TERM OF THE PATENT. PREMISES FOR THE CREATION OF THE SUPPLEMENTARY PROTECTION CERTIFICATE

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Abstract

The legal nature of the rights derived from the patent was object of numerous theories and discussions in literature. Their main features represent recognized characteristics for the property right, nevertheless the limitation in time, in space and the ubiquity make the difference. Especially for new medicinal or plant protection products, due to the limitation in time, the period of effective protection under the patent is insufficient to cover the investment put into the research. There exists a risk of research centres situated in the Member States relocating to countries that offer greater protection. The uniform solution at Community level was created in form of regulations, as the most appropriate legal instrument to prevent the heterogeneous development of national patent laws affecting the free movement of products in the internal market. The duration of the protection granted by the patent may be extended to additional 5 years, by a supplementary protection certificate, granted, under same conditions provided by the regulation, by each Member State. The Community regulations created a legal form of a new national sui generis right, belonging both to the intellectual property right, namely patent right, and the administrative right of the marketing authorization. The main objective of the paper consists in informing the Romanian specialists in the field about the latest evolutions in intellectual property rights, especially in protection of the inventions, as a consequence of Romania's accession to the European Community.

***Key Words**: Patent rights- Legal character-Term of the patent- Medicinal products- Plant protection products- Extension of term- Uniform legislation-Supplementary Protection Certificate- Council Regulations.*

Introduction

The supplementary protection certificate, a new industrial property title concerning the inventions in the field of medicinal products or plant protection products, appeared in Europe at the end of the last century. The supplementary protection certificate is currently seen as one of the great challenges faced by both the national industrial property offices and, especially, the law courts, due to the complexity of this field characterized by the coexistence and combination of two different fundamental law norms, namely the norms relating to the patent and the norms relating to the authorization for medicaments and plant protection products. Although this sub-field of the patent was established more than 20 years ago, we may say that the number of supplementary protection certificate applications filed within the EU Member States is negligible in comparison with the number of patent applications, nevertheless their economic importance is huge. It is proved by the numerous trials that have been on the roll of the Court of Justice of the European Union and, last but not least, on the roll of the national courts of the Member States, Romania included.

Council Regulation (EEC) No 1768/92[1] concerning the creation of a supplementary protection certificate for medicinal products created, within the European Union, the legal framework for regulating the situations in which a pharmaceutical company, owner of a patent for a medicament and authorized to place the said medicament on the market, may benefit by an extension of the duration of its exclusive rights based on the grant of a „supplementary protection certificate". Another highly important economic field, in which the investment made in the identification, creation, research and development of new active substances is huge, is the field of plant protection

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[1] Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ L 182, page 1, Special Edition, 13/vol.11, p.130).

products. A legal framework was also created to regulate, at the Community level, the grant of the supplementary protection certificate for these active substances or combinations thereof intended to be placed on the market, in particular, as pesticides, i.e. the Regulation (EC) 1610/96[2].

This paper aims at presenting the premises which led to the creation of this new protection title, with a special emphasis on the importance thereof in the internal market of the European Union, and, at the same time, at analyzing the legal characteristics of the supplementary protection certificate, as compared with the patent, in the light of the modern patent right doctrine, under the conditions of Romania's accession to the European Patent Convention and to the European Union, too. Given the ascertained scarce interest, in Romania, for the patent literature and given the fact that, before Romania's passing to the market economy, the law courts did not face many cases of patent-derived rights, we intend to present the conditions and premises of the creation of the supplementary protection certificate, with a view to clarifying certain aspects relating to the interpretation of Community regulations articles and the effect of the rights they establish.

At the same time, it is worth mentioning that the Romanian specialized literature includes a very low number of articles concerning the supplementary protection certificate and, although in the foreign literature there are many articles and reviews on this topic, a single important work on this subject is currently known, which comments the articles of the Community regulations while exemplifying them by national or Community case law; it was published in 2011, in Germany, and it was consulted and cited within this paper.[3]

Legal nature of the right arising from the patent. General considerations.

The specialized Romanian literature shows various approaches regarding the nature of the right conferred by the patent. It is unanimously agreed that the patent granted by the competent authority, i.e., in Romania, the Romanian State Office for Inventions and Trademarks, is an intellectual property title which confers exploitation and prohibitory rights to its owner who may be the creator of the invention – the inventor, or other person to whom the right to the patent has been assigned.

Retrospectively, it can be ascertained that, during the period of the French Revolution, the legislation established for the first time, in a modern form, similar to the current meaning of the term, the inventor's right in his creation as a property right.[4] The French Revolution laws deal with it as a type of property which is different from the concept of property in the civil law. This approach is still valid, the property is different as far as it is limited in time and richer in content. Starting therefrom, the subjective industrial property right arising from the patent as the recognized patent owner's prerogative of exclusively using the protected invention, has the following legal characteristics: an absolute *erga omnes* right, a patrimonial right, an alienable right (alienability which regards the patrimonial rights). Besides these general property right legal characteristics, there is a series of specific features which have led to extensive criticism concerning the legal nature of the right conferred by the patent, as a property right.

