

THE ROLE OF INTELLECTUAL PROPERTY RIGHTS IN THE (UN)AVAILABILITY OF VACCINES DURING THE PANDEMIC

Gordana Damjanović, PhD¹

Faculty of Law, University of Priština, Kosovska Mitrovica, Serbia

Abstract: Intellectual property law is dedicated to promoting inventions, while ensuring the protection of socio-economic interests. The financial aspects of research and the lack of alternative protection for investments impose the need for their patent protection. Many countries, especially developing ones, have resisted the patent protection of pharmaceutical products, fearing that these products would become inaccessible to them, as patent protection increases the price of medicines. However, it is exactly the rules of intellectual property that, through the institute of compulsory licensing, enable the renunciation of the monopoly over pharmaceutical products, in the time of epidemics and pandemics. The institute of compulsory licensing in the period of pandemics gives priority to human lives over the profits of several pharmaceutical companies. The question then arises as to why organisations and countries such as the EU, the United States and others rebelled within the WTO against the proposal of South America, Africa and India to implement the institute of compulsory licensing for covid-19 vaccines.

Keywords: *monopolies, patents, compulsory licensing, pharmaceutical products, vaccines.*

INTRODUCTION

Pharmaceutical products are specific with regard to their purpose. They are used for treatment and improvement of population health. Their production is a serious work that requires large investments in research and development, from which a big profit is expected. Therefore, patent protection for pharmaceutical products was established under the pressure of pharmaceutical industry.

In order to regain invested means, innovative companies pay special attention to patent protection of their products. The protection lasts for 20 years and in that period generic companies cannot produce

¹ gordana.damjanovic@pr.ac.rs



medications based on the original ones. After the protection expires they can put remedies on the market. They are equivalent to the original medicines. They are also of the same quality, safety and efficacy as the innovative medicines but they are cheaper since the generic companies are devoid of research and development expenses. Because of this, innovative companies tend to defend against the generic companies by producing their own generic medicines or by disputing their bioequivalence.

Preclinical and clinical trials are the most expensive phases of developing a medicine. These trials require permission by Medicines and Medical Devices Agency that also issues the permission for putting the products on the market. The Agency was established by The Law on Medicines and Medical Devices and operates according to the guidelines of The Good Clinical, Laboratory and Manufacturing Practices. They are published by the Ministry authorised for health matters.

PATENTS

Patent is a right belonging to physical persons or legal entities via which a certain invention is protected. Patent holder acquires exclusive and absolute right of usage and disposal together with the right of accomplishing compensation if another person uses the invention (legal-property authorisations). If a holder of the right to a patent is also the inventor, he holds the moral right to be marked as such in all documents regarding the patent.

Besides positive authority to economically exploit the invention, a titleholder has the negative authority to ban exploitation of the protected invention by all third parties. But patent also succumbs to limitations that represent an attempt to balance between interests of a titleholder and interests of the community. The limitations may be predicted for many reasons. They can be ethical; with purpose of acknowledging the needs of an individual; originate from the need for undisturbed unfolding of international traffic; with the goal of enabling further technical development.

An invention must fulfil the conditions set by Article 10, 12 and 13 of the current Patent Law so it has privilege of protection in the form of a patent. Those are novelty, inventivity and industrial applicability the Patent Law (Official gazette RS, no. 99-2011, 113-2017- other law, 95-2018 and 66-2019).

An inventor must create something original that is based on studies and imagination even if he relies on the old data and inventions during the process (Idris, 2003:71).

Most of Patent Laws in the world don't contain definition of an invention. Such is the case with Serbian Patent Law that contains a mixture of elements for definition of an invention and conditions needed to protect the invention with a patent. Once the mentioned conditions are separated, an invention becomes a technical solution for a certain problem (Markovic, 1997: 63).

An invention must be clearly and precisely exposed together with its technical parameters, with clearly and precisely described characteristics that define it and make it different from other inventions. This is needed so that an authorised person of an authorised organ could inspect the mentioned conditions. Important characteristics are the ones that are altogether necessary. When they are taken in total, they are enough to make a subject of the invention more different and inventive than other solutions from a known state of the art (Saraboh, Tesankic, 2009: 2).

An invention is new if it is not contained within the state of the art. This state is composed of two technical solution groups that became available for the public (by written or oral description, use or in



any other way) before the date of submitting application for patent acknowledgment anywhere in the world (absolute novelty), at any time before submitting the application and in any way.

