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GLOBAL CHALLENGES IN THE PROCESS FROM INNOVATION TO PHARMACEUTICAL PRODUCT: INTELLECTUAL PROPERTY BALANCING MARKET INTERESTS AND PUBLIC HEALTH

Abstract:

The legal framework of intellectual property in the pharmaceutical sector encompasses multiple forms of protection that enable right holders to maintain exclusivity and market dominance. Patent protection and the Supplementary Protection Certificate (SPC) are the most prominent mechanisms for extending commercial control over innovative medicines. In addition to these tools, other forms of protection play a relevant role, including trademarks, industrial design, and copyright related to documentation and software solutions.

This paper offers a descriptive analysis of these instruments and their function within the pharmaceutical market, with the aim of examining the legal rationale, effect, and interrelationship of various forms of protection. Special emphasis is placed on the parallel between patent protection and the SPC, which frequently operates as a mechanism for postponing the market entry of competing products.

The central research question posed is whether the current system of legal protection contributes to the realization of the right to health by encouraging innovation, or whether it primarily serves the interests of pharmaceutical companies by restricting access to essential therapies. Through legal analysis of the function, scope, and implications of intellectual property protection in the pharmaceutical context, the paper seeks to enhance understanding of the interplay between private rights and public interest in the field of health law.

Key words: *intellectual property, patent, supplementary protection certificate, pharmaceutical industry, public health*

1. INTRODUCTION: THE INTEGRAL ROLE OF INTELLECTUAL PROPERTY IN THE PHARMACEUTICAL INDUSTRY

Intellectual property represents a key element in the pharmaceutical industry, as it enables the protection of innovations, fosters research and development (R&D), and ensures a balance between market interests and public health. In this context, it is particularly important to emphasize that the role of intellectual property is not limited solely to patent protection but encompasses a wide range of rights—patents, supplementary protection

certificates (SPCs), trademarks, industrial designs, copyrights, and trade secrets—which collectively function to safeguard competitive advantage and encourage innovation.

Pharmaceutical companies face extremely high costs and lengthy timelines in the development of new medicines, which involve complex clinical trials and strict regulatory procedures. Under such conditions, the legal instruments of intellectual property provide protection for research results and guarantee economic incentives for further investment. At the same time, they ensure patient safety through the regulation of pharmaceutical product quality and strengthen trust in the healthcare system. Nevertheless, numerous controversies arise regarding the effects of these rights: while some argue that they contribute to scientific progress and enable the introduction of new therapies, others warn that excessive and prolonged protection may limit access to medicines and thereby endanger the realization of the right to health.

Large multinational companies dominate the global market with pharmaceutical raw materials and finished products—medicines. They have secured strong patent protection in this sector and ensure compliance with legal regulations and the enforcement of intellectual property rights.[1] The purpose of this paper is to examine, through legal analysis, the function and scope of various forms of intellectual property in the pharmaceutical industry, with particular attention to the relationship between patents and supplementary protection certificates. The central research question is: do existing intellectual property mechanisms genuinely foster innovation and serve the public interest in healthcare, or do they primarily cater to the economic interests of pharmaceutical companies?

2. OVERVIEW OF INTELLECTUAL PROPERTY RIGHTS

2.1 Copyright and Related Rights

Copyright and related rights constitute an important segment of the intellectual property system and play a specific role in the pharmaceutical industry. Although the pharmaceutical sector is primarily associated with patents and other forms of industrial property, copyright emerges as a key mechanism for the protection of educational, scientific research, and marketing materials, given that a copyrighted work is regarded as an original intellectual creation[2] and is therefore in undeniable correlation with the field of pharmacy.