Such specific characteristics of the right arising from the patent are:

-temporariness representing a time limitation, i.e. a certain duration of the property titles,

-territoriality or space limitation, as the patent is granted for the territory of a certain country or region established by international treaties or conventions,

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[2] *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 (OJ L 198, 8.8.1996, page 30)

NB: The terms "plant protection products" and "phytosanitary products" have the same meaning and, consequently, both of tem will be used throughout this paper.

[3] Brückner C, von Czettritz P, Ergänzende Schutzzertifikate mit Pädiatrischer Laufzeitverlängerung, Carl Heymanns Verlag, Köln, 2011.

[4] Ştrenc A.C., Ionescu B., Gheorghiu G., Dreptul brevetului, vol. I, page.52, Ed. Lumina Lex, Bucureşti, 2005.

-ubiquity, namely the invention capacity of being simultaneously present in each and every object in which it is materialized. For instance, an invention which represents a technical solution to a problem relating to a motor vehicle gear box, shall be present in each and every gear box carried out based on said invention.

The criticism showed that, although features common with the property on tangible goods exist, i.e. the exclusive and *erga omnes* features, there are major differences, such as the acquisitive prescription of rights and the fact that the specific defense is not the action for the recovery of possession, resulting in the patent right not being classifiable in the category of property rights.

In time, a series of solutions were stated within the universal doctrine, such as considering the intellectual rights as a separate fourth category of patrimonial rights, besides the rights *in rem*, rights to receive payment of a debt and rights *in personam*. Another solution was to classify the inventors' rights in a distinct category named „monopoly rights", the essence of which is represented by the prerogative of making and economically exploiting the invention, as well as the right to prevent third parties, who occasionally acquire the same, from reproducing, multiplying and selling it.[5]

We do not intend to insist within this paper on conceptions regarding the legal nature of the inventor's subjective right in the Romanian post-war doctrine. As, in relation with the intellectual creations, both non-patrimonial and patrimonial rights arise, the right resulting from such creations, inventions included, is a complex right consisting of a number of distinct rights which neither appear nor become extinct at the same moment. For example, there are non-patrimonial personal rights such as: the right to authorship of the invention, the inventor's priority right, the right to make the invention public, while there are patrimonial rights, as well, such as: pecuniary rights resulting from the direct exploitation and from the indirect exploitation of a patent, by assignment and license, or the right to damages due to the unauthorized use of the patented invention. As regards the arising and extinction of invention-related rights at different moments, a good example is the right to the authorship of an invention which arises upon its creation, while the right to exclusive exploitation arises upon the grant of the patent.

Having in view that, in Romania, the doctrine established the term „rights arising from the invention" which is a generic one, intended to cover the entire diversity of rights, we will simply retain the conception according to which the right in the invention is ***a right in rem over an intangible asset, meant to be used in industry***[6]. It is worth mentioning that the phrase „to be used in industry" relates, in fact, to the „industrial application" whose meaning does not need to be analyzed in this paper. The rights arising from the invention were intended to comprise the patent owner's rights, the rights of the inventor who is not at the same time the patent owner and the rights of the company which is not at the same time the patent owner[7].

It should be mentioned that, after Romania's accession to the European Patent Convention in 2003, and, even more, after Romania's becoming a member of the European Union, the patent legislation, the practice of the State Office for Inventions and Trademarks and of the Romanian law courts, and, last but not least, the doctrine, have been highly influenced by these events. The European patent system is deeply anchored in the German patent law which thereby influenced the Romanian legislation harmonized with the European Patent Convention. At the same time, the complexity and the number of rights arising from an invention have defined a branch of the intellectual property rights, i.e. the patent right, concept which was introduced into the Romanian specialized literature in 2005.

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[5] Lucian Mihai, Invenția. Condițiile de fond ale brevetării, page 86 and following, Drepturi, Ed. Universul Juridic, București, 2002.

[6] A. Petrescu, Introducere, p-29-33, cited in L. Mihai, op.cit., page 96.

[7] Lucian Mihai, op.cit., page 22.

The patent right (in Romanian *dreptul brevetului*, in German *Patentrecht*, in French *droit du brevet*) comprises all the rights arising from the moment of creating the invention until they lapse, and it is divided, according to the German patent literature[8], into three categories:

- ***the right in the invention***, the so-called general inventor's right, arises from the very act of creation, the same as the copyright. It is a right *in rem* which comes into existence at the moment of finalizing the invention and making it available to third parties, in a simple measure, allowing it to be recognized, which does not mean publication or communication within a specially organized framework. This right could be assimilated to the „right arising from the invention" existing in the Romanian doctrine; however its components show significant differences. The inventor's right in the invention has two components that confer it a double legal nature: the right to the patent and the right to inventorship, of a personal non-patrimonial nature[9].