The other group is composed of technical solutions contained within national applications but also the ones contained within international applications (according to The Patent Cooperation Treaty concluded in 1970² at the diplomatic conference in Washington) in which Serbia is marked (if they are in the national phase). This also applies to European patent applications that are expanded because of Serbia, that have an earlier date of submission compared to an application for a subject and that are published on that date or later. This group of applications is characterised by spatial limitation (limited to the territory of Serbia) and temporal limitation (applications submitted in the period of 18 months before submitting an application for a subject). In accordance with The European Patent Convention (EPK)³, article 10 of The Patent Law prescribes that the findings of a substance or composition are considered novel even though they are contained within state of the art, conditioned that they are applied for the first time in one of the surgical, diagnostic procedures or treatment procedure - all of which are applied directly onto living human or animal bodies and are excluded from patent protection (Article 52, paragraph 2 EPK).

Via this so-called “pharmaceutical regulation” a retreat from the basic principle of absolute novelty is made. Therefore, in case of finding the first application for a certain matter (which is already contained within state of the art) in surgery, treatment or diagnostics, it is considered that the matter (pharmaceutical product) is new and therefore suitable for protection as an invention of pharmaceutical product. In this case, the demanded novelty is derived from new pharmaceutical application, The first application of a known matter as a medicine creates a fiction of novelty for the matter so that it could be patented as a medicine (and not as an application procedure) (Markovic, 1997:116).

Examination of novelty at an authorised organ (in Serbia its Intellectual Property Office) is done by an authorised person by firstly determining the subject of an invention based on content of patent demands. Then the person determines state of the art by gathering relevant patent documentation and finally, compares the subject of the invention with the existing state of the art.

There is an invention level if solution of a technical problem does not derive from the existing state of the art in an obvious way, which is related with an expert in a certain area.

Third condition that an invention must fulfil in order to accomplish protection in the form of a patent is industrial applicability. Article 13 of The Patent Protection Law points out that an invention is industrially applicable if the subject of the invention can be made or used in any branch of industry or agriculture. Applicability should be noted in accordance with directives of The Paris Convention, adopted in 1883 (article 1, paragraph 3) which assumes that industrial applicability, besides industry, encompasses commerce, agriculture, refining industry as well as all manufactured and natural products (Besarovic, 2005: 76). Article 57 of European Patent Convention says that an invention is industrially applicable if its subject can be manufactured in any area of industry, including agriculture.

The fact is that our country is (still) not a member of the EU so there is no formal obligation of adjusting our regulations with the ones of the EU. However, it is necessary because European rules con-

2 Our country is a member of the Agreement on Cooperation in the Field of Patents of February 1, 1997, Official Gazette of the FRY-International Treaties and Agreements, No/96.

3 The EPK was concluded on October 5, 1973 in Munich, entered into force on October 7, 1997, our country (then Yugoslavia) ratified the Convention on August 29, 1996, and finally the Law on Ratification of the KEP was passed, with amendments to Article 63 of 17 December 1991 and amendments of 29 November 2000, Official Gazette of RS-International Agreements No. 5/2010.



tain solutions that are result of a long-term successful application and because of conversion towards EU member states. This is dictated by development of new technologies and economy globalisation. Changes in technological development affect patent diversity because new discoveries are being made in the field of medicine, biotechnology and genomics.

PHARMACEUTICAL PRODUCTS PATENT PROTECTION

Medications are specific with regard to their purpose and their production is a serious work that requires large investments in research and development but in production and marketing as well. Large profit is expected of them. The costs of introducing a new medicine are enormous, which is the key reason for joining pharmaceutical companies in order to reduce costs of research and development. Mighty pharmaceutical companies wanted to secure monopoly over their products so the protection of pharmaceutical products was introduced.

The reasons why medications were not the subject of patent rights until the 70s of the last century in European countries (until the 90s in our county) were basically the same in all countries. It was considered that you cannot monopolize the matters that serve to maintaining human health and that the protection in the form of a patent would significantly increase the price of medicines joined by their substantially more difficult accessibility for a community (Vlaskovic, 1989: 124).

