the import authorisation. These will inform the Committee for medicinal products and the Commission about any case where the manufacturer or importer do not comply with their obligations. The holder of a marketing authorisation for human use or veterinary use is obligated to implement all the necessary changes, taking into account the manufacture methods

and technical and scientific progresses, in accordance with the Directives 2001/83/CE and 2001/82/CE.

Whenever urgent action is essential to protect human health or the environment, a Member State may suspend the use on its territory of an authorized medicinal product.

Notwithstanding the legislative efforts of the European Commission and of the Council, one cannot talk as yet about a single pharmaceutical market of all the EU Member States, mainly because the health provisions are the responsibility of each State, and their governments apply differentiated policies in terms of social, ethical values or GDP level. However, inasmuch as nowadays a harmonization has been achieved on large scale in the European Union in respect of the marketing authorisation system and mutual recognition and related formalities, the distortion effects regarding the operation of the single market are created by the regulation of the medicinal product pricing. In the majority of the Member States, the price of the prescribed medicinal product has to be determined prior to its release and based on the social security system, in order to maintain the control of the health budget. Thus, certain national policies encourage the sale of generic medicinal products, by fighting the practices of request and establishment of supply prices, and obligating the pharmacies to offer the cheapest product. Other Member States have instituted medicinal product pricing control measures.

7. Supplementary protection certificate for medicinal products

In all the invention domains the actual lifetime of the patents is shorter than their term of validity (which is 20 years from the regular filing date). However, in the case of the medicinal products, due to their specificity, in particular the long and costly research entailed by them, but also the tests and formalities required for the purposes of their placement on the market (which can last more than twelve years[5]), a compulsory condition for their marketing, the actual lifetime of the patents is shorter than in any other field.

As already mentioned, the expenses incurred to create a new medicinal product and placing it on the market have increased over 40 years by 1,000% (from 138 million to 1.38 billion dollars). However, the protection through patent of the new medicinal products, within the limits of the actual patent lifetime, does not allow the recovery of the investments in the achievement of new medicinal products, and implicitly is not likely to encourage the activity of research and development in this field. That is why all over the world means have been sought for to achieve a balance between the interests of the industry (investment recovery and profit) and people's health interests (new and state of the art medicinal products), respectively solutions likely to make attractive the achievement of new medicinal products for the benefit of the pharmaceutical industry and the consumers.

Similar solutions were adopted in US in 1984, when the intellectual property law was amended to provide the possibility to extend a patent term through a „patent term extension certificate", followed by Japan in 1988, which adopted an extension procedure called the „registration of extension of a patent right term".

Similar measures were adopted in Europe at the end of the 80s of last century in France, Italy and Germany, which made possible the extension of the patents for medicinal products for human use and veterinary use, and for phyto-pharmaceutical products in the countries where the longer protection term allowed the recovery of investments and obtaining of higher profits.

However, at the same time the development of certain heterogeneous laws in the European Communities could also create hindrances against the circulation of products within the single market, therefore a new instrument has been created to solve the problem Community-wise: the supplementary protection certificate for medicinal products, and a similar one for plant protection products.

The supplementary protection certificate for medicinal products was instituted by the **Regulation (EEC) no. 1768/92** of the Council of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (CSPM), the **European Medicines Agency** being established under the same act. This Regulation was repealed by the **Regulation no. 469/2009** of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, which however did not significantly change the previous text, actually the new act codifying the prior regulation and its successive amendments.

Subsequently, the Parliament and the Council passed the **Regulation no. 1901/2006 on medicinal products for pedriactic use** and amending the Regulation (EEC) no. 1768/92, Directive 2001/20/EC and Regulation (EC) no. 726/2004, whereby: a **Paediatric Committee** has been established within the **European Medicines Agency**, and the right to the **extension of the supplementary protection certificate for medicinal products of paediatric use by another 6 months** has been regulated to reward the research, preclinical tests and clinical studies required in respect of this class of medicines, and designed to guarantee their safety, high quality and efficiency for use by the target population.

