JOURNAL of Humanities, Culture and Social Sciences, Vol. 2, No. 2, 2016
ISSN 2393 – 5960; ISSN – L 2393-5960, pp. 129-146

Supplementary protection certificate for medicinal products

Izabela Bratiloveanu, Ph.D.[*]
Mihail-Dan Dogaru, Ph.D.[**]

[*]University of Craiova, Faculty of Law, Romania
bratiloveanuisabela@yahoo.com

[**]University of Craiova, Faculty of Law, Romania
dogarum@rdsmail.ro

Abstract

In the current period, there is great concern for obtaining new drugs created through research and development. Marketing of these drugs is conditioned not only by the issuance of a patent, but also for authorizing the marketing of them, a procedure that shortens the effective life of the patent. S.O.I.T. is the authority responsible for issuing supplementary protection certificate for medicinal products. They have direct effect in Romanian law: 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 and Regulation (EC) No. 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for pediatric use and amending Regulation (EC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No. 726/2004.

Key-words: State Office for Inventions and Trademarks; patent; supplementary protection certificate.

1. Introduction

The patent is an administrative legal act which is unilateral and attributive of rights, holding the role of protection title (Olteanu, 2008: 157). It grants its owner the exclusive right to exploit or the

indirect right to prohibit others from making, using, selling, importing or hold the invention for marketing purposes without his consent (Constantin, 1993: 24; Danilă, 2008: 255). The patent is in fact a "contract" between the patent applicant (who by receiving the patent he becomes the patent holder) and the State granting the patent, represented by its patent offices (Cocoș, 1999: 130).

"The Patentable invention" can be defined as an intellectual creation in the technical field, concerning a product or a process, is new, involves an inventive activity and is industrially applicable (Bodoaşcă & Tarnu, 2015: 254).

According to art. 31 para. 1) of Law no. 64/1991, republished, the duration of the patent is twenty years starting from the date of filing. The same is the duration of the European patent, as required by art. 63 para. 1) of the Convention on the Grant of European Patents (The European Patent Convention).

Since the period that elapses between filing a patent for a medicinal product and the marketing authorization of the product reduces the period of effective protection under the patent to an insufficient period to cover the investment in research, internationally regulated the grant of a supplementary protection certificate by the service that is competent in industrial property which issued the basic patent; in Romania, the Romanian State Office for Inventions and Trademarks.

2. The arguments in favor of creating a supplementary protection certificate for medicinal products

According to the World Health Organization (W.H.O.) is called a drug any substance or product that is used in order to modify or explore the physiological systems or pathological condition in the interest of the subject that it is administered to. The drug can be defined as a substance or product (resulting from the combination of several substances) used for the diagnosis, prevention, improvement or cure of certain diseases (Ionică, 2014: 12). According to art. 1 of Regulation (EC) no. 469/2009 of the European Parliament and of the Council on supplementary certificate for medicinal products, the

notion of medicinal product is any substance or composition presented for treating or preventing disease in human beings or animals and any substance or composition that can be administered to humans or animals in order to establish a medical diagnosis or to restoring, correcting or modifying the physiological functions in humans or animals.

In the composition of a drug enters the active substance which, in the meaning of art. 699 of Law no. 95/2006 on healthcare reform, republished, is any substance or mixture of substances used in the manufacture of a product that, by using the manufacturing process becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view in restoring, correcting or modifying physiological functions or to restore a medical diagnosis and excipients, which are substances pharmaceutically inactive, but which have a positive manifestation of the pharmacological effect of the drug substances fulfilling many roles, which are essential to use the active substances for therapeutic purposes.

Patent-protected drugs are called "originator" or "organic drugs" or "innovative drugs". The average cost of innovative medicines currently reach over 1.38 billion dollars, and the average duration of achievement is fifteen years. The main pharmaceutical companies invest huge amounts of money for research and development, preclinical and clinical testing, marketing and promotion activities. In our country, the innovative drugs are authorized in accordance with Art. 700 and 702 of Law no. 95/2006 or they are authorized through the centralized procedure in the European Union, based on clinical trials. They are considered innovative drugs, drugs for which was granted a Pediatric Use Marketing Authorization (PUMA).