In the pharmaceutical context, copyright protection covers a wide range of works—from scientific monographs, manuals, and promotional brochures to multimedia educational courses and digital applications intended for physicians, pharmacists, and patients (e.g., **Medscape**, **Epocrates**). These works often contain complex scientific and professional information whose accuracy and quality have a direct impact on medical practice and patient safety. Copyright grants the holders control over the use and distribution of such materials, thereby protecting the intellectual contribution of the authors and providing incentives for the continuous creation of high-quality and innovative resources. From a legal perspective, protection is based on the Law on Copyright and Related

1 Radosavljević, L., & Jovanović, S. (2000). Intellectual Property in the Field of Pharmaceutical Products. Procesna Tehnika, 2000(1-2), 45–50

2 Law on Copyright and Related Rights, "Official Gazette of the Republic of Serbia", Nos. 104/2009, 99/2011, 119/2012, 29/2016 – Constitutional Court decision, and 66/2019.

Rights of the Republic of Serbia, while the international framework consists of the Berne Convention,[3] the WIPO Copyright Treaty[4], and the TRIPS Agreement (WTO). In this way, harmonization and international protection of copyrighted works used and distributed in the digital environment are ensured

2.2 Industrial property rights

Industrial property rights represent the fundamental pillar of innovation protection in the pharmaceutical industry. They encompass patents, trademarks, industrial designs, as well as other specific institutes.

Patents are the most significant form of innovation protection in pharmacy. They relate to new chemical substances, pharmaceutical formulations, dosage forms, methods of administration, as well as manufacturing processes. The patent system provides the patent holder with the exclusive right to exploit the invention for a period of 20 years, thereby ensuring the recovery of substantial investments in research and development. However, the specificity of the pharmaceutical sector lies in the lengthy nature of clinical trials and regulatory procedures, which is why the legal system of the European Union introduced the Supplementary Protection Certificate (SPC) as a special instrument for the extension of protection. In the Republic of Serbia, this matter is regulated by the Patent Law[5], which is harmonized with EU law and TRIPS standards. If patents are not adequately protected, various forms of infringement may occur, including counterfeiting, unauthorized copying, and placing products on the market. For this reason, pharmaceutical companies seek to extend the protection of their innovations. While such measures may be justified from the perspective of companies and inventors, legislators must simultaneously take into account the interests of society and public health[6].

Trademarks enable the differentiation of products and services in the market and play a multifaceted role in the pharmaceutical sector. They protect not only the name of the medicine (e.g., Aspirin), but also the visual elements of packaging, colors, shapes, or sound marks. In this way, they build trust among patients and healthcare professionals while also preventing confusion in the marketplace. A particular significance of trademarks in pharmacy lies in the fact that they often remain in force even after the expiry of patent protection, thereby extending the market value of the brand, considering that the duration of a trademark is ten years with the possibility of indefinite renewal.[7]

Industrial design provides legal protection for the external appearance of an industrial product. In the pharmaceutical sector, this includes the design of medical devices and aids (such as inhalers, applicators, and injectors), as well as packaging. The aesthetics of

3 Law on the Ratification of the Berne Convention for the Protection of Literary and Artistic Works, "Official Gazette of the SFRY", No. 14/75 and "Official Gazette of the SFRY – International Treaties", No. 4/86 – regulation.

4 Law on the Confirmation of the WIPO Copyright Treaty, "Official Gazette of the FRY – International Treaties", No. 13/2002.

5 Law on Patents, "Official Gazette of the Republic of Serbia", Nos. 83/2015, 113/2017 – authentic text.

6 Killick, J., Schultz, A., & Dawes, A. (2008). The Stockholm Network Experts' Series on Pharmaceutical Intellectual Property Rights: The special regime of intellectual property for the pharmaceutical industry (pp. 3–5). Stockholm: Stockholm Network.

7 Lasić, I. (2010). Pharmaceutical Patents: General Characteristics and Current Issues in an International Law Context. Pravni Zapisi, V(1), 176–196.

a product has a direct impact on its functionality and accessibility for patients, and through design protection, manufacturers also secure differentiation in the market.[8]

Although less frequently applied in the pharmaceutical industry, the legal framework also provides for the protection of geographical indications and plant varieties. These may be relevant in the case of natural substances originating from specific regions, as well as in the development of medicinal plants used as raw materials. In this way, the pharmaceutical sector remains connected with both agricultural and biotechnological fields.