-***The right to the patent or the right in the patent*** is an absolute and incomplete patrimonial right concerning an intangible asset, the active subject thereof being the inventor, i.e. the creator. As one of the components of the right over an invention, it comes into existence at the moment of creation, the same as the copyright. This is the subjective material right opening the inventor's way to the granting of the patent and, this way, unlike the copyright which arises and is recognized without any formality, it needs to be recognized by a national or European administrative act, materialized in a property title. It is an absolute right because it is an *erga omnes* right, as its owner can act against any third party. It is incomplete because it does not confer the prerogative of the exclusive use or of prohibiting the use by third parties, these prerogatives being only accorded after the patent is granted or, with certain restrictions, after the patent application is published. It is considered, by the specialists in the field, an authentic property right;

-the right to the grant of the patent, a right of procedural nature which comes into existence for the first applicant, namely the first person who files an application for the grant of a patent (*first to file*) with the competent authority. The active subject of the right is the applicant for a patent, a legal fiction which is exclusively used in respect of the patent granting procedure;

-the right resulting from the patent is a material right which is distinct from the right to the grant of the patent and consists of the prerogative of exclusivity and of prohibition of unauthorized use. The active subject of this right is the patent owner which most of the times differs from the inventor, the author of the intellectual creation. The right comes into existence upon the grant of the patent and becomes extinct upon the expiry of the patent. The right arising from the grant of the patent is a private intellectual property right by which the inventor, by means the patent owner as his successor in title, is rewarded by the State for making his invention available to the public and thereby enriching the prior art. The reward consists of the positive right of exclusive expoitation, namely the prerogative of exclusive use of the patented invention conferred by the patent to its owner. Said positive exploitation right has a negative correspondent in the owner's possibility of preventing third parties from using the patented products and processes without his authorization.

The right arising from the patent may be subject to assignment or license, either total or partial. As it can be ascertained, this right is a full right *in rem* which confers to its owner the three attributes: *usus*, *fructus* and *abusus*.

Romanian legislation in the field, namely the Patent Law 64/1991, as republished, establishes these categories of rights, wherefrom a series of other rights derives[10].

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[8] Schulte R., Patentgesetzt mit EPU, Kommentar 8. Auflage, page 295 and the following, Karl Heymanns Verlag, 2008.

[9] For those inventions which are created within the company, the so-called employees' inventions, the right in the invention generally belongs to the employer, the legal system which regulates these inventions being the labour law, not the patent law (Benckard G, Patentgesetz und Gebrauchmustergesetz, C.H.Beck'sche Verlagsbuchhandlung, Munchen 1993).

[10] Patent Law No. 64/1991, as republished, Art. 45 (1): „The right to the patent, the right to the grant of a patent and the rights deriving from a patent shall be transferable, either wholly or in part."

A newer characteristic, which is specific to this right, is the fact that the patent confers to its owner the possibility of extending the duration thereof under the conditions set by the Community Regulation concerning the medicaments and the Community Regulation concerning the plant protection products, which shall be analyzed below.

Patent duration

As we have previously shown, the property right arising from the patent is characterized, besides the general characteristics of property rights concerning material goods, by a series of features specific to the property rights concerning intangible assets: temporariness, territoriality and ubiquity. The temporariness is given by the limited duration of the patent, **generally 20 years from the application filing date**.

This time limitation of the exclusive right of exploitation of the protected invention comes from the high economic importance of the patent. Firstly, the patent documentation, i.e. the description of the invention and the claims, provides, by publication, the exceptional informational contribution to the prior art, with the advantage of making highly actual and detailed documents available to the public. These documents permit to specialized persons who consult them to start research and developments in the field from a certain already explored level, thereby sparing important intellectual and financial efforts. The so disclosed information reduces long and costly parallel efforts made nationally or internationally for finding original solutions to problems that need to be solved. Secondly, the patent is granted for a technical creation complying with the conditions of worldwide novelty, inventive step as compared with other solutions available to a person skilled in the art and industrial applicability. Protected novelty and originality represent the base of the innovation and create a suitable environment for economic growth in a country. The inventor having found a new solution to a certain problem is rewarded with a „monopoly" for exploitation that the State grants him in exchange for his contribution to the society development[11]. But this monopoly cannot be a perpetual one, as the novelty becomes obsolete in time, and the solution once new must be an incentive for newer and newer better and more creative solutions permitting the development and growth of an economy. This is why it was considered that a 20 year-term would be an equitable reward for him to exploit the invention, a period long enough for the expenses made for applying the invention to be paid off.

The TRIPS Agreement[12] which is currently considered to be „the foundation on which the international system of intellectual property, in general, and the patent law, in particular, rest […], is the most comprehensive international document ensuring recognition of the minimal level of protection and enforcement of patent rights"[13]. According to *Article 33* of this Agreement, „the term of protection available shall not end before the expiration of a period of twenty years counted from the filing date".

Within the same meaning, the European Patent Convention states, under Art. 63(1) that "the term of the European patent shall be 20 years from the date of filing of the application". Moreover, the most countries in the world established, in application of the provisions of TRIPS Agreement, a patent term of 20 years from the filing date. As far as the Romanian patent law is concerned, it was amended for harmonization purposes, because it previously had provided, for the improvement inventions, a lower limit of 10 years and an upper limit equal to the duration of the patent. The current Patent Law 64/1991, as republished in 2007, provides, under Art. 31(1): "Patent duration shall be 20 years as from the date of filing the application".