After the expiry of the patent for the original drug, the pharmaceutical companies can sell "the generic drug". According to art. 708 par. 2) b) of Law no. 95/2006, the generic drug has the same qualitative and quantitative composition in active substances and the same pharmaceutical form with the reference drug, and its bioequivalence with the reference drug is demonstrated by

appropriate bioavailability studies. Different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance are considered the same active substance, if not having some significantly different properties in terms of safety and/or effectiveness. The generic drugs are not protected by patent, and their price is 20-80% lower than the price of the original drugs. In Romania, art. 8 of the Health Ministry Order no. 75/2009 approving the Standards on the calculation of prices for medicinal products for human stipulates that the generic reference price may not exceed 65% of the innovative drug whose generic is.

In the pharmaceutical sector, innovation is of extreme importance, allowing patients to benefit from medical treatments that were impossible in the past. Without consistent efforts on the line of research - development of innovative companies and without significant investment, these achievements would not have been possible.

As indicated in the Commission Communication of 16 July 2008 on a strategy of industrial property rights for Europe between 2000-2007, the originator companies spent on average 17% of their turnover comes from prescription in research and development worldwide, of which about 1.5% of the turnover was invested in fundamental research to identify potential new drugs and 15.5% for developing potential drugs identified through testing in products that are sufficiently safe and effective in order to be sold. Over the same period, spending on marketing and promotional activities accounted for 23% of turnover and production costs about 21% of their turnover. The situation is different as it concerns the generic manufacturers who have invested in research and development only 7% of their turnover, while costs of manufacturing accounted for 51% and trading 13 % of turnover. At the European level, in order to stimulate the innovative companies to continue their work, given that there is a risk of travel research centers in those countries that would have provided better protection, it was decided that the term of a patent for an active substance in medicines or plant protection products can be extended to a period which takes into account the

administrative procedures that are necessary for the authorization of placing them on the market. It was envisaged that the period that elapses between the filing of a patent application for a new drug and the authorization of its market was reducing the protection conferred by the patent for that product in a period insufficient to cover the investments in research.

It was considered that a Community Regulation to provide a uniform solution at Community level to prevent such a heterogeneous development of national laws, which would have led to new disparities that would have prevented the free movement of medicinal products within the European Union, and would thus affected the functioning of the internal market, was the appropriate legal instrument.

The supplementary protection certificate is a distinctive title of industrial property protection, which supplements the duration of a patent and that gives its holder a right *sui generis*, which is in fact the patent holder (Ionescu, 2013: 170). The legal nature of the supplementary protection certificate is twofold, and is given by patent law and administrative law governing the marketing authorization of medicinal products or plant protection products.

In light of these considerations, Council Regulation (EEC) No. 1768/92 concerning the creation of a supplementary protection certificate for medicinal products came into force on 2 January 1993 and Regulation (EC) No. 1610/96 of the European Parliament and of the Council concerning the creation of a supplementary protection certificate for plant protection products, which entered into force on 8 February 1997. Since Regulation (EC) No. 1768/92 of 18 June 1992 has been substantially amended several times, for reasons of clarity and cohesion was adopted the codified version of the regulation for medicines, 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. According to art. 20 j) of the Regulation "any medicinal product protected by a basic patent and for which the first marketing authorization as a medicinal product was obtained after 1 January 2000 shall be granted a

certificate in Romania. If the period referred to in art. 7 par. (1) has expired, the certificate request may be submitted within six months starting no later than 1 January 2007".