Four years after the passing of the Regulation no. 1768/92, the European Parliament and the Council passed the **Regulation no. 1610/96 of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products**,

[5] In the case of the medicinal product for human use called "Circadin" the obtaining of its marketing authorization lasted more than 15 years. Thus, at the authorization issue date, 28 June 2007, the patent was due to expire within less than five years.

designed to ensure a protection level for the innovations in this domain equivalent to that secured for the medicinal products, having regard to the contribution of this class of products to the continuing improvement of good quality food, and with a view to ensuring an effective protection to cover the research investment, and generate the resources required to maintain a high level of such research.

In the Romanian law, provisions regarding the obtaining of such supplementary protection certificates have been included in art. 30 of the Patent Law no. 64/1991[6], the Law no. 28/15.01.2007, however the text as revised[7] merely makes reference to the first two regulations (**Regulation (EEC) no. 1768/92**, respectively **Regulation no. 469/2009** and **Regulation no. 1610/96)**, without referring as well to the **Regulation no. 1901/2006 regarding the extension of the supplementary protection certificate for medicinal products for paediatric use**. However, even in the absence of any specific reference in the Romanian patent law to this last regulation as well (on medicinal products for paediatric use), such regulation is, like all the other regulations[8], of direct applicability in the Romanian law. The authority competent to issue the supplementary protection certificate for medicinal products is the State Office for Patents and Trademarks.

Previously, in order to comply with the criteria of accession to the European Union, the Law no. 581/2004 on the supplementary protection certificate for medicinal products and plant protection products was passed, which was to become effective at the date of Romania's accession to the European Union[9]. However, this law had no effects, and was specifically repealed by the Law no. 107/2007, because as of the date of our country's accession to the EU the aforementioned regulations have become of direct applicability in our country as well, therefore the supplementary protection certificates are granted by the national authority pursuant to the implementation as such thereof.

The basic patent related to the supplementary protection certificate may also be a European patent, granted by the European Patent Office[10]. Article 63 of the European Patent Convention referring to the term of the European patent stipulates under paragraph (2), point b) the **possibility to extend its term**, and confers the contracting parties the possibility to extend the term of a European patent in respect of products requiring authorisation immediately after the expiry of the legal term of the patent[11].

8. Subject matter of the supplementary protection certificate

The subject matter of the supplementary protection certificate is the „product", which means the „***active ingredient or combination of active ingredients of a medicinal product***". Medicinal product means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or

[6] In the form prior to the amendment brought by the Law no. 83/2014 on employee inventions, the provision referring to the supplementary protection certificate being included under art. 31. Subsequent to the law modification, the texts have been renumbered, and this provision is now included under art. 30 thereof.

[7] Art. 30 paragraph (3) of the Law no. 64/1991 republished has the following contents: *„In respect of the patented medicinal products or plant protection products a supplementary protection certificate may be obtained in accordance with the terms of the Regulation (EEC) of the Council of 18 June 1992 concerning the supplementary protection certificate for medicinal products, and of the Regulation (EC) no. 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products."* The Guideline no. 146 of the general director of OSIM concerning the supplementary protection certificate for medicinal products and plant protection products was published in BOPI no. 12 of 29.12.2006.

[8] Art. 288 al. (2) of TFEU provides for that the treaty „shall be directly applicable in all Member States".

[9] The Law no. 93/1998 has introduced the „**transitional protection certificate**" for the „inventions having as subject-matter substances obtained by nuclear and chemical methods, pharmaceuticals, methods for diagnostic and medical treatment, disinfectants, food stuffs and spices and new plant varieties, bacteria and fungi strains, new animal breeds and silkworms", in favor of the holders of patents having a priority date before 21 January 1991, issued in a Member State of the Paris Union for the Protection of Industrial Property or of the World Trade Organization, and not patented in Romania. This transitional protection certificate is subject solely to the regime established by the patent law, and has the same subject matter of the invention, and the conferred rights are identical to those conferred by the basic patent. The transitional protection starts at the date on which an application is filed with OSIM, and ceases at the date on which the validity of the patent for invention expires, or on which the patent is cancelled or at the date of forfeiture of the patent owner's rights, and does not exceed 20 years of the date of the regular filing in the country of origin.