2.3 Trade Secrets (Know-How)

Trade secrets, or know-how, represent an indispensable form of protection in the pharmaceutical industry. Unlike patents, which require the disclosure of an invention, trade secrets allow the retention of key information under a confidential regime by the holder, who may be either a natural or a legal person[9]. In practice, this relates to specific formulations, manufacturing processes, laboratory protocols, or research data that are not publicly available.

The protection of trade secrets is based on the Law on the Protection of Trade Secrets of the Republic of Serbia, and at the international level on the standards of the TRIPS Agreement. The particular importance of trade secrets in the pharmaceutical field lies in the fact that they are often combined with patent protection—while certain segments of an innovation are patented, others remain protected as trade secrets, thereby providing an additional layer of competitive advantage. Unauthorized disclosure or use of trade secrets may have serious consequences, both economic and legal, including potential criminal liability.

3. PATENT PROTECTION IN THE PHARMACEUTICAL INDUSTRY

Patent protection represents a key legal instrument in the pharmaceutical industry, granting holders of innovations exclusive rights to the use and commercialization of their inventions. The purpose of a patent is to provide recognition and legal protection for innovative solutions, thereby encouraging investment in research and development. The essential characteristics of a patent include novelty, inventiveness, and industrial applicability. An invention is patentable only if it is clearly distinguishable from previously known solutions, contains inventive elements, and can be applied in industrial production.

3.1 Specificities of Pharmaceutical Patents

In the context of the pharmaceutical industry, patents are generally divided into three main categories[10]: Product patents – protect the pharmaceutical product itself, i.e.,

8 Law on Legal Protection of Industrial Design, "Official Gazette of the Republic of Serbia", Nos. 104/2009, 45/2015, and 44/2018 – other law.

9 Law on the Protection of Trade Secrets, "Official Gazette of the Republic of Serbia", No. 53/2021

10 Correa, C. M. (ed.), 2008, A Guide to Pharmaceutical Patents, Vol. I, p. 4; Correa, C. M., 2004,

the active substance or the medicine;Process patents – protect the technical methods and processes used in the production of the medicine;Second medical use patents (new indications) – protect the specific application of an already known substance for the treatment of new diseases or conditions.

These patents provide companies with legal exclusivity regarding formulations, manufacturing processes, and therapeutic indications, thereby ensuring market advantage and fostering further innovation.

3.2 Duration of Patent Protection

In accordance with the applicable legislation, a basic patent lasts for 20 years[11] from the date of filing. During the patent term, the holder has the exclusive right to manufacture, use, and sell the protected medicine, which enables the recovery of R&D investments and serves as an incentive for continued innovation.

3.3 Strategies for Extending Protection

Pharmaceutical companies often employ legally permissible strategies to extend the market exclusivity of their innovative products, taking into account the legal and regulatory frameworks governing intellectual property in the pharmaceutical sector. These strategies are of crucial importance for safeguarding investments in research and development, as well as for maintaining competitive advantage in the medicines market. The most common strategies include secondary patents, new dosage forms, or the use of Supplementary Protection Certificates (SPCs).[12]

Secondary patents refer to additional patents that may be granted for new forms of already patented medicines, including different crystalline forms, salts, esters, or new pharmacological indications. Although these patents do not concern the basic invention itself, they allow pharmaceutical companies to obtain legal protection for incremental innovations that enhance the efficacy, stability, or safety of a medicine. It is important to note that such patents must meet the standards of novelty, inventiveness, and industrial applicability in order to be valid under national and international patent law.[13]

Changes in pharmaceutical dosage form,[14] such as transforming tablets into capsules, applying transdermal patches, or developing inhalers, represent a strategy that can not only improve the bioavailability and pharmacokinetic properties of a medicine but also secure legal protection through new patents. These innovations are often combined with secondary patents to maximize the extension of a product's market exclusivity.