Article 3, paragraph 1 and article 7 of the 1995 Patent Law introduced patent protection for medicines. By that time, a medicine was excluded from patent protection in different ways via appropriate directives that referred to exceptions. Examples include the term “medicines” and article 13, paragraph 3 directives of the 1960 Law as well as the term “pharmaceutical products for people and animals” and article 4, paragraph 5 of the 1981 Law. Article 77a of The Law on Amendments and Modifications of the Law and article 77a of The 1990 Law on Protection of Inventions, Technical Advancements and Differentiation Signs state that the inventions that refer to applying matters in treating people and animals will not be patented until 31 December 1992, while the article 77b prescribes that using a matter as a medicine for people and animals does not represent patent harm for an invention of the matter if application for the invention was submitted until 31 December 1992. This is the exact date of changing regime of patent protection of pharmaceutical products but it was unclear whether a medicine was excluded from patent protection or not. Distribution and Marketing of Drugs Law of that time contained a definition of a medicine which describes it as a product and not an application as it was defined by The Patent Law.

Since 1990, a new substance has had protection status, while the 1995 Patent Law enabled protection of new application too.

Inventions of medicines are specifically significant group of inventions because they are used for preventing or treating diseases, i.e. health preservation. Without reliable monopoly such as a patent, there is no goad regarding investments in research and development of new medicines. Although economists sometimes debate on whether the general patent system is useful, they never seriously disputed patent protection of medicines as the investments in this area are risky (Jacobs, 2011).

Clinical trials last for several years in order to gather data on a medicine efficiency and safety. Authorised organ makes a decision whether the medicine should be distributed. This is based on the aforementioned data.



For these reasons, a person holding the rights title doesn't have the possibility to use an invention during the whole period of protection so he could primarily regain financial means invested in examination and development of the product and then make enough money to undertake new research that would eventually lead to new products. Medicine patents are required at a very early stage of their development (before clinical trials begin). Early patenting is required because of the competition from rivaling companies. Why invest up to several tens of millions of dollars if someone could copy and commercialize the medicine after it was licenced for distribution? This is the reason why a period of patent protection goes by without usage before the medicine gets distributed. Pharmaceutical company must prove that the medicine is safe and efficient and must enable that an authorised organ gains insight into the results of preclinical and clinical trials.

Preclinical trials provide initial indications related to the medicine safety while clinical trials are performed on volunteers. They last long, represent the most expensive phase of drug development and cannot be done without approval of an authorised organ. In our country it is Medicines and Medical Devices Agency of Serbia. It was first established in 2004 by The Law on Medicines and Medical Devices. The Agency is a legal entity that decides on issuing permissions for distributing medicines. This is done based on documentation that must contain administrative, pharmacological, toxicological, pharmaceutical, chemical, biological and clinical data. In accordance with EU Directives (2001/83, 2001/82, 2002/98 and 2003/63) a medicine is tested in accordance with guidelines of Good manufacturing practice, Good laboratory practice and Good clinical practice. They are all issued by Ministry of Health. Permission holder for distribution of medicines can be a medicine manufacturer with headquarters in Serbia, i.e. an agent or representative of a foreign legal entity that is not medicine manufacturer but is permission holder for the medicine within EU countries. It can also be legal entity with headquarters in the Republic of Serbia that holds permission for the medicine that was transferred onto it by the manufacturer, i.e. that was given the right for acquiring the property of licence holder from the manufacturers' program. The Agency makes decision on issuing the permission after receiving request for gaining permission to distribute the medicine. It is issued for the period of 5 years.

Permission for a medicine is no longer valid with its expiry date, if the licence holder demands so and if The Agency confirms that the medicine is harmful, that it has no therapeutic efficiency, that therapeutic results cannot be achieved during the treatment, that quantitative and qualitative composition of the medicine does not match the one on declaration or if the licence holder for the medicine no longer fulfils prescribed conditions.

COMPULSORY LICENCE WITHIN TRIPS⁴

By signing The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), developing countries had to introduce patent protection for medicines. Many countries found themselves in unequal position because this lead to an increase in medicine prices and these countries are burdened by serious health problems, especially diseases such as AIDS, tuberculosis and malaria.

The Agreement prescribes that member states can include necessary measures when formulating national laws. The goal of such action is protection of public health and diet (Article 8, paragraph 1).