In 2009, it entered into force Regulation (EC) No. 1901/2006 of the European Parliament and of the Council on medicinal products for pediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No. 726/2004. The Regulation has ordered the establishment of the Pediatric Committee within the European Medicines Agency (EMA) and was willing to reward in the form of a 6-month extension of the supplementary protection certificate in respect of products to be submitted pediatric data and compliance with all measures contained in the agreed pediatric investigation plan, where the product is authorized in all member states and relevant information on the results of studies are included in the product information. The reward is for conducting studies in the pediatric population and not for demonstrating that the product is safe and effective for this population, therefore it is granted even when a pediatric indication is not authorized.

We mention that regarding orphan medicinal products, the reward on the extension of the supplementary protection certificate does not apply. For these products, incentives were made available in the U.S. in 1983 and in Japan in 1993. It is reported that Regulation (EC) No. 141/2000 on orphan medicinal products was instituted in order to establish a Community procedure for the designation of medicinal products as orphan medicinal products and to provide incentives for research, development and placing them on the market. According to art. 3 of that Regulation, a medicinal product is designated as an orphan if: it is intended for the diagnosis, prevention and treatment of a life-threatening that chronically debilitates the body or for a serious and chronic condition affecting not more than 5 in 10,000 persons in the Community when the application or it is intended for the diagnosis, prevention and treatment of a life-threatening that chronically debilitating body or for a condition serious and chronic condition in the Community and

that without incentives is less likely that dissolution generate sufficient return to justify the necessary investments and there is no satisfactory method of diagnosis, prevention or treatment of the condition in question authorized in the Community or, if such method exists, that the medicinal product will be of significant benefit to those affected by this condition. These products benefit of a market exclusivity for ten years from the grant of a marketing authorization for the orphan indication extended to twelve years when they meet the requirement for data on use in the pediatric population.

Art. 31 par. 3) of Law no. 64/1991, republished stipulates the possibility of granting supplementary protection certificate in Romania: "For medicinal or plant protection products patented can get a supplementary protection certificate under the conditions of Regulation (EEC) No. 1768/92 of 18 June 1992 concerning the supplementary protection certificate for medicinal products and Regulation (EC) no. 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning a supplementary protection certificate for plant protection products".

As of 1.01.2007, the regulations are directly applicable in our country, under art. 6 par. (3) of Government Decision no. 573/1998 on the organization and functioning of the State Office for Inventions and Trademarks, it was issued by the General Director of Romanian State Office for Inventions and Trademarks the Instruction No. 146 of 28.12.2006 concerning the supplementary protection certificate for medicinal products and the supplementary protection certificate for plant protection products published in the Official Bulletin of Industrial Property no. 12/2006. Previously, in order to meet criteria for joining the European Union, Law No. 581/2004 concerning the supplementary protection certificate for medicinal and plant protection products has been adopted, but has had no effect and was abrogated by Law no. 107/2007.

3. The conditions of granting supplementary protection certificate for medicinal products

According to art. 3 of Regulation (EC) No. 469/2009, the conditions for obtaining a certificate are: product, as a medicinal product has obtained a marketing authorization valid from the filing of the certificate in accordance with European Directives (Directive 2001/83/EC and Directive 2001/82/EC) permit is the first authorization to place the product on the market as a medicinal product; the product is protected by a basic patent in force; the product has not already been the subject of a certificate.

Next, we make developments on each of these conditions.

For the purposes of art. 1 c) of the Regulation for medicinal products, the basic patent protects a product, a process for obtaining a product or a product implementation. It is worth mentioning that at the time of application for certificate, the patent shall be in force in the country which issued the authorization for marketing of the drug. The patent can be national, assimilated to the national or to a European patent (Roş, 2015: 43).

The authorization to place the product on the market is the act of proving when the patent began to be exploited on the market, justifying its extension. In Romania, any drug can not be marketed without an authorization for marketing issued by the National Drugs and Medical Devices Agency (N.D.M.D.A.) or without an authorization through the centralized procedure of the European Medicines Agency (E.M.A.). It is worth mentioning that the authorizations can benefit from mutual recognition in other Member States of the European Union. In addition, since 1st January 1998, the mutual recognition procedure is compulsory for medicinal products to be marketed in another Member State than where the product was first authorized.