[10] This office was established by the Munchen European Patent Convention of 5 October 1973, effective as of 7 October 1977. Its establishment is the expression of the joint political will of the European countries to create a uniform patenting system in Europe. **The European patent has the same effects in Romania as the national patents issued by OSIM, subject to the compliance with the conditions laid down in art. 6 paras. 2-5 of the Law no. 611/2002 regarding the adhesion of Romania to the Convention on the Grant of European Patents**. In pursuance of art. 64 para. (1) of the Convention, ***„A European patent shall confer its proprietor from the date on which the mention of its grant is published in the European Patent Bulletin, in each Contracting State in respect of which it is granted, the same rights as would be conferred by a national patent granted in that State***". Some authors have stated that the „patent thus issued must be validated in each nominated State in order to be effective" (Bernard Remiche, Vincent Cassiers, Droit des patents d`invention et du savoir-faire. Bruxelles, Larcier, 2010, p. 49), while others are of the opinion that after being issued, in the countries nominated by the applicant, patents are subject to the national law of each State. According to art. 63 of the Munchen Convention, the patent thus issued „shall confer its proprietor in each Contracting State the same rights as would be conferred by a national patent granted in that State". This means that only a patent thus issued may be cancelled in accordance with the law of the State of destination, however we do not believe that the validation is required, or that OSIM may decide to revoke the patent.

[11] Romania adhered to this Convention and to the Act revising it adopted at Munchen on 29 November 2000 by the Law no. 611/2002 (OJ no. 844/22.11.2002).

combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals.

Therefore, there is no full identity between the subject matter of a patent for medicinal protect and the subject matter of the supplementary protection certificate. Unlike the patent, the **supplementary protection certificate does not refer to the entire medicinal product**; it only covers the **product** referred to under art. 1(b), respectively the **active ingredient or combination of active ingredients of a medicinal product, and not the medicinal product as a whole**, the last one also comprising those components that make the active ingredient therapeutically usable (adjuvants).

The recital 10 of the Regulation explains the **definition of the product** as follows: „*The protection granted (by the SPC) should furthermore be **strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product***". And art. 4 of the Regulation defines the subject matter of the protection through supplementary certificate as follows: „***Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market** and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.*"

The definition given by the Regulation to the „product" making the subject matter of the SPC demonstrates its double nature: on the one hand basic patent, and on the other hand administrative authorisation of placement on the market of the medicinal product. Furthermore, the Regulation institutes quantity and quality limits as regards the subject matter of the protection conferred by the supplementary certification relative to the subject matter of the protection conferred by the patent.

Quantity limits because if **a granted patent refers to several products**, the certificate may be obtained **solely for those in respect of which a marketing authorisation for medicinal product exists**, but also because if there are **several patents of products with the same active substance a single supplementary protection certificate will be granted**, and **not as many certificates as patents for products with the same active substance an owner holds**[12]. However, with reference to **owners of patents for different products comprising the same active substance**, **as many supplementary certificates as owners of patents for different products** having applied for the protection supplementation will be granted[13].

Quality limits because the supplementary protection certificate does not have a subject matter identical to that of the patent, respectively of the patented product, but only to the essential part thereof, being the active ingredient or combination of active ingredients, as the case may be. In the case of the combinations of active ingredients, supplementary protection certificates may be obtained as well for an individual active ingredient, if this complies with the basic condition to be deemed an active ingredient.

The case law of the national courts, in agreement with the interpretations given to the provisions of the Regulation no. 469/2009 by the ECJ, has ruled that a combination between an active ingredient and a polymer, when the active ingredient is already known, cannot substantiate the issue of a supplementary protection certificate. The specialized literature also affirms that a substance without its own therapeutic effect, serving only to obtain a certain pharmaceutical form of the medicinal product, cannot be deemed an „active ingredient", which in its turn allows the definition of the „product". A substance like that, associated with a substance having its own therapeutic effects, cannot create a „combination of active ingredients" within the meaning of article 1 point (b) of the Regulation no. 469/2009. The fact that the substance without any own therapeutic effect allows the obtaining of a pharmaceutical form required for the therapeutic efficacy of a substance endowed with therapeutic effects is not of a nature to invalidate this interpretation[14].