Ownership of knowledge – the role of patents in pharmaceutical R&D, Bulletin of the WHO, 82:784–790, p. 785

11 Law on Patents, "Official Gazette of the Republic of Serbia", Nos. 83/2015, 113/2017 – authentic text.

12 Council Regulation (EEC) No. 1768/92 of 18 June 1992 on the Creation of a Supplementary Protection Certificate for Medicinal Products, Official Journal L 182, 02/07/1992, p. 1–5.

13 Trips

14 Killick, J., Schultz, A., Dawes, A., 2008, The Stockholm Network Experts' Series on Pharmaceutical Intellectual Property Rights: The special regime of intellectual property for the pharmaceutical industry, Stockholm Network, pp. 3–5.

The Supplementary Protection Certificate (SPC) is a legal instrument provided under European law[15] that allows for the extension of a medicine's exclusive protection after the expiration of the basic patent. SPCs are granted to compensate for time delays arising during the regulatory approval process of a medicine and can extend protection for up to five years. An example of this mechanism is the medicine Nexium by AstraZeneca, where an SPC enabled additional market exclusivity following the expiration of the basic patent. The Supplementary Protection Certificate (SPC) represents a specific legal instrument within intellectual property law, developed primarily for the pharmaceutical industry, which allows for the extension of a medicine's exclusivity after the expiration of the basic patent, compensating for the period lost during clinical trials and regulatory approval (Killick, Schultz, Dawes, 2008, p. 5). The legal basis for SPCs in the European Union is Council Regulation (EC) No. 1768/92 of 18 June 1992, which introduced the possibility of issuing SPCs for medicinal products and pharmaceutical drugs.

An SPC has the same effect as a patent but does not extend the original patent term itself; rather, it constitutes a sui generis instrument with a limited extension effect, the maximum duration of which cannot exceed five years, starting from the expiry of the basic patent (Council Regulation 1768/92, Article 13). The function of the SPC is to enable pharmaceutical companies to recover the time lost between the filing of a patent application and the approval of the medicine, thereby encouraging further research and development of new drugs by ensuring a period of exclusive marketing that compensates for R&D investments (Killick, Schultz, Dawes, 2008, pp. 9–10; Tritton et al., 2002, p. 177). Within the EU regulatory framework, the SPC is implemented through Regulation (EC) No. 726/2004 and Directive 2004/27/EC, which govern the procedures for authorization and supervision of medicinal products and establish the European Medicines Agency. Considering that pharmaceutical products can be brought to market only after lengthy clinical trials, the basic patent often does not provide a full period of exclusive protection, which the SPC successfully compensates.

At the same time, SPCs carry significant market and legal implications, as they allow companies to extend market exclusivity and protect investments, but their misuse can serve as a tool to block competition from generic medicines, which is subject to regulatory oversight and case law. In this context, SPCs represent a balance between incentives for innovation and public interest, as they provide pharmaceutical companies with fair compensation for time lost during regulatory procedures, while their abuse may trigger intervention by regulatory authorities and courts.These strategies are frequently the subject of litigation and regulatory scrutiny, particularly regarding access to medicines and public health. While pharmaceutical companies seek to maximize market exclusivity, regulators and legal systems must balance the interests of innovators with the societal need for the availability of generic drugs.

3.4 Regulatory Data Protection

In addition to patent protection, pharmaceutical companies can also rely on regulatory data protection (Data Exclusivity)[16]. This mechanism grants companies exclusive rights to use

15 Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, Official Journal L 136, 30/04/2004, p. 34–57.

16 Lasić, I. (2010). Pharmaceutical Patents: General Characteristics and Current Issues in an International

clinical data on the safety and efficacy of a medicine for a specified period. Pursuant to Article 39 of the TRIPS[17] Agreement, member states are obliged to protect such data from unfair commercial use, except where necessary to safeguard public interest. The European model „8+2+1" defines eight years of data exclusivity, an additional two years of market protection, and the possibility of an extra one year if specific criteria are met.

3.5 Social and Market Effects

Patent protection has a direct impact on public health and the market. On one hand, it allows companies to recover their investments and encourages the development of new medicines. On the other hand, it may lead to high medicine prices and limited access, particularly in developing countries. Litigation concerning secondary patents and SPC strategies, such as in the case of AstraZeneca, demonstrates that legal protection can be challenged, and successful lawsuits by generic manufacturers can facilitate broader access and lower prices.

4. LEGAL FRAMEWORK AND CRITICAL ANALYSIS OF THE SUPPLEMENTARY PROTECTION CERTIFICATE (SPC) THROUGH CASE LAW

Although the SPC was originally conceived as an instrument to ensure fair compensation for investments in research and development and to encourage innovation, its application can be misused to delay the entry of competing generic medicines into the market, as demonstrated in practice by the AstraZeneca Group case. In the specific case, AstraZeneca was subject to proceedings before the EU General Court[18] due to attempts to mislead several European patent offices regarding its medicines for the treatment of ulcers, including **Losec**[19]. The company sought to revoke marketing authorizations for **Losec** capsules in Denmark, Norway, and Sweden, withdraw the original product from the market, and simultaneously introduce a modified version (**Losec MUP**), thereby attempting to illegitimately extend market exclusivity using the SPC. The EU General Court emphasized in its decision that, while patent protection is essential for fostering pharmaceutical innovation, the SPC must not be used as a means to monopolistically block competition or maintain higher market prices for a product. AstraZeneca Group was fined USD 60 million for the unlawful use of the SPC to delay the market entry of generic medicines.

The analysis of this case highlights several critical legal and economic aspects of SPC application. First, the SPC is clearly defined as a limited protection extension instrument, with a maximum duration of five years[20], intended to compensate for regulatory time lost from the filing of a patent application to the authorization to place a medicine on the market. Second, misuse of the SPC to strategically block competition and maintain a market

Law Context. Pravni Zapisi, V(1), 176–196.

17 Trips

18 AstraZeneca v. Commission, Case T–321/05, Judgement of the General Court, 1 July 2010, European Court of Justice of the European Union, par. 1–2.

19 AstraZeneca v. Commission, Case T–321/05, Judgement of the General Court, 1 July 2010, European Court of Justice of the European Union, par. 1–2.

20 Council Regulation (EC) No. 1768/92 of 18 June 1992 on the Creation of a Supplementary Protection Certificate for Medicinal Products, Article 13.

monopoly is subject to sanctions, as confirmed by EU case law. Third, the AstraZeneca precedent serves as a critical guide for balancing the interests of pharmaceutical innovators with the public interest regarding access to medicines at reasonable prices.

From an academic perspective, the case demonstrates that legal instruments such as the SPC do not operate in isolation but interact with market dynamics and regulatory frameworks. They must be carefully interpreted and applied in accordance with the fundamental principles of competition law and public health. Jurisprudence clearly indicates that the SPC cannot be transformed into a mechanism to delay competition; rather, its primary function remains to provide fair compensation for regulatory processes, thereby ensuring incentives for innovation without compromising public interest.

5. CONCLUDING CONSIDERATIONS

Pharmaceutical patents, due to their specific nature, represent a key incentive for scientists and researchers, as they provide protection for the results of their work and investments in drug research and development, particularly in countries with well-developed financial and technological infrastructures. However, in developing countries, where a significant portion of the population is impoverished and healthcare facilities are insufficiently developed, patent protection has limited effectiveness in stimulating research and development of new products.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) sets minimum standards of intellectual property protection for members of the World Trade Organization (WTO), while least-developed countries were granted the possibility to delay the implementation of these standards for a period of ten years. Nevertheless, this does not resolve the issues faced by countries lacking the capacity to manufacture medicines, nor for underdeveloped states that are not WTO members, as in such circumstances patent protection does not contribute to improving access to essential medicines.