[11] Intellectual Property Reading Manual, www.wipo.org.

[12] TRIPS Agreement – Trade-Related Aspects of Intellectual Property is a WIPO-administered international agreement deemed to be the most important multi-national instrument of globaliaztion of intellectual property laws, negotiated in 1994, at the end of Uruguay Round (GATT).

[13] Ştrenc A.C., Ionescu B, Gheorghiu G., op.cit., vol.I, page 86.

The 20 year-term of the patent has in view a maximal period of time in which the patent is valid, subject to payment of the maintenance fees. However, there is a difference between the patent term referring to the patent validity and the period of time during which the patent protection is really and effectively exerted, namely the duration of protection. While the first one, i.e. the patent term, relates to the above-mentioned maximal period of validity, in other words, the patent life, the second one, i.e. the duration of protection, is the period during which the patent owner benefits by his exclusive exploitation right. But the said right is only obtained after the grant of the protection title, namely the patent, the procedure up to grant being many times complicated and long lasting, generally ranging between 2 and 4 years from the filing date. In other words, the effective duration of protection is never equal to the 20 year-long validity of the patent. Nevertheless, the idea of a protection starting on the date of granting the patent was considered to be an unfair treatment for the applicant who, after 18 months from the filing date, makes his invention available to the public by publication; this is why, starting on the publication date, a provisional protection of the invention is established.

The Romanian patent law establishes the provisional protection under Art. 33 which stipulates that*: "Starting from the date of its publication […], the patent application shall provisionally confer on the applicant the protection laid down in Art. 32"*[14]. This provisional protection situation which is also known in the literature as "conditional"protection results, under the Romanian law, from the incomplete character of the action for damages. Thus, Art. 59(3) of the Patent Law 64/1991, as republished in 2007, provides that: *"Infringement of the rights referred to in Art. 32, paragraph (1), by third parties, after the publication of the patent application shall make the infringers liable for damages under civil law, and the entitlement to the payment of damages shall be enforceable after the grant of the patent."* By the amendment brought to this law in 2007, the applicant is given the option that, where, even before the publication of the application, he ascertains or considers that a third party uses the object of his patent application, he could summon such a third party to stop any potentially infringing act. This amendment is the subject of Art. 59(4) of the law, which stipulates that: *"Notwithstanding the provisions of Art. 32, paragraph (1), the acts referred to in Art 32, paragraph (2), performed by third parties before the date of publication of the patent application or before the date of the summons made by the applicant and accompanied by a certified copy of the patent application, shall not be deemed to infringe the rights conferred by the patent."*

Moreover, the duration of 20 years from the filing date is a maximal legal term of the patent which can only be reached subject to payment of the annual maintenance fees. The said duration may be however limited by a series of events that can occur during the patent life, as follows:

-failure to pay the maintenance fees shall lead to the loss of owner's rights;

-the owner's waiving the right conferred by the patent;

-patent revocation in whole within the legal time limit of 6 months from the date of publication of the patent issuance;

-patent revocation in whole, throughout its duration.

Having in view that, despite the 20 year-long patent term, the patent owner does not benefit all throughout this period by the full exercise of the rights conferred thereby, a mechanism was created for the industry of medicaments and plant protection products intended to permit an effective longer owner's protection. This extension of duration was limited to medicaments and plant protection products, because the period of time elapsed between the filing of a patent application for

[14] Art. 32 of the Patent Law 64/1991, as republished, sets out under paragraph (1): *„The patent shall confer on its owner an exclusive right of exploitation throughout its entire duration."* While, under paragraph (2), it stipulates that*: "It is prohibited to perform the following acts without the owner's consent: a) manufacturing, using, offering for sale, selling or importing for the purpose of using, offering for sale or selling, where the subject-matter of the patent is a product; b) using the process and using, offering for sale, selling or importing for those purposes the product directly obtained by the patented process, where the subject-matter of the patent is a process."*

a new medicament or plant protection product and the authorization for placing that product on the market reduces the effective protection conferred by the patent to a period of time which is not sufficient for the investment in research to be recovered. This internationally enacted mechanism is a regulation which recognizes the protection duration either by the registration of the extension, or, in Europe, by a supplementary protection certificate granted by the patent-granting industrial property authority.

Premises for the creation of the supplementary protection certificate

The remarkable technological evolution at the end of the 20th century led to creation and invention of new active substances representing the base of the development of the pharmaceutical industry and the chemical industry for plant protection products. The development of many companies which focused their strategy on the creation of new active substances was possible due to a sustained patent protection policy concerning these substances. Nevertheless the full exploitation of the obtained patents had to overcome a series of obstacles. On the one hand, the huge costs implied, in fundamental research, for the creation and preparation of active substances and, subsequently, for authorizing and marketing the medicinal products or pesticides made therefrom. Unlike many patented products that lose their economic significance by the decrease, in time, of their market attractivity, which leads to a patent life of 8 – 10 years, at the most, the medicaments and plant protection products are generally still on the market in the 20th year of patent life and their market value grows.