The patent claims are important because they determine the subject matter and extent of the patent protection. The claims, in the case of medicinal products, should however refer as well to the therapeutic indications, inasmuch as the medicinal product does not tend to protect a substance in general, but its use as a medicine in the treatment or prevention of certain affections. In that regard, the ECJ has ruled that article 3 point (a) of the Regulation (EC) no. 469/2009 concerning the supplementary protection certificate for medicinal products must be interpreted as precluding the competent industrial property office of a Member State from granting a supplementary protection certificate where the active ingredients specified in the SPC application include active ingredients not identified in the wording of the claims of the basic patent relied on in support of that application[15].

Where the claims in relation to one and the same patent refer to a single active ingredient but entail the grant of several marketing authorisation, a single supplementary certificate will be granted, and its coverage will not be limited by the specialty of either

[12] Frederic Pollaud-Dulian, Propriete intellectuelle. La propriete industrielle, Paris, Ed. Economica, 2011, p. 323.
[13] ECJ, Case C 482/07, AHP Manufacturing BV vs Bureau voor de Industriële Eigendom
[14] Bernard Remiche, Vincent Cassiers, Droit des patents d`invention et du savoir-faire, Bruxelles, Larcier, 2010, p. 197.
[15] Case C-6/11, Daiichi Sankyo Company c/ Comptroller General of Patents, Designs and Trade Marks, Order of 25 November 2011.

one of the authorisations. At the same time, if two patents have as subject matter (different) processes for obtaining the same active product, only one certificate may be obtained.

Accordingly, the regulation concerning the plant protection products defines under article 1 the „plant protection products" as the active substances and preparations containing one or more active substances, intended to protect plants against all harmful organisms, influence the life processes of plants, destroy undesirable plants, or prevent undesirable growth of plants. The Regulation comprises definitions of the active substance, preparations, plant products, harmful organisms, which have allowed a more clear interpretation of the regulation in these matters, however not entirely unambiguous. The definitions of the „product", „basic patent" are similar to those under the regulation concerning the medicinal products.

A more accurate definition of the terms of „product" and „active ingredient would facilitate, however, the establishment of those forms of active ingredients in a medicinal products that may be deemed to represent the product within the meaning of the regulation.

The **ECJ** has had the occasion to rule in relation to several cases on the meaning of „**active ingredient**", and it is interesting that the court has referred in its solutions also to considerations of appropriateness of instituting the certificate, and not only to the legal rules and principles and its case law.

Thus, in the case C-631/13, Arne Forsgren c/ Österreichisches Patentamt settled by the judgment of 15 January 2015, the Court ruled under paragraph no. 51, the same as in other occasions, that „***It is appropriate, consequently, to refer to the fundamental objective of Regulation No. 469/2009, which is to ensure sufficient protection to encourage pharmaceutical research, which plays a decisive role in the continuing improvement in public health"***, concluding that „*In that regard, it follows from paragraph 25 above that the term «active ingredient». for the purposes of applying Regulation no. 469/2009, relates to* ***substances which produce a pharmacological, immunological or metabolic action of their own*** *(....)",* and that *„In the light of the* ***wording*** *and* ***purpose*** *of Regulation No. 469/2009, it must be held that Article 1(b) of that regulation does not permit an «active ingredient» to be categorised as a carrier protein conjugated with a polysaccharide antigen by means of a covalent binding, unless it is established that it produces a pharmacological, immunological or metabolic action of its own*".

In the case C-210/13, Glaxosmithkline Biologicals SA and Glaxosmithkline Biologicals, Niederlassung der Smithkline Beecham Pharma GmbH & Co. KG c/ Comptroller General of Patents, Designs and Trade Marks, settled at 14 November 2013 by motivated order (considering, therefore, that the answer to a question referred for a preliminary ruling by a British court may be clearly deduced from existing case-law or admits of no reasonable doubt), the court concluded that, „*Article 1(b) of Regulation (EC) No. 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as meaning that,* ***just as an adjuvant does not fall within the definition of «active ingredient»*** *within the meaning of that provision, so* ***a combination of two substances****, namely an* ***active ingredient*** *having therapeutic effects on its own, and* ***an adjuvant*** *which, while enhancing those therapeutic effects,* ***has no therapeutic effect on its own, does not fall within the definition of «combination of active ingredients» within the meaning of that provision***".