⁴ The World Trade Organization, abbreviated: WTO, is an international multilateral organization designed to monitor and liberalize international trade. The organization was established on January 1, 1995 under the Marrakesh Treaty, which was signed by 123 states¹⁵ April 1994.



One part of The Agreement addresses patent holder limitations. It prescribes that member countries can establish exclusive rights limitations, conditioned that such exceptions do not clash with the usual patent exploitation and do no harm to legitimate interests of rights titleholder while being considerate about legitimate interests of third parties (article 30).

The use implies economic exploitation. Therefore, all the measures that do not penetrate significantly or do not penetrate at all into economic interests of patent holder are allowed (Zivkovic, 2008:32).

Article 31 prescribes other cases of usage without permission by titleholder. The article points out that if The Law of a member state allows different use of a patent (the different use is the one that is different from the use prescribed by article 30) without permission of the titleholder (which includes usage by Government or third parties authorised by the Government) the following rules must be respected: firstly, issuing permission for usage is considered for each case. Then, usage can be allowed only if presumed user tried to get usage permission from titleperson under reasonable commercial conditions and deadlines and if that effort has not been fruitful in a reasonable time period. A member state can give up this request in case of a national plight, in other cases of extreme necessity or in case of non-commercial public use.

This directive represents a result of a compromise because it cites negotiations with the rights holder, which is of titleperson's interest. On the other hand, there are appropriate means that a country can use to prevent irrational behaviour of patent holder and react in case of interest jeopardy.

The Agreement gives much attention to the need to find balance between interests of a holder and users. Therefore, possibility of approving compulsory licences exists only in the cases of non-commercial public usage and in cases of state of emergency in a country that can be caused by large-epidemics and most recently – pandemics.

Thanks to Compulsory Licence Institute, Taiwan avoided Roche patent for Tamiflu medicine that is used for treating bird flu. Thanks to The Institute, patent holders with no conscience were disabled from misusing their rights. This refers to charging too much for a medicine in a period of serious health emergency state.

A new round of TRIPS negotiations was held in Doha and was followed by 2001 Declaration that confirmed the right of member states to protect public health and issue compulsory licences (Zivkovic, 2008:43).

Article 31 enables that member countries of The Agreement can enable production of their own medicines via compulsory licences in case of big epidemics. However, problem emerges when a developing country does not have production capacities for medicine manufacturing and import of generic medicines that were made in accordance with compulsory licence is not possible. It is prescribed that compulsory licences are non-transferable which disables compulsory licence to be transferred onto a business entity that has production capacities.

The decision on implementation was adopted at 2003 Cancun meeting. It enables granting a compulsory licence for exporting to a country that doesn't have its own production capacities. TRIPS Council must be informed (not in the case of the least developed countries – they are devoid of this obligation) and all manufactured contingents must be exported. The importing country must prove that it really does not have production capacities.⁵

5 WTO- Intellectual property, TRIPS and public health, <http://www.wto.org/english/trips /pharmpatent-e.htm>, 11.12.2010.



After the 2003 Decision was changed, member states were proposed in Hong Kong with adopting TRIPS amendment by adding Article 31 bis, which would enable pharmaceutical products to be exported to the countries that don't have their own production capacities. This would be done based on mandatory licence. The General Council adopted The Protocol Amending the Agreements in accordance with the 2003 Decision. Regulation number 816/2006 of The European Community, The European Parliament and Council, introduced on 17 May 2006 refers to mandatory licencing for the patents concerning pharmaceutical products production. These products are exported to countries with public health problems. The Regulation gives a legal basis for EU member states to give mandatory licences for exporting patent medications.⁶

Example of a state of emergency as listed in the Article 31 is certainly the lack of vaccines against COVID-19. According to the British NGO Oxfam, rich countries that make 13% of the world population have now bought more than half of so far planned vaccine production. Considering that research meant for development of the vaccine against COVID-19 was financed with the money of taxpayers, results should be accessible to the public. The right of pharmaceutical companies to profit cannot be above the health right!⁷

In October 2020, India and South Africa suggested (within TRIPS) limiting certain authorisations of COVID-19 vaccine patent titleholders with the aim of preventing, combatting or treating COVID-19. Aforementioned countries proposed that limitations on authorisation last as long as the pandemic goes on. The proposal was supported by many countries (firstly by developing states). However, the USA, the UK, Switzerland, Japan, Brazil, Canada, Australia and some EU states were against it.

India, South African Republic and 60 other (mainly the least developed countries) submitted revised proposal to TRIPS regarding the time period. To be exact, the period of limitations of titleholder rights was reduced to 3 years and referred to health products and technologies, including diagnostics, therapy, vaccines, medical devices, personal protective equipment, their materials or components together with their methods and means of production that are meant for prevention, treating or combating COVID-19. However, a scope of potential limitation remains the key question. The EU has submitted alternative suggestion to TRIPS concerning equal approach to vaccines and treatments against COVID-19. It implies reduction of export limitations that will expand vaccine production and make it easier.⁸

CONCLUSION

TRIPS member states have not yet succeeded in accomplishing an agreement that would temporarily give up an intellectual property rights for COVID -19 related vaccines and treatments while the pandemic goes on all over the world.

Mandatory licencing is a powerful means of protecting public health which can be essential for alleviating insufficient supplies of vaccines against COVID-19.

Vaccines are complex biological medicines that are harder to replicate than the small-molecule medicines. Therefore, a new manufacturer who would like to create his own version of Pfizer-BioNTech

6 WTO- Intellectual property, TRIPS and public health, <http://www.wto.org/english/trips /pharmpatent-e-htm>, 11.12.2010

7 <https://www.dw.com/sr/treba-li-vesti-prisilne-licence-za-vaccine/a-5649848>, 23.08.2021.

8 Potential WTO TRIPS Waiver and COVID-19. Updated September 13, 2021 <https://crsreports.congress.gov/product/pdf/IF/IF11858>, 18.09.2021



vaccine would have to start his own clinical trials to prove efficiency and safety of the vaccine. Key obstacle in expanding production involves not only patent issues but business secrets, knowledge and poor physical supplies needed to run a new manufacturing facility. For example, Moderna has already given up its patent right in October but other manufacturers still cannot use its technology without an active cooperation with Moderna. This is the key question that creators of politics should focus on – to think of a way to goad an active transfer of knowledge on vaccine technology and then to ensure more righteous global vaccine distribution (Larrimore, 2021).

Expansion of global approach to vaccines against COVID-19 is a moral imperative. Record-breaking development of these vaccines is a triumph but the existing distribution reflects differences between countries.

Majority of doses that come from production lines of big pharmaceutical companies are distributed to the USA, European countries and several other rich countries. It is not expected that most parts of Africa, South America and Asia will accomplish mass vaccination until 2023. The USA has bought far more doses than it needs so it can share the extra ones from its supplies. The Irish Times gives an insight into export for the vaccines that the EU has gathered starting from February of the last year in the following order: 10.9 for UK, 6.6 for Canada, 5.4 to Japan, 4.4 for Mexico, 1.5 million doses for Saudi Arabia and the same number for Singapore. Vaccine ingredients and production capacities are limited, leaving the world to fight using the available doses (Larrimore, 2021).

In order to produce enough doses for global vaccination there needs to be a global increase of the existing production too. As it has already been mentioned, the key is goading or behesting knowledge transfer from the existing manufacturers together with efficient compulsory licence application. Building a stronger infrastructure network for vaccine production would not only help in ending this pandemic but would also leave the world better prepared for the next one.

REFERENCES

1. BESAROVIĆ, V., 2005, *Intelektualna prava, industrijska svojina i autorsko pravo*, četvrto, izmenjeno i dopunsko izdanje, Centar za publikacije, Beograd.
2. CARER D., 2011, "Drug Production, Public Interest vs. Intellectual property rights", *Yale Journal of Medicine and Law*, 18.02.2010., Vol. VI, issue 2, www.yalemed.law.com/2010/02-drug-production-public-interest-w-i.p.r.
3. IDRIS K., 2003, *Intelektualna svojina, mocno sredstvo ekonomskog rasta*, Beograd.
4. LARRIMORE O., Stanford's Lisa Ouellette on Waiving COVID-19 Vaccine Patents, <https://law.stanford.edu/2021/05/04/>.
5. MARKOVIĆ S., 1997, *Patentno pravo*, Beograd.
6. MARKOVIĆ S., 2007, O nedopustenoj retroaktivnosti zakona na primeru patentibilnosti pronalaska lekova u pravu Republike Srbije, *Pravo i privreda* 5-8, 595-608.
7. Pravo farmaceutskih kompanija na dