WORLD JOURNAL OF PHARMACY AND PHARMACEUTICAL SCIENCES
SJIF Impact Factor 7.421
Volume 7, Issue 5, 1-11 Research Article ISSN 2278 – 4357

COMPARATIVE ANALYSIS BETWEEN BULGARIAN AND EUROPEAN PATENT LEGISLATION IN REGARD TO MEDICINAL PRODUCTS

Nadezhda I. Marchokova[1], Valentina B. Petkova[1]*, Milen V. Dimitrov[2]

[1]Department of Social Pharmacy, Faculty of Pharmacy, Medical University-Sofia, Sofia, Bulgaria.

[2]Department of Pharmaceutical Technology, Faculty of Pharmacy, Medical University-Sofia, Sofia, Bulgaria.

Article Received on
01 March 2018,

Revised on 22 March 2018,
Accepted on 11 April 2018

DOI: 10.20959/wjpps20185-11557

***Corresponding Author**
Valentina B. Petkova
Department of Social Pharmacy, Faculty of Pharmacy, Medical University-Sofia, Sofia, Bulgaria.

ABSTRACT

Background: The aim of the study is to compare Bulgarian and European patent legislation in regard to medicinal products and to determine if Bulgarian legislation was harmonized with the EU. **Methods:** Documentary analysis was carried out. Use was made of the database of European Patent Office, Patent Office of the Republic of Bulgaria and eur-lex. The documents found were subjected to comparative analysis. **Results:** The Law on Patents and Utility Model Registration, as compared against the European Patent Convention in respect to the analyzed items, patentable inventions, exceptions to patentability, term of a patent and requirements of a patent application, has been harmonized. The Bulgarian Ordinance on the filing of applications and issuing of supplementary protection certificates for medicinal products and plant protection products has been harmonized to a certain degree with the European legislation with respect to definitions, conditions for obtaining a certificate, applying for a certificate, filing of an application for a certificate and term of the certificate. The specific cases in the Ordinance on extending the duration of a supplementary protection certificate were not analyzed. **Conclusion:** The Bulgarian Ordinance on the filing of applications and issuing of supplementary protection certificates for medicinal products and plant protection products has been harmonized with Council Regulation (EEC) № 1768/92, but was not updated in terms of Regulation (EC) № 469/2009 concerning the supplementary protection certificate for medicinal products.

KEYWORDS: Patent, Supplementary protection certificate, Medicinal Product, Comparative analysis.

INTRODUCTION

A patent is a document granted by a government or a regional office on the basis of a submitted application. It describes an invention and creates legal conditions in which the invention could be exploited with the approval of the patent owner only.[1]

Patents are of great importance for pharmaceutical industry because they facilitate the continuation of the process of innovation due to the fact that developing and launching a new drug on the market is a long, expensive and risky process.[2]

Patents which an innovator could receive for a "pioneer drug" in pharmaceutical industry are for an active substance or compound in a drug, for the manufacturing process of a drug, for a specific application of a drug and for drug composition, which includes the active substance and the excipients used.[3] Patent owners make use of two main strategies to enhance the protection of a patent. The first strategy aims at widening the patent portfolio (preparation of broad claims and use of divisional applications) and the second one refers to subsequent patenting.[4] The approach of additional patent protection, known as "life-cycle management", is also analyzed by Whitehead et al., who present examples for this strategy - the use of new crystal forms of existing drugs, new salts, esters and other derivatives, single enantiomers of existing drugs, new formulations of existing drugs, new preparation methods for existing drugs, combinations of existing drugs and metabolic products of existing drugs.[5] The supplementary protection certificates (SPCs) ensure continuation of the protection of a medicinal product. An SPC acts from the end of the legal duration of the basic patent over a period equal to the period from filing date of the application for the basic patent through the date of the first marketing authorization in the Community, reduced by a period of five years and its term may not exceed five years.[6] As regards medicinal products for paediatric use the duration of an SPC could be prolonged with a period of six months if all measures included in the adopted investigation plan are observed, if the product is approved in all Member States and if the product information contains results from the conducted investigations.[7]

The aim of the present study is to compare Bulgarian and European patent legislation concerning medicinal products and to determine whether Bulgarian legislation is harmonized with that of EU.

MATERIALS AND METHODS

Documentary analysis was performed of 6 documents representing one convention, three regulations, one law and one ordinance. The examined literary sources were selected by applying the keywords "Patent", "Supplementary protection certificate", "Medicinal product". Databases of the European Patent Office, Patent Office of the Republic of Bulgaria and eur-lex were used. The following documents were analyzed:

1. Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973 as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000;
2. Council Regulation (EEC) № 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products;
3. Regulation (EC) № 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products;
4. Regulation (EC) № 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) № 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) № 726/2004;
5. Law on Patents and Utility Model Registration (SG № 64/2006; in force as from 09.11.2006);
6. Ordinance on the filing of applications and issuing of supplementary protection certificates for medicinal products and plant protection products (adopted by Council of Ministers Decree № 36/19.02.2007, promulgated in SG № 19/02.03.2007; in force as from 01.01.2007);
7. By relying on the documents mentioned above comparative analysis was carried out between the Bulgarian and European legislation focused on the patenting of medicinal products.