In the case C-443/12, Actavis Group PTC EHF and Actavis UK Ltd c/ Sanofi, settled by the judgment of 12 December 2013, the ECJ ruled that, *„In circumstances such as those in the main proceedings, where, on the basis of a patent protecting an innovative active ingredient* ***and a marketing authorisation for a medicinal product containing that ingredient as the single active ingredient, the holder of that patent has already obtained a supplementary protection certificate for that active ingredient*** *entitling him to oppose the use of that active ingredient, either alone or in combination with other active ingredients, Article 3(c) of Regulation (EC) No 469/2009* ***must be interpreted as precluding that patent holder from obtaining – on the basis of that same patent but a subsequent marketing authorisation for a different medicinal product containing that active ingredient in conjunction with another active ingredient which is not protected as such by the patent – a second supplementary protection certificate relating to that combination of active ingredients***".

In the case C-484/12, Georgetown University c/ *Octrooicentrum Nederland, settled by the Judgment of 12 December 2013, the ECJ ruled that, „It should be noted in that regard that, where the holder of a patent obtains an SPC relating to an active ingredient on the basis of the MA for the first medicinal product placed on the market comprising, among its active ingredients, the active ingredient protected by the basic patent (…), such as, in the main proceedings, an SPC relating to HPV-16 on the basis of the MA for Gardasil,* ***the wording of Article 3(c) of Regulation No 469/2009 itself precludes that holder from obtaining, on the basis of that same patent, another SPC relating to the very same HPV-16 as a «product»*** *on the basis of a subsequent MA for another medicinal product which also contains HPV-16,* ***unless, in that other medicinal product, the «product» that is the subject of the SPC application relates in fact to a different HPV-16 falling within the limits of the protection conferred by the basic patent relied upon for the purposes of that application*** *(...)".*

In the case C-493/12, Eli Lilly and Company Ltd c/ Human Genome Sciences Inc settled by the Judgment of 12 December 2013, the ECJ ruled that, *„Article 3(a) of Regulation (EC) No 469/2009 must be interpreted as meaning that, in order for an active ingredient to be regarded as «protected by a basic patent in force» within the meaning of that provision,* ***it is not necessary for the active ingredient to be identified in the claims of the patent by a structural formula. Where the active ingredient is covered by a functional formula in the claims of a patent issued by the European Patents Office, Article 3(a) of that regulation does not, in principle, preclude the grant of a supplementary protection certificate for that active ingredient****, on condition that it is possible to reach the conclusion on the basis of those claims, interpreted inter alia in the light of the description of the invention, as required by Article 69 of the Convention on the Grant of European Patents and the Protocol on the interpretation of that provision, that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question, which is a matter to be determined by the referring court*".

9. Conditions for the grant of the supplementary protection certificate

The application for the supplementary protection certificate has to be submitted by the holder of a basic patent or his successor in rights to the **intellectual property office of the country that has issued the first marketing authorisation for the medicinal product**. The application for the grant of a certificate has to comply with the requirements under art. 8 of the Regulation no. 469/2009.

The certificate application has to be lodged within six months of the date on which the first market authorisation was obtained for the respective product as medicinal product. If the marketing authorisation was obtained prior to the grant of a basic patent, the certificate application has to be lodged within six month of the date on which the patent was granted.