The Commission on Intellectual Property Rights, Innovation, and Health Protection [21]emphasizes that in underdeveloped regions of the world, where the population has very limited purchasing power, patents are neither an effective factor in stimulating R&D nor in enabling access to new products in the market. Until a balance is achieved between the interests of pharmaceutical companies and the needs of developing countries for access to essential medicines, the challenges discussed in this study will persist.

As highlighted by Bill Gates at the World Health Assembly in 2005[22], political and market systems operate efficiently in developed countries, enabling the financing of research and the provision of healthcare to citizens who can afford it. However, in much of the world, these conditions are largely absent. This underscores the need for a better global approach that ensures access to medicines for the poorest populations without undermining the innovative potential of the pharmaceutical sector.

Achieving a compromise between pharmaceutical companies and human rights activists is a necessary yet challenging task, as solutions are rarely fully satisfactory to both

21 Commission on Intellectual Property Rights, Innovation, and Health (CIPIH). (2006). Public Health, Innovation and Intellectual Property Rights. Geneva: World Health Organization. Available at: https://www.who.int/publications/i/item/9241563416

22 Gates, B. (2005, May). Remarks at the World Health Assembly. Geneva, Switzerland

parties. A final agreement harmonizing intellectual property rights with access to essential medicines would enable, on the one hand, the population to fully exercise their human rights, while, on the other hand, inventors and scientists enjoy the fruits of their labor and companies continue to earn profits. The mere removal of patent protection would not guarantee access to medicines, since funding for innovation would still be required; however, it would create space for the implementation of appropriate regulatory measures and selective distribution of medicines, while simultaneously reducing prices and increasing availability.

Market economics indicate that producing medicines at lower prices increases demand and, consequently, the profits of pharmaceutical companies. This dynamic, combined with global population growth, leads to a continuous increase in the production and sale of medicines, which allows for reinvestment in the development of new patents and innovations. Lowering the prices of essential medicines in underdeveloped countries not only contributes to the full realization of human rights but also enhances the reputation of companies and stimulates further innovation in the pharmaceutical sector.

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GLOBALNI IZAZOVI NA PUTU OD IDEJE DO LEKA: INTELEKTUALNA SVOJINA IZMEĐU TRŽIŠNIH INTERESA I JAVNOG ZDRAVLJA

Apstrakt:

Pravni okvir intelektualne svojine u oblasti farmaceutske industrije obuhvata više oblika zaštite koji omogućavaju nosiocima prava da očuvaju ekskluzivitet i tržišnu prednost. Patentna zaštita i sertifikat dodatne zaštite (SPC) predstavljaju najznačajnije mehanizme za produženje komercijalne kontrole nad inovativnim lekovima. Osim ovih instrumenata, značajnu ulogu imaju i drugi oblici pravne zaštite: žigovi, industrijski dizajn, kao i autorsko pravo u vezi sa pratećom dokumentacijom i softverskim rešenjima.

Rad se bavi deskriptivnom analizom navedenih instrumenata i njihovom funkcijom u kontekstu farmaceutskog tržišta, sa ciljem razmatranja pravne svrhe, efekta i međusobnog odnosa različitih oblika zaštite. Poseban akcenat stavlja se na paralelu između osnovne patentne zaštite i SPC-a, koji često funkcioniše kao sredstvo za odlaganje tržišnog ulaska konkurentskih proizvoda.

Ključno istraživačko pitanje koje rad pokreće jeste: da li postojeći mehanizmi pravne zaštite doprinose ostvarivanju prava na zdravlje kroz podsticanje inovacija, ili,

pak, pretežno pogoduju interesima farmaceutskih kompanija ograničavanjem dostupnosti terapije? Kroz pravnu analizu funkcije, domašaja i posledica zaštite intelektualne svojine u farmaciji, rad nastoji da doprinese razumevanju odnosa između prava i javnog interesa u oblasti zdravstva.

Ključne reči: *intelektualna svojina, patent, sertifikat dodatne zaštite, farmaceutska industrija, javno zdravlje*

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