RESULTS AND DISCUSSION

Comparative analysis between the European Patent Convention and the Law on Patents and Utility Model Registration

The comparative analysis was carried out in respect to the following relevant problems in both documents: patentable inventions, exceptions to patentability, term of a patent and requirements of a patent application.

Table 1: Comparative analysis between the European Patent Convention and the Law on patents and Utility Model Registration.

European Patent Convention	Law on patents and Utility Model Registration
Patentable inventions	
1. "European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application. 2. The following in particular shall not be regarded as inventions within the meaning of paragraph 1: discoveries, scientific theories and mathematical methods; aesthetic creations; schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; presentations of information;"[8]	1. " Patents shall be granted for inventions in any field of technology, which are new, involve an inventive step and are susceptible of industrial application. 2. The following shall not be regarded as inventions: discoveries, scientific theories and mathematical methods; artistic work results; schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; presentation of information;"[9]
Exceptions to patentability	
1. "Inventions the commercial exploitation of which would be contrary to "order public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States; 2. Plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof; 3. Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods."[10]	1. "Inventions the commercial use of which would be contrary to social order or morality, including methods of cloning human beings; methods of altering the genetic identity of human embryo; use of human embryos for industrial or commercial purposes; methods of modifying the genetic identity of animals, where this may cause them suffering without any substantial use from a medical point of view for humans or animals, as well as of animals obtained by such methods; 2. Methods for treatment of the human or animal body by therapy or surgery, as well as diagnostic methods practiced on the human or animal body. This shall not apply to products, in particular substances or compositions, for use in any of these methods; 3. Plant or animal varieties; 4. Essentially biological processes for obtaining plants and animals; The use referred to in 1. shall not be deemed to be so contrary merely because it is prohibited by legislation."[11]
Term of the patent	
"The term of the European patent shall be 20 years from the date of filing of the application."[12]	"The term of validity of a patent shall be 20 years from the date of filing of the application."[13]
Requirements / Contents of a patent application	
1. "A European patent application shall	1. "A request for the grant of a patent

contain: a. a request for the grant of a European patent; b. a description of the invention; c. one or more claims; d. any drawings referred to in the description or the claims; e. an abstract; 2. A European patent application shall be subject to the payment of the filing fee and the search fee. If the filing fee or the search fee is not paid in due time, the application shall be deemed to be withdrawn."[14]	containing the title of the invention and the data identifying the applicant, in the Bulgarian language; 2. A description of the invention, disclosing at least its essential elements;"[15] 3. "One or more claims; 4. Drawings, if needed to understand the invention; 5. An abstract; 6. A written statement and a priority certificate, where priority is claimed; The application shall be accompanied by a document certifying payment of the fees for filing, formal requirements examination, preliminary examination and admissibility, patent claims and priority claims."[16]

It was found that the Law on Patents and Utility Model Registration has been harmonized with the European Patent Convention in relation to the analyzed items.

Comparative analysis between Regulation (EC) № 469/2009 concerning the supplementary protection certificate for medicinal products and Ordinance on the filing of applications and issuing of supplementary protection certificates for medicinal products and plant protection products

Council Regulation (EEC) № 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products was repealed and replaced by Regulation (EC) № 469/2009. Regulation (EC) № 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use made provision for extending the term of SPCs. Regulation 469/2009 encompassed the cases for extension of the duration of SPC.

The comparative analysis between Regulation (EC) № 469/2009 and Bulgarian Ordinance was conducted with regard to the following problems dealt with in both documents: definitions, conditions for obtaining a certificate, applying for a certificate, filing of an application for a certificate and term of a certificate.

Table 2: Comparative analysis between Regulation (EC) № 469/2009 and Ordinance on the filing of applications and issuing of supplementary protection certificates for medicinal products and plant protection products.