On the other hand, the extremely long and complicated administrative procedures related to the grant of the authorization for placing the product on the market, make the real market patent exploitation duration significantly shorter than the legal 20-year term. The owners of the exclusive right conferred by the patent which protects an active substance on which a medicament or plant-protection product is based cannot benefit by their right until the complex authorization procedure for placing the medicament or plant-protection product on the market is completed. Thus, within the Community area, the concern for public health protection led to the enactment, on 26.01.1965 of the Council Directive 65/65/EEC[15] on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products. Meanwhile, it was replaced by the Directives 2001/83/EC[16] and 2001/82/EC[17]. Moreover, the Directives 75/318 EEC[18] and 75/319/EEC[19] provide certain details concerning the requirements to be met in developing and authorizing a medicinal product. All these are procedures that can last for years.

In the last century, the private sector produced the most of the medicaments, treatments and vaccines existing on the market. When a pharmaceutical company makes investments in research and development of new medicinal products, the first step is the evaluation of chemical and biological compounds which are potentially useful in the treatment of newly appeared situations. Such an evaluation may comprise about 10000 compounds, a part of which are selected and tested for 10 – 15 years as relates to their effectiveness and safety, before their being launched on the market.[20] So, in 2009, 25 new compounds were launched on the market, while 3050 compounds were being in various development stages, which proves the high number of hindrances and difficulties to be

[15] OJ L of 9.12.1965, page 369.
[16] OJ L 311 of 28.11.2001, page 67.
[17] OJ L 311 of 28.11.2001, page 1.
[18] OJ L 147 of 09.06.1975, page 1.
[19] OJ L 147 of 09.06.1975, page 13.
[20] Innovation.org. *Drug Discovery and Development: Understanding the R&D Process*. Cited in The Pharmaceutical Industry and Global Health: Facts anf Figures, Issue 2011, International Federation of Pharmaceutical Manufacturers &Associations (IFPMA), page 12.

overcome for converting new compounds into safe and effective medicinal products.[21] It is also worth mentioning that, from the data provided by pharmaceutical companies, it results that the process of development of existent products implies huge costs, as the development of a single medicinal product currently costs more than 1.38 billion USD, in comparison with 138 million USD in 1975; it is a 1000% increase which in fact reflects the necessity of safer medicinal products of higher quality, in the sense of reducing the side effects in patients.[22] As a consequence of the higher quality standards used, in particular, in case of medicinal products, with a view to reducing the risks for public health, a significant time lag appears between the date of filing the patent application and the date of placing the product on the market.

Having ascertained that the said time lag caused an alarming decrease in the European pharmaceutical industry research and development activity for new active substances, the European Commission was concerned, starting from the '70s, to achieve a balance between the public health system and the interests of the industry, in order to allow it to keep up with the innovative pharmaceutical products developed in USA or Japan. The statistics made in the Community area after the implementation of the Directive 65/65/EEC showed that the real exclusivity period conferred by a patent for proprietary active substances authorized to be placed on the market had reached no more than 9 - 10 years; the incentive to be given to the medicinal product producers was based on the principle of a reward meant to permit them to recover the investment by extending the patent protection term with a period of time equivalent to the period required for the grant of the market authorization.

At the same time, it was ascertained that the already known active substances can represent an important source of new products, when the research efforts are focused to develop them instead of finding new active substances. But the products based on the said active substances, in particular those created after a long-lasting and expensive research, cannot be subject of a sufficient further development, in Europe, in the absence of a favouring legal regulation intended to provide a sufficiently long protection to encourage research. And, in the pharmaceutical field, research must be encouraged as it has a decisive contribution to the continuous public health improvement. In the filed of plant protection, as well, the research has an important contribution to the permanent improvement of crops and to the manufacture of high quality food products.

In this context, it was internationally agreed that, based on new legal provisions, the duration of a patent granted for an active substance on which a medicinal product or a plant-protection product is based could be extended with a certain period taking into account the administrative procedures needed for placing the product on the market and ensuring an exclusive protection sufficient for the patent owner to recover the investment made in research.

In the USA, the extension of patent duration was made possible by the Act of 24 September 1984, the legal framework for this regulation in respect of medicinal and plant-protection products being represented by the intellectual property law *United States Code, Title 35 Patents, Sections 155, 155A and 156 on Extension of Patent Term, 35USC§155-156 (2000), as well as the Code of Federal Regulations (CFR) Rules of Practice in Patent Cases, Extension of Patent Term: 37CFR§1710-1785(2000)*[23].

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[21] Innovation.org. *New Medicines in Development*. Cited in The Pharmaceutical Industry and Global Health: Facts anf Figures, Issue 2011, International Federation of Pharmaceutical Manufacturers &Associations (IFPMA), page 12.

[22] PhRMA 2011. Cited in The Pharmaceutical Industry and Global Health: Facts anf Figures, Issue 2011, International Federation of Pharmaceutical Manufacturers &Associations (IFPMA), page 12.

[23] WIPO Handbook on Industrial Property Information and Documentation „Survey on the Grant and Publication of Supplementary Protection Certificates (SCPs)" published in 1994 and updated in 2002, www.wipo.int/standards/en.

In Japan, by the 1988 amendment of the patent law, there was created the legal framework for the extension of the term of patents on pharmaceuticals for human and animal use and plant protection products, by 5 years, at the most. These provisions are the subject matter of Sections 67/2, 67 bis and 67 ter of the Japanese Patent Law.

In Europe, at the end of the '80s, France, and then Italy and Germany, created, at the national level, the legal framework for the extension of the term of patents for medicinal products, by up to 5 years. The so-created situation led to a lack of balance at the level of the European Community and the risk of transferring the research centres from certain Member States to the States in which the duration of the exclusive protection gave the owners the possibility to recover the investment made in research, such as USA or Japan. At the same time, the development, at the Community level, of heterogeneous national legislations could result in obstacles to the free circulation of pharmaceutical products within the Community, thereby affecting the functioning of the internal market. Consequently, it was agreed upon a uniform solution at the Community level, to extend the patent duration by means of a Community legal instrument intended to enact the grant, within each Member State, in the same conditions, of a protection title for extending the duration of a patent granted for an active substance in respect of which an authorization for placing the product on the market as a medicinal product was issued within the Community. This way, a Community regulation was issued for the creation of a supplementary protection certificate capable to confer a *sui generis* right which extends *de facto* the patent duration while not affecting the national patent legislations, *per se*[24].

It is worth mentioning that, if in Europe the industrial property title extending the patent duration was named "Supplementary Protection Certificate" (in French - *Certificat complémentaire de protection*, in German - *Ergänzendes Schutzzertifikat*, in Romanian – *Certficat suplimentar de protecție*), in the United States of America it is called "Certificate Extending Patent Term" and in Japan there is no special name for the extension procedure which is simply known as "Registration of extension of term of patent right".

The Regulation (EEC) 1768/92[25] concerning the creation of a supplementary protection certificate for medicinal products creates the legal framework meant to regulate situations in which a pharmaceutical company owning a patent concerning a medicinal product and having an authorization to place said medicinal product on the market may benefit by a total duration of its exclusive rights of 15 years, at the most, based on the grant of a "supplementary protection certificate". The above-mentioned Regulation entered into force on 2 January 1993 and, starting on 1 July 1994, as a consequence of the establishment of the European Economic Area, it was extended to the said entire area which comprised the European Union plus Austria, Finland, Norway, Iceland and Sweden (published in JO L 198, page 30). After the date of 1 May 1995, the EEA was extended to Liechtenstein, as well.

For the other field of high economic importance, in which the investment made in the identification, creation, research and development of new active substances is huge, i.e. the field of plant protection products, there was also created the Community legal framework which regulates the grant of the supplementary protection certificate, namely the Regulation (*EC*) No 1610/96[26] (hereinafter Regulation for plant protection products).

Both regulations have been amended following the accession of the group of 10 countries: Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia and Slovenia, to the European Union, in 2003. The accession, in 2007, of Romania and Bulgaria imposed

[24] Brückner c, von Czettritz P, op.cit., page 17.

[25] Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ L 182, p.1, Special Edition, 13/vol.II, page 130).

[26] 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 (OJ L 198, 8.8.1996, page 30).

Note: The terms „plant protection products" and „phytosanitary products" have the same meaning and they shall be both used throughout this paper.

the amendment of Art. 19a of the Regulations[27]. The Act of accession of Bulgaria and Romania was published in the Official Journal of the European Union No L 157/11 of 21.06.2005. Annex III to the Protocol concerning the conditions and arrangements for admission of Republic of Bulgaria and Romania to the European Union, the chapter referring to the Company Law contains the section Industrial Property Rights, sub-section Supplementary Protection Certificates.

It is worth mentioning that, before Romania's accession to the European Union, the concern for creating the legal framework for extending the patent duration existed in our country, as a consequence of the legitimate interests of important producers of medicinal products and plant-protection products, patent owners and producers of generic products in these industrial fields.