Under Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31st March 2004, the compulsory centralized authorization procedure is applicable for: high-tech medicines, particularly those derived from biotechnology, orphan medicinal products and any medicinal product for human use containing an

active substance completely for which new therapeutic indication is the acquired immune deficiency syndrome, cancer, neurodegenerative diseases, diabetes, autoimmune diseases and other immune dysfunctions and viral diseases.

The marketing authorization shall take effect on the date of application for certificate granting at the State Office for Inventions and Trademarks, i.e. not revoked, withdrawn or expired. In addition, it must be the first marketing authorization as a medicinal product in Romania. Therefore, this condition is not met when for the product with the same indication, the applicant or a third party previously obtained the permit.

Another condition for the granting of a supplementary protection certificate is that the product do not have a certificate already granted in the Member State concerned, which would be equivalent to a prior exploitation of the product on the market and an unjustified extension of patent. According to art. 1 b) of the Regulation on medicines, the "product" means the active ingredient or combination of active ingredients of a medicinal product, and not the excipients. The name of the active substance or combination of active substances must be that which is provided in the marketing authorization of the product (Ionescu, 2007: 119).

As noted in the literature, where the claims of the same patent raise several authorizations, it will be granted one supplementary protection certificate and its scope will not be limited to the product of a single authorization for marketing.

4. The application for the supplementary protection certificate

According to art. 2 of the Instruction no. 146/2006, in Romania, the demand for supplementary protection certificate is drawn up in Romanian and shall be filed with the State Office for Inventions and Trademarks to the registration of institution or by post.

The demand for supplementary protection certificate must contain:

-the form requesting the grant of the certificate which can be downloaded from the website of the institution;

-a copy of the authorization for marketing in Romania, which is valid at the date of application, including: the product name, the number and date of the authorization, the summary of product characteristics and the duration of the authorization;

-the first marketing authorization in the European Economic Area, if not the first authorization for marketing in Romania, comprising: the identity of the authorized product, the legal basis for granting marketing authorization and a copy of the reference of the publication authorization into an official publication. If such a publication is missing, it must be submitted a document showing the following: the authorization, date of authorization, the Member State in which it is given and the identity of the product authorized.

For the purposes of art. 7 of Regulation for medicinal products, the application for additional certificate must be filed within six months from the date on which the product obtained the marketing authorization. But if the authorization was issued before the basic patent is granted, the certificate request must be filed within six months from the date of issuance of the patent. For pediatric medicines, the application for extension of the duration of the supplementary protection certificate is submitted with the application for a certificate or when the application for the certificate is pending; in the latter case, the request for an extended duration must refer to an application for a certificate already filed. It is worth mentioning that the application to extend the duration of a certificate already granted shall be lodged not later than two years before it expires. If the applicant is not the basic patent holder, he shall prove that he is the successor in title of the holder.

Last but not least, the demand for supplementary protection certificate must contain all particulars enabling the identification of the product protected by the basic patent, for example by indicating the claim relating to the product.

5. Examination of the application for granting a supplementary protection certificate for medicinal products

The State Office for Inventions and Trademarks examines the application for the certificate in terms of the conditions of form and substance.

Thus, if it is found that the formal conditions set out by art. 4 par. (1) of the Instruction No. 146/2006, the State Office for Inventions and Trademarks publish the application in the Official Bulletin of Industrial Property - Section Supplementary protection certificate, stating at least the following: the number and filing date, the identification data of the applicant, the number of the basic patent, title of the invention, the name of the product for which it is demanded the certificate, date and issuing authority of first authorization for marketing in Romania, and, if applicable, number, date and the State of first marketing authorization in the European Economic Area.