The supplementary protection certificate cannot be granted unless in the State where the grant of the certificate is applied for, and at the date of submission of the application for the grant of a certificate:

(a) **The product is protected by basic patent in force;**

The patent has to be in force in the country where the marketing authorisation for the medicinal product was obtained. The patent may be national, similar to the national one or a European patent. If the same basic patent protects several different „products", it is possible, in principle, to obtain several SCPs in relation to each of those different products provided, *inter alia*, that each of those products is „protected" as such by that „basic patent" within the meaning of article 3, point (a) of the Regulation no. 469/2009 read in conjunction with article 1, points (b) and (c) thereof, and is included in a medicinal product in respect of which a marketing authorisation has been obtained.[16]

(b) **A valid authorisation to place the product on the market as a medicinal product has been granted** in accordance with Directive 2001/83/CE or Directive 2001/82/CE, as appropriate;

This authorisation has to be granted by the relevant authority in the country where the grant of the supplementary protection certificate is requested, the competence to grant the supplementary certificate belonging to the intellectual property office where it operates, and which has granted the marketing authorisation.

The medicinal product patent and the marketing authorisation are independent, that is, if any medicinal product may be marketed only if authorized for placement on the market, the medicinal product does not necessarily has to be patented. However, in order for a supplementary protection certificate to be granted, it is required both a basic patent and a valid marketing authorisation for the medicinal product containing the active ingredient or combination of active ingredients in respect of which the supplementary certificate is applied for.

(c) The product has not already been the subject of a certificate;

This condition connects the patent, authorisation and certificate. Only the patented product, in respect of which a marketing authorisation for medicinal product has been obtained, may benefit from a single protection supplement. In other words, this condition is inferred from the unicity of the certificate for the same active product and holder of patent or patents relating to the same product.

In the case of several holders of patents where the active ingredient is the same, each one of them may obtain a supplementary protection certificate. In other words, the unicity of the product or combination of active products is relevant in connection with the holder(s) of the patent(s). Where several patent holders exist, each having a marketing authorisation for his product with the same active ingredient, each patent holder is entitled to obtain a supplementary certificate for the same active ingredient and same product.

In the case of the combination of active ingredients in respect of which a single basic patent exist, the solution to the problem is different. The ECJ has ruled that where, on the basis of a basic patent and a marketing authorisation for a medicinal product consisting of a **combination of several active ingredients**, the patent holder **has already obtained a supplementary protection certificate for that combination of active ingredients**, protected by that patent within the meaning of Article 3(a) of Regulation (EC) No 469/2009, Article 3(c) of that regulation **must be interpreted as not precluding the proprietor from also obtaining a supplementary protection**

[16] ECH, Judgment of 12 December 2013, Actavis Group PTC and Actavis UK, C-443/12, paragraph 29.

certificate for one of those active ingredients which, individually, is also protected as such by that patent holder[17].

The ECJ has also ruled that where a basic patent includes a claim to a product **comprising an active ingredient** which constitutes the sole subject-matter of the invention, for which the holder of that patent **has already obtained a supplementary protection certificate**, as well as a subsequent claim to a product comprising a combination of that active ingredient and another substance, article 3, points (a) and (c) of the Regulation (EC) no. 469/2009 precludes the holder from obtaining a second supplementary protection certificate for that combination[18].

(d) **The authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.**

The Regulation no. 469/2009 does not specify whether the first authorisation to place the product in the market is that from the Member State or that from the Community. However, the interpretation given by the specialization literature and the case law in in the sense that, „it follows without doubt from the general context of the Regulation that for the purposes of examining the pre-conditions under art. 3, point (d), the first authorisation to place the product in the market is that obtained in the respective Member State".

This condition has to be examined solely where multiple authorisations to place the product (active ingredient) in the market exist, no issue arising in the case where a single authorisation exists. The case where the holder of rights over the patent has obtained multiple authorisations for the same product also does not raise any special issues, the first one within the meaning of art. 3(d) of the Regulation 469/2009 being the first one in the chronological order of their granting. Where the authorisation(s) to place a product on the market as medicinal product is required, obtained or held by one of the same person, things are simple. No special issues can arise as well where several holders of patents for medicinal products with the same active ingredient obtain each authorisations for placement on the market of the medicinal product: in respect of each one of them entitled to obtain a supplementary certificate, the first authorisation will be taken into consideration.

However, what happens where an authorisation for a medicinal product for veterinary use is obtained, and thereafter an authorisation for a medicinal product for human use, both medicinal products having the same active ingredient, and consequently supplementary protection certificates are requested for both of them?