Law No 581/2004 on the supplementary protection certificate for medicaments and phytosanitary products was published in the Official Gazette of Romania No 1233 of 21 December 2004. The law never produced effects and was expressly abrogated by the Law 107/2007, because from the date of Romania's accession to the European Union, the Community Regulations have become directly applicable and prevailed over any conflicting provisions of the national legislation. At the moment of creation of said act, there was an intense debate concerning the name of the certificate to be granted by the State Office for Inventions and Trademarks, i.e. either supplementary protection certificate or certificate for supplementary protection. An argument in favour of the second option was that the certificate was intended to extend (supplement) for a certain period of time the protection conferred by the patent. At the same time, the certificate was assimilated, as far as the reparation rights are concerned, with another provisional title granted on the territory of Romania, namely the transitional (pipeline) protection certificate. Under the trade agreement concluded with the United States of America in 1992 and ratified by the Law No.52/1992, a transitional (pipeline) protection was established in Romania for patents having as a subject-matter medicinal products for which, in Romania, up to the entry into force of the Patent Law 64/1991, foreign applicants were not allowed to enjoy patent protection. Besides the medicinal products, the substances obtained by chemical or nuclear methods, food products and spices were prohibited as subject-matter of foreign owners' patents. Thus, under the Law No 93/1998 concerning the pipeline protection, the so-called certificate of transitional (pipeline) protection was granted upon request and based on an examination procedure, for the owners of patents granted in the USA, the reference patent being, on the date of filing the certificate application with OSIM, a granted patent in force in its country of origin. We will not analyze further details regarding the protection established by this certificate, although there is a series of similarities with the supplementary protection certificate, however, in our opinion, the main difference between these protection titles consists of the legal system governing them. If the pipeline protection certificate is regulated only by the patent legislation and the scope of protection granted thereby is the same as the protection granted by the reference patent and it expires at the same moment as the reference patent, the supplementary protection certificate operates at the same time under the patent legislation and under the administrative legislation, by the market authorization, and the protection it grants is limited to the product indicated in the said authorization and to a duration which cannot exceed the legal patent term with more than five years. In this context, in our view, the suitable name is „supplementary protection certificate" which is, in fact, the term officially adopted within the European Union.

In 2009, as a consequence of the evolution of exigencies in the pharmaceutical field, on the one hand, and of the changes occurred in the geo-political area of the Community, on the other hand,

[27] The Protocol, in the Annex III of the Accession Treaty, stipulates under number II, „Supplementary Protection Certificates", that Art. 19a of the Regulation for medicinal products shall be amended by adding the following text: „l. any medicinal product protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2000 may be granted a certificate in Romania. In cases where the period provided for in Article 7(1) has expired, the possibility of applying for a certificate shall be open for a period of six months starting no later than the date of accession.' Under number II (2), Art. 19a is completed by letter (I) comprising a similar provision regarding the phytosanitary products.

the Regulation (EEC) 1768/92 was amended and the codified version thereof was adopted: the Regulation (EC) 469/2009[28] which shall be referred to hereinafter as Regulation for medicinal products.

The legal basis for the grant of the supplementary protection certificates on the territory of the European Union is represented by the two Community regulations: the Regulation (EC) 469/2009 for medicinal products and the Regulation (EC) 1610/96 for plant protection products, as well as the national legislation. The said regulations are, of course, normative acts directly applicable in the Member States, so that essential changes of the national legislation in the field of patents were not required, except for the introduction of a provision relating to the possibility of obtaining such a protection title following the patent for invention, under the conditions set out by the Community regulations concerning the supplementary protection certificate.

Consequently, in Romania, the Patent Law 64/1991, as republished in 2007, was completed by introducing, under Art. 31 referring to the patent duration, a paragraph (3) having the following content*: „For patented medicaments or plant protection products, supplementary protection certificate may be granted under the Council Regulation (EEC) no. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicaments and 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."* In order to ensure a unitary procedure for implementing the regulations and also to come to the assistance of the applicants, the Director General of the State Office for Inventions and Trademarks issued the Instruction No 146 of 28.12.2006 concerning the supplementary protection certificate for medicinal and plant protection products, published in the OSIM Official Industrial Property Bulletin (BOPI) No 12 of 29.12.2006. In our opinion, the amendments brought to the Community regulations should entail further amendment of the paragraph within the Romanian law, having in view that, for the field of medicinal products, the certificate applications as well as the Office decisions are currently made under the Regulations, in the codified version of 2009. That is why, *de lege ferenda*, a new drafting of this provision would be required in order to cover future situations in which new amendments of Regulations could occur.

As regards the rights conferred by the European patent, the European Patent Convention, under Art. 63 (2) which concerns the term of the European patent, sets out the patent term extension possibility and offers to the Contracting Parties the possibility of extending the duration of the European patent for products undergoing an authorization procedure, immediately after the expiry of the patent term[29].

Legal characteristics of the supplementary protection certificate

The Explanatory Memorandum of the European Commission of 11 April 1990, COM (90) final, published in the OJ 1990, C114, under the title "Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products" stated, under paragraph 20, that a Community solution capable of taking into account the interests of all Member States, as regards the issue of the reduced effective duration of the patent within the medical sector of the Community market, is a Community regulation ensuring the legal form of a new *sui generis* right and lying at the interface between two systems, namely that of the authorization for placing the product in the market and the patent system. The 19th paragraph of the said Memorandum

[28] *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 (codified version) (OJ L 152/1).

[29] Art. 63 EPC: „Term of the European patent. (1) The term of the European patent shall be 20 years from the date of filing of the application. (2) Nothing in the preceding paragraph shall limit the right of a Contracting State to extend the term of a European patent, or to grant corresponding protection which follows immediately on expiry of the term of the patent […] (b) if the subject-matter of the European patent is a product or a process for manufacturing a product or a use of a product which has to undergo an administrative authorisation procedure required by law before it can be put on the market in that State [...].

shows that the idea of extending the patent duration by amending the national patent legislations could not be adopted because of the necessity to preserve the harmonization between the national legislations and the European legislation, i.e. the European Patent Convention. The situation in which one and the same medicinal product was protected for different periods of time under the national legislation and under the Convention had to be, by all means, avoided. At that moment, in 1990, in the European Patent Convention there were 14 Contracting States, 10 of which were Community Member States. In this context, the extension of patent duration within the framework of the Convention, by amending Art. 63 was impossible as a consequence of the extremely complicated procedure imposed by Art. 172 (a) of the EPC. This is why the final option was to include the possibility of extending the patent term within Art. 63(2), as mentioned above, and the amendment entered into force in 1997, which means six years after the date of the EPC Revision Conference.