The examination board of The Romanian State Office for Inventions and Trademarks decides to grant supplementary protection certificate when examining the merits, finds that at the filing date, the conditions of art. 3 a), b) and c) of Regulation for drugs were enacted, namely: the product is protected by the basic patent; marketing authorization is valid in our country and is not the subject of another certificate in Romania.

Mention of the decision to grant the certificate or the rejection of the application shall be published in the Official Bulletin of Industrial Property within one month of the expiry of three months from the notification term in which may be challenged the decisions of the Board, stipulated in art. 9 par. (2) of the Instruction No. 146/2006 or within one month from notification of a decision of the Commission for review.

In addition, the decision of the State Office for Inventions and Trademarks shall be justified and communicated to the applicant within one month of receiving it.

6. The duration of the supplementary protection certificate

For the purposes of art. 13 of the Regulation for medicinal products, the supplementary protection certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period of time between the date of filing and the date of issue of the first authorization to place on the market in the Community of the product, reduced with a period of five years. However, the additional duration of the certificate may not exceed five years from the date of entry into force. Periods referred to above shall be extended by six months when the requirements for art. 36 of Regulation (EC) No. 1901/2006 concerning the extension of protection for pediatric medicines. Duration may include years, months, and a number of days.

Unless otherwise stipulated for patent (end of period of validity, waiving holder, unpaying maintenance fees in force), according to art. 14 (d) of Regulation (EC) No. 469/2009, the certificate expires if and as long as the product covered by the certificate is no longer authorized to be placed on the market following the withdrawal of the authorization of proper marketing in accordance with Directive 2001/83/EC or Directive 2001/82/EC. In Romania's case, the State Office for Inventions and Trademarks is authorized to decide on the expiry of the certificate either on its own or at the request of a third party.

7. The rights conferred by a supplementary protection certificate

According to art. 5 of Regulation No. 469/2009, the supplementary protection certificate confers the same rights as conferred by the basic patent and shall be subject to the same limitations and obligations, but the protection conferred is limited to the product covered by the marketing authorization of the drug, "for any use of the product as a medicinal product that has been authorized before the expiry of the certificate". The protection conferred by the certificate is determined by the claims of the basic patent (Ștrenc, Ionescu & Gheorghiu, 2007: 271).

Throughout the period of validity, the holder of the supplementary protection certificate enjoys the monopoly of exploitation in Romania of the product and/or process that is the subject of the certificate, namely, manufacturing, using, offering for sale, selling or importing for use, offering for sale or sale of this product in its pure form or processed as medicine (Roş, 2015: 48).

8. Procedures for complaint, revocation and annulment of the supplementary protection certificate

The provisions of Law no. 64/1991, republished, regarding procedures for complaints, revocation and cancellation of patents also apply to supplementary protection certificates.

The Commission decisions can be contested at the State Office for Inventions and Trademarks within 3 months from the communication, according to art. 9 par. (2) Instruction no. 146/2006. Supplementary protection certificate revocation can be requested by any interested person within six months of publication of the decision to grant, citing one of the reasons specified in Art. 15 of the Regulations for medicinal products, namely:

- The Certificate has been issued contrary to the provisions of art. 3;

- The basic patent has been stopped before its lawful term expires;

- The basic patent has been declare null or canceled so that the product which has been granted the certificate is no longer protected by the basic patent, or if, after the expiration of the basic patent, grounds for revocation exist which would have justified the revocation or the limitation.

Where the basic patent has been declared null or the patent holder gave up or was revoked, a patent application for revocation has no legal basis and it is rejected.

It should be noted that a Commission review of the Department Appeals - Strategy of the State Office for Inventions and Trademarks decide the appeals against the decisions of the Examination Commission and Certificate Revocation requests.

9. Fees

According G.O. No. 41/2015 amending and supplementing G.O. No. 57/2002 on scientific research and technological development, Annex 1, item 24, the fee is 2,206 RON (€ 500) for registering and examining the application for a supplementary protection certificate for medicinal or plant protection product. The fee must be paid with the request. If fees are not paid, the application is considered withdrawn.

For maintenance in force of the supplementary protection certificate, the fees, for every year of protection are: 1st year (RON 4,411 - € 1,000); 2nd year (RON 4,853- € 1,100); 3rd year (RON 5,294 - € 1,200); 4th year (RON 5,735 - € 1,300) and 5th year (RON 6,176 - € 1,400). The fee for maintenance in force shall be paid until the first day of the respective year of protection. A final protection period less than 12 months will be considered for full year payment of taxes (Ionescu, 2007: 136). The requests for certificates in respect of which the State Office for Inventions and Trademarks has not acted up to the expiry of the basic patent, the maintenance fee is paid with the publication of the decision of granting the certificate.

For the 6 month extension of the duration of the supplementary protection certificate for medicinal products, the fee will be assimilated with the five year fee for maintenance in force of the supplementary protection certificate.

10. Supplementary protection certificates granted and issued by the State Office for Inventions and Trademarks in 2015, arranged by name holder

	The holder of the supplementary protection certificate	**The publication number**
1.	ASTRAZENECA AB, SE-151 85, 151 85 SODERTALJE	c 2013 012 I2
2.	BAYER CROPSCIENCE AG, ALFRED-NOBEL-STRASSE 50, D-40789 MONHEIM, DE	c 2013 037 I2

3.	FAES FARMA S.A., MAXIMO AGUIRRE 14, 48940-LEIOA, ES	c 2012 006 I2
4.	ASTRAZENECA AB, SE-15185, SODERTALJE, SE	c 2012 023 I2
5.	BAYER CROPSCIENCE AG, ALFRED-NOBEL-STRASSE 50, D-40789	c 2008 022 I2
6.	BAYER CROPSCIENCE S.A., 16 RUE JEAN MARIE LECLAIR, LYION, FR	c 2008 014 I2
7.	BRISTOL-MYERS SQUIBB COMPANY, NJ 08543-4000, PRINCETON, U.S.	c 2011 015 I2
8.	IPSEN PHARMA S.A.S., 65 QUAI GEORGE GORSE F-92100, F-92100 BOULOGNE – BILLANCOURT, FR	c 2013 026 I2
9.	NOVO NORDISK A/S, NOVO ALLE DK-2880, BAGSVAERD, DK	c 2013 019 I2
10.	NOVO NORDISK A/S, NOVO ALLE DK-2880, BAGSVAERD, DK	c 2013 022 I2
11.	PFIZER INC, 235 EAST 42ND STREET, NEW YORK, 10017 NEW YORK, U.S.	c 2013 011 I2
12.	AGOURON PHARMACEUTICALS, INC., 10646 SCIENCE CENTER DRIVE, 92121, SAN DIEGO, CA, U.S.	c 2013006 I2
13.	ASTELLAS PHARMA INC., 3-11 NIHONBASCHI-HONCHO 2-CHOME, CHUO-KU, TOKYO 103-8411, 103-8411 TOKIO, JP	c 2013 020 I2
14.	BAYER CROPSCIENCE AG, ALFRED-NOBEL-STRASSE 50, D-40789 MONHEIM, DE	c 2013 018 I2
15.	BEOHRINGER INGELHEIM VETMEDICA GMBH, INGELHEIM AM RHEIN, D-55218 INGELHEIM AM RHEIN, DE	c 2013 027 I2
16.	SUGEN INC., 235 EAST 42ND STREET, NY 10017 NEW YORK,US; PHARMACIA & UPJOHN COMPANY LLC, 7000	c 2010 003 I2

	PORTAGE ROAD, MI 49001 KALAMAZOO, U.S.	
17.	ADVERIO PHARMA GMBH, WILLY-BRANDT-PLATZ 2, 12529	c 2014 026 I2
18.	BOEHRINGER INGELHEIM VETMEDICA GMBH, INGELHEIM AM RHEIN, D-552 18 INGELHEIM AM RHEIN, DE	c 2013 030 I2
19.	GENENTECH, INC., 1 DNA WAY, SOUTH SAN FRANCISCO, CO 94080-4990, U.S.; CURIS, INC., 4 MAGUIRE ROAD, LEXINGTON, MA 02421, U.S.	c 2013 038 I2
20.	MERCK FROSST CANADA LTD., TRANS-CANADA HIGHWAY, KIRKLAND, QUEBEC H9H 3L1, CA	c 2009 003 I2

11. Supplementary protection certificates for which the State Office for Inventions and Trademarks granted extension of the duration for 2015

The number of supplementary protection certificate	Number and date of application for extension	Date by which expanded the duration
c 2007 045	1017640 from 28.06.2013	12.03.2016
c 2007 068	1002281 from 27.01.2014	28.07.2016

References

1. Bodoaşcă, T. & Tarnu, L. I. (2015). *Dreptul proprietăţii intelectuale [Intellectual property law].* Bucharest: U.J. Publishing House.
2. Bodoaşcă, T. (2007). *Dreptul proprietăţii intelectuale[Intellectual property law].* Bucharest: C.H.Beck Publishing House.

3. Cocoș, Ș. (1999). *Protecția și valorificarea proprietății industriale* [*Protection and enhancement of industrial property].* Bucharest: Economic Tribune Publishing House.
4. Cocoș, Ș. (2004). *A-B-C-ul protecției și valorificării proprietății industriale* [*A-B-C the protection and enhancement of industrial property].* Bucharest: Rosetti Publishing House.
5. Constantin, I. (1993). *Brevetarea invențiilor în străinătate* [*Patenting inventions abroad].* Bucharest: All Publishing House.
6. Dănilă, L. (2008). *Dreptul de autor și dreptul de proprietate industrială* [*Copyright and industrial property rights].* Bucharest: C.H.Beck Publishing House.
7. Ionescu, B. (2007). Extinderea duratei brevetului de invenție. Certificatul suplimentar de protecție pentru medicamente și produse de protecție a plantelor [Extending the patent. Supplementary protection certificate for medicinal and plant protection products]. *Revista Română de Dreptul Proprietății Intelectuale* [*Romanian Journal of Intellectual Property Law].* 3, 113-137.
8. Ionescu, B. (2013). Durata brevetului de invenție. Premisele creării certificatului suplimentar de protecție [The duration of the patent. Premises for creating a supplementary protection certificate]. *Revista Română de Dreptul Proprietății Intelectuale* [*Romanian Journal of Intellectual Property Law].* 2, 153-171.
9. Ionică, F. (2014). *Farmacologie generală* [*General pharmacology].* Craiova: Sitech Publishing House.
10. Macovei, I. (2010). *Tratat de drept al proprietății intelectuale [Intellectual property law treaty].* Bucharest: C.H.Beck Publishing House.
11. Olteanu, G. (2008). *Dreptul proprietății intelectuale* [*Intellectual property law].* Bucharest: C.H. Beck Publishing House.
12. Roș, V. (2001). *Dreptul proprietății intelectuale* [*Intellectual property law].* Bucharest: C.H. Beck Publishing House.
13. Roș, V. (2015). Protecția invențiilor din domeniul farmaceutic. Brevetul de invenție, autorizația de introducere pe piață și certificatul suplimentar de protecție. [Protection of inventions in

the pharmaceutical field. The patent marketing authorization and supplementary protection certificate]. *Revista Română de Dreptul Proprietății Intelectuale [Romanian Journal of Intellectual Property Law]*. 2, 7-49.

14. Ștrenc, C., Ionescu, B. & Gheorghiu, Ghe. (2005). *Dreptul brevetului* [*The patent law]*. Bucharest: Lumina Lex Publishing House.