Asked to rule on the question: *"Is the grant of a supplementary protection certificate in a Member State of the Community on the basis of a medicinal product of human use authorized in that Member State precluded by a marketing authorisation for that product as a veterinary medicinal product granted in another Member State of the Community (...), or is the sole determining factor the date on which the product was authorized in the Community as a medicinal product for human use?",* the ECJ ruled that, "having in view the fact that the term «product» used in the regulation refers to any active ingredient in the medicinal product, and a certificate may be granted for the product under the authorisation corresponding to a medicinal product, irrespective of its human or animal use (…), it follows, first, that the decisive factor for the grant of the certificate is not the intended use of the medicinal products, and, second, that the purpose of the protection conferred by the certificate relates to any use of the product as a medicinal product without any distinction between use of the product as a medicinal product for human use and as a veterinary medicinal product use." However, in these circumstances the Court ruled that, „The grant of a supplementary protection certificate in a Member State of the Community on the basis of a medicinal product for human use authorised in that Member State is precluded by an authorisation to place the product on the market as a veterinary medicinal product granted in another Member State of the Community (….).

However, recently the ECJ has refined its position, ruling that, *"Articles 3 and 4 of the Regulation (EC) no. 469/2009 (...) are to be interpreted as meaning that, in a case such as that in the main proceedings, the mere existence of an earlier marketing authorisation obtained for a veterinary medicinal product does not preclude the grant of a supplementary protection certificate for a different application of the same product for which a marketing authorisation has been granted,* ***provided that the application is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the supplementary protection certificate***"[19].

The issue of the first authorisation is important for the third parties willing to manufacture generic medicinal products, which are interested in the expiry of the protection term, computed as regards the certificate from the date of the first marketing authorisation. The specialized literature has stated that, „the status of the first authorisation of placement on the market within the Community is necessarily related to the product, and cannot be interpreted as being related to the applicant, since in the case of

[17] ECJ, Judgment of 12 December 2013 in the case C-484/12, Georgetown University c/ Octrooicentrum Nederland.

[18] ECJ, Judgment of 12 March 2015 in the case C-577/13, Actavis Group PTC EHF and Actavis UK Ltd c/ Boehringer Ingelheim Pharma GmbH & Co. KG.

[19] ECJ, Judgment of 19 July 2012 in the case C-130/11, Neurim Pharmaceuticals (1991) Ltd c/ Comptroller-General of Patents. Subject matter: Medicinal products for human use. Supplementary protection certificate. Regulation (EC) no. 469/2009. Article 3. Conditions for obtaining a supplementary protection certificate. Medicinal product having obtained a valid marketing authorization. First authorization. Product subsequently authorized as a veterinary medicinal product and a human medicinal product.

several authorisations for the same product only one of these can be the «first»".

Mention: In accordance with art. 10(5) of the Regulation no. 469/2009, the Member States may provide for that a certificate may be granted by the authority referred to in article 9, paragraph (1) without examining the conditions laid down in article 3, points (c) and (d) of the Regulation. Romania has not formulated such a reserve, therefore the compliance with the conditions has to be verified as a whole.

10. Rights conferred by the supplementary protection certificate

In accordance with art. 5 of the Regulation no. 469/2009, the supplementary protection certificate confers the same rights as conferred by the basic patent, and is subject to the same limitations and the same obligations, however such protection "shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorized before the expiry of the certificate".

With reference to the duration of the certificate, art. 13 of the Regulation provides for that:

(1) The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the Community, reduced by a period of five years.

(2) Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect.

(3) The periods laid down in paragraphs 1 and 2 shall be extended by six months in the case where Article 36 of Regulation (EC) No 1901/2006 regarding the extension the supplementary protection certificate for medicinal products for paediatric applies. In that case, this period may be extended only once.

As regard the expiry of the supplementary protection certificate, except for the cases applicable to patents as well (elapse of period of validity, holder's renunciation, failure to pay the relevant taxes), this becomes invalid also where and as long as the product covered by the certificate is no longer authorized to be placed on the market pursuant to the withdrawal of the corresponding marketing authorisation(s), in accordance with Directive 2001/83/CE or Directive 2001/82/CE. The authority that has granted the certificate may decide on the lapse of the certificate either of its own motion or at the request of a third party.

In pursuance of article 15 of the Regulation, (1) the certificate shall be invalid if:

(a) It was granted contrary to the provisions of Article 3 of the Regulation;

(b) The basic patent has lapsed before its lawful term expires;

(c) The basic patent is revoked or limited to the extent that the product for which the certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.

Any person (who has an interest, we believe) may submit an application or bring an action for a declaration of invalidity of the certificate before the body responsible under national law for the revocation of the corresponding basic patent. In the case of Romania, only the courts are competent to declare the invalidity of a certificate.

Article 16 of the Regulation no. 469/2009 regulates the revocation of a certificate extension, possible only in the case of medicinal products for paediatric use. The Regulation no. 469/2009 provides for that the extension of the certificate duration may be revoked if it was granted contrary to the provisions of article 36 of Regulation (EE) no. 1901/2006 regarding the extension of the supplementary protection certificate for medicinal products for paediatric use. Any person may submit an application for revocation „to the body responsible under the national law for the revocation of the corresponding basic patent". Since the revocation can only be declared by the body that has granted the certificate, it follows that this is the relevant authority to order the revocation upon request. However, this solution is valid in our jurisdiction solely where the act whose revocation is requested has not entered the civil circulation.

In accordance with art. 31 of the Patent Law no. 64/1991 as republished, the protection coverage is determined by the content of the claims, which is interpreted on the basis of the relevant description and drawings.

Throughout the validity thereof its holder enjoys the exclusive monopoly of exploitation on the territory of Romania of the product and/or the process making the subject matter of the certificate, that is, the manufacture, use, offering for sale, sale or import for the purposes of using, offering for sale or selling such product, in its pure form or processed as a medicinal product.

Any deeds committed in breach of the provisions of art. 31 of the Law no. 64/1991 as republished shall be deemed counterfeiting. In respect of any losses caused to him the holder is entitled to damages in accordance with the general law, and may request the courts to order the confiscation or, as the case may be, destruction of the counterfeited products. The same sanction may be imposed as well in respect of the materials or equipment that have directly served to the commission of the counterfeiting deeds. Not only the certificate holder but also the beneficiary of a license is entitled to relief, in accordance with the general law.

However, the fact has to be taken into consideration that albeit the certificate is a protection

title granted on the basis of a patent, these two represent different protection titles, and distinct from intellectual property, therefore the rights pertaining to the payment of damages or the confiscation measure granted in relation to an action brought forward by a patent holder cannot be automatically extended to the supplementary certificate. In other words, a distinct action has to be brought forward in court in respect of each of these two titles.

The limitations regarding the rights of the certificate holders refer mainly to the exceptions laid down in article 33 of the Invention Law of Romania, possible in the case of medicinal products, as follows:

- The right to exclusive private and non-commercial use (art. 33, point c);

- Use for experimental, solely non-commercial purposes of the subject matter of the patented invention, that is, in respect of which a supplementary protection certificate has been obtained (art. 33, point e). However, the fact should be noticed that in the case of medicinal products the use for experimental purposes of commercial nature is allowed, since the Directive 2001/83/EC on the Community code relating to medicinal products for human use provides for under art. 10, paragraph (6) that, *"Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products"*. The aforementioned paragraphs refer to the studies and authorisations regarding generic medicinal products, however these **clearly are aimed at marketing these medicinal products**.

Of course, the class of limitation of rights within the meaning of art. 5 of the regulation may also include the existence of certain licenses, which if validly executed in respect of the patent may extent over the certificate, inasmuch as that is stipulated in the agreement. The compulsory licenses (art. 43-45 of the Law no. 64/1991) also apply to the protection certificates. However, it has to be noticed that the time limits provided for by the law in respect of the patents cannot apply to the supplementary protection certificates, the case law having not ruled on the issue of the interpretation of the cases of non-application or insufficient application of the invention.

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- Regulation no. 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products;
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