In order to define the legal features of the rights arising from the supplementary protection certificate, the provisions of the two Regulations concerning the subject-matter of protection[30] and the effects of the certificate[31] shall be taken into consideration. As we have already shown in this paper, the supplementary protection certificate is deemed to be a **distinct industrial property protection title** which extends the patent duration and confers a *sui generis* right to its owner who is, in fact, the patent owner. The legal nature of this right is a double one, given by the patent right, as a branch of the intellectual property right, and the administrative right relating to the authorization for placing the medicaments or plant protection products on the market. This comes from the protection it confers, which is limited to the protection conferred by the basic patent and to the product for which the authorization was granted. At the same time, the effects of the certificate, i.e. the rights acquired by the entity of law, which is the protection title owner, are the same as the rights conferred by the basic patent and subject to the same obligations. Which means that it has the same legal features as the patent: an absolute *erga omnes* right, a patrimonial right, an alienable right, as well as the special characteristics, such as the time limit and the territorial limit of a national right. The time limit differs from the patent time limit, as it can reach five years, at the most, or exceptionally, five years and six months, in case of the medicaments for paediatric use.

The certificate is however different from the patent in that the protection it confers is limited to the product for which the authorization was issued for placing the product on the market as a medicinal or plant protection product. Taking into account that by the publication of the certificate application or of the granted certificate, the publication of the patent document on which the certificate is based is not ensured, as in the case of the patent, for interpreting the scope of the protection conferred by the certificate it is necessary to start from the scope of protection conferred by the basic patent, given by the content of the claims, which is, in its turn, interpreted by using the description of the invention. Thus, within the limits defined by the patent and the market authorization, the certificate confers the same rights and obligations as the patent on which its grant is based, namely the exclusive right of exploitation and the right to prohibit third parties the unauthorized use of the products protected by the certificate. Furthermore, there are other rights deriving therefrom, such as the right to transfer the same by assignment, licence or succession, the right to renouncement, as well as the defense of rights provided for by the law – security measures ordered by the law court, infringement actions, entitlement to damages. At the same time, the abuse of right may be sanctioned by third parties by actions of revocation or cancellation of the granted

[30] Art. 4 - Subject-matter of protection.

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 authorizations to place the corresponding medicinal product/plant protection product on the market and for any use of the product as a medicinal product/plant protection product that has been authorized before the expiry of the certificate.

[31] Article 5 - Effects of the certificate .

Subject to Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.

certificate, with effect *ex tunc*. The same as in the case of the patent, the certificate may be maintained in force subject to payment of the legal fees throughout its entire term[32]

The supplementary protection certificate, the same as the patent, confers a national protection, on the territory of the Member State where an application for the grant of the certificate has been filed with the competent authority that also granted the patent on which the certificate is based. Ensuring uniform conditions, at the level of each Member State, relating to the grant of the certificate, the publication, in order to make it available to third parties, the duration and the cancellation thereof represent the subject of the Community regulations provisions, the uniform interpretation of which is the competence of the Court of Justice of the European Union.

Conclusions

The paper starts from the presentation of the legal characteristics of the right arising from the patent, as a property right having the generally-recognized features thereof as well as a series of characteristics specific to the property over intangible assets, i.e. temporariness, territoriality and ubiquity. The temporariness limits the patent term to 20 years, at the most. The patent term institution is presented in the light of international regulations and national laws, and also of the effects it has over the protection conferred by the patent. One of these effects is the reduced effective duration of the owners' exclusive rights which, in the field of products which undergo a market authorization procedure – medicinal and plant protection products – is even shorter as a consequence of the time elapsed up to the grant of such authorizations. These were the premises for the creation of a new industrial property title, the supplementary protection certificate, which was introduced 20 years ago in the European Community by means of two Council Regulations: Regulation (EEC) 1768/92 concerning the creation of a supplementary protection certificate for medicinal products and Regulation (EC) 1610/96 concerning the creation of a supplementary protection certificate for plant protection products. They both mainly aim at providing a uniform regulation, at the Community level, for the extension of the patent term by five years, at the most. Further on, the legal features of the certificate are presented in comparison with the patent features and the effect thereof upon the owners.

In our view, the paper is useful to the specialists in the field, helping them understand the conditions of creation of a new industrial property title generated by the market economy, and, at the same time, it contributes to the enrichment of the Romanian doctrine in this matter. This paper can be a starting point for other studies concerning the uniform interpretation of Community provisions by the Romanian authorities competent for protecting or settling the supplementary protection certificate cases.

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