Regulation (EC) № 469/2009	**Ordinance on the filing of applications and issuing of supplementary protection certificates for medicinal products and plant protection products**
I. Definitions	
"Medicinal product means 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; Product means the active ingredient or combination of active ingredients of a medicinal product; Basic patent means a patent which protects a product as such, 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; Certificate means the supplementary protection certificate; Application for an extension of the duration means an application for an extension of the duration of the certificate;"[17]	Medicinal product means a product within the meaning of Art.1, p. "a" of Regulation №1768/92; Product means a product within the meaning of Art.1, p. "b" of Regulation №1768/92; Basic patent means a patent within the meaning of Art.1, p. "c" of Regulation №1768/92; Date of marketing authorization is the date on which the authorization is issued for placing the product on the market;[18]
II. Conditions for obtaining a certificate	
1."The product is protected by a basic patent in force; 2. A valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate; 3.The product has not already been the subject of a certificate; 4.The authorisation referred to in point 2 is the first authorisation to place the product on the market as a medicinal product". [19]	The application for a certificate shall contain: 1. The first authorisation to place the product on the Community market; 2. Authorisation to place the product on the market in the Republic of Bulgaria over the period from 01.01.2000 to 01.01.2007; 3. Confirmation that there is a valid authorisation to place the product on the market in the Republic of Bulgaria as on the date of filing the application;[20] 4. The product is covered by the basic patent;[21]
III. Application for a certificate	
1. "The application for a certificate shall be lodged within six months of the date on which the	1. The application for a supplementary protection certificate shall be filed in the

authorisation to place the product on the market as a medicinal product was granted; 2. Notwithstanding paragraph 1, where the authorisation to place the product on the market is granted before the basic patent is granted, the application for a certificate shall be lodged within six months of the date on which the patent is granted; 3. The application for an extension of the duration may be made when lodging the application for a certificate or when the application for the certificate is pending and the appropriate requirements are fulfilled; 4. The application for an extension of the duration of a certificate already granted shall be lodged not later than two years before the expiry of the certificate; 5. Notwithstanding paragraph 4, for five years following the entry into force of Regulation (EC) №1901/2006, the application for an extension of the duration of a certificate already granted shall be lodged not later than six months before the expiry of the certificate;"[22]	Patent Office within the time limit specified in Article 7 of the Regulation, either by post or by a communication tool, which transmits facsimile or electronic copy. 2. The application submission date is the date on which the documents specified in Article 8, paragraph 1 of the Regulation are received at the Patent Office. 3. When the application is submitted by means of communication tool the applicant shall submit, within one month, the original application and the documents mentioned in 2; 4. When the documents are in a foreign language the Patent Office may request the documents to be translated into Bulgarian. The translation shall be filed within three months upon receipt of the notification.[23]
IV. Filing of an application for a certificate	
"The application for a certificate shall be lodged with the competent industrial property office of the member State which granted the basic patent or on whose behalf it was granted and in which the authorisation to place the product on the market was obtained, unless the Member State designates another authority for the purpose. The application for an extension of the duration of a certificate shall be lodged with the competent authority of the Member State concerned.[24]	The application for a supplementary protection certificate shall be filed in the Patent Office;[25]
V. Term of the certificate	
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 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) 1901/2006 applies. In that case, the duration of the period laid down in paragraph 1 may be extended only once.	The term of the certificate is defined in accordance with Article 13 of Regulation №1768/92;[27]

4.Where a certificate is granted for a product protected by a patent which, before 2 January 1993, had its term extended or for which such extension was applied for, under national law, the term of protection to be afforded under this certificate shall be reduced by the number of years by which the term of the patent exceeds 20 years."[26]	

It was established on the basis of the comparison thus made that the Bulgarian Ordinance has been harmonized with Council Regulation № 1768/92, yet it was not updated in terms of Regulation (EC) № 469/2009. In relation to the items under consideration the following conclusions were drawn:

- **Definitions**: Definitions were given for medicinal product, product and basic patent in both documents and they are identical. Provided in Regulation (EC) № 469/2009 were also definitions for certificate and application for extension of the duration, while these additional definitions were not included in the Ordinance. A definition for marketing authorization date was formulated in the Ordinance as well;
- **Conditions for obtaining a certificate:** The conditions have been totally harmonized in both documents.
- **Application for a certificate and filing an application for a certificate:** The points which concern the extension of the duration of a certificate were not analyzed in the Ordinance;
- **Term of the Certificate:** Harmonization was observed in regard to term of the certificate. Due to the fact that the Ordinance was harmonized with Council Regulation № 1768/92 and not with the updated Regulation (EC) № 469/2009 the case which concerned Article 36 of Regulation (EC) 1901/2006 was not analyzed;

CONCLUSIONS

- As a result of the comparison made between the European Patent Convention and the Law on Patents and Utility Model Registration with regard to the analyzed items, a conclusion can be drawn that the Bulgarian legislation has been harmonized with European law.

- The Ordinance on the filing of applications and issuing of supplementary protection certificates for medicinal products and plant protection products has been harmonized with Council Regulation № 1768/92 concerning the creation of a supplementary

protection certificate for medicinal products, but was not updated relative to the currently effective Regulation (EC) № 469/2009.

REFERENCES

1. World Intellectual Property Organization. Fields of Intellectual Property Protection, chapter 2. In: WIPO Intellectual Property Handbook: Policy, Law and Use. 2nd ed.; WIPO Publication: 2004; 17.
2. Aktinson JDM, Jones R. (Intellectual property and its role in the pharmaceutical industry). Future Med. Chem., 2009; 1(9): 1547-50.
3. Helm KA. (The battle over global drug markets: enforcement of pharmaceutical patents in the United States, Europe and Japan). Journal of Intellectual Property Law & Practice, 2009; 4(1): 39-50.
4. Minn M. (Strategic patenting decisions in the European pharmaceutical industry: the use of divisional applications and follow-on patenting practices). Journal of Intellectual Property Law & Practice, 2016; 11(8): 619-27.
5. Whitehead B, Jackson S, Kempner R. (Managing generic competition and patent strategies in the pharmaceutical industry). Journal of Intellectual Property Law & Practice, 2008; 3(4): 226-35.
6. Regulation (EC) № 469/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009; Art. 13(1)(2); 5.
7. REGULATION (EC) № 1901/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 December 2006 on medical products for paediatric use and amending Regulation (EEC) № 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) № 726/2004, OJ L 378, 27.12.2006; 4.
8. European Patent Convention, Part II Substantive Patent Law, Chapter I Patentabilty, Art. 52(1)(2), 16th ed.; European Patent Office: 2016; 108.
9. Law on Patents and Utility Model Registration, Chapter II Patentability of Inventions, Patentable Inventions, Art.6(1)(2).
10. European Patent Convention, Part II Substantive Patent Law, Chapter I Patentabilty, Art. 53, 16th ed.; European Patent Office: 2016; 110.
11. Law on Patents and Utility Model Registration, Chapter II Patentability of Inventions, Exceptions to Patentability, Art.7.

12. European Patent Convention, Part II Substantive Patent Law, Chapter III Effects of the European patent and the European patent application, Art. 63 (1), 16th ed.; European Patent Office: 2016; 120.
13. Law on Patents and Utility Model Registration, Chapter III Patents, Term of Patent, Art. 16.
14. European Patent Convention, Part III The European Patent Application, Chapter I Filing and requirements of the European patent application, Art. 78, 16th ed.; European Patent Office: 2016; 140.
15. Law on Patents and Utility Model Registration, Chapter IV Proceedings Before the Patent Office, Filing of Patent Application, Art. 34(2).
16. Law on Patents and Utility Model Registration, Chapter IV Proceedings Before the Patent Office, Filing of Patent Application, Art. 35(1)(2).
17. OJ L 152, 16.6.2009; Art. 1; 2.
18. Ordinance on the filing of applications and issuing of supplementary protection certificates for medicinal products and plant protection products (adopted by Council of Ministers Decree № 36/19.02.2007, promulgated in SG № 19/02.03.2007; in force as from 01.01.2007), Additional Provision §1(1)(2)(3)(5); 3.
19. OJ L 152, 16.6.2009; Art. 3; 2.
20. Ordinance on the filing of applications and issuing of supplementary protection certificates for medicinal products and plant protection products (adopted by Council of Ministers Decree № 36/19.02.2007, promulgated in SG № 19/02.03.2007; in force as from 01.01.2007), Transitional and Final Provisions §2(2): 4.
21. Ordinance on the filing of applications and issuing of supplementary protection certificates for medicinal products and plant protection products (adopted by Council of Ministers Decree № 36/19.02.2007, promulgated in SG № 19/02.03.2007; in force as from 01.01.2007), Chapter III, Art. 6(2); 2.
22. OJ L 152, 16.6.2009; Art. 7; 3.
23. Ordinance on the filing of applications and issuing of supplementary protection certificates for medicinal products and plant protection products (adopted by Council of Ministers Decree № 36/19.02.2007, promulgated in SG № 19/02.03.2007; in force as from 01.01.2007), Chapter II, Art. 2(1)(2)(3)(4); 1.
24. OJ L 152, 16.6.2009; Art. 9(1); 4.
25. Ordinance on the filing of applications and issuing of supplementary protection certificates for medicinal products and plant protection products (adopted by Council of

Ministers Decree № 36/19.02.2007, promulgated in SG № 19/02.03.2007; in force as from 01.01.2007), Chapter II, Art. 2(1); 1.

26. OJ L 152, 16.6.2009; Art. 13; 5..
27. Ordinance on the filing of applications and issuing of supplementary protection certificates for medicinal products and plant protection products (adopted by Council of Ministers Decree № 36/19.02.2007, promulgated in SG № 19/02.03.2007; in force as from 01.01.2007), Chapter III, Art. 6(8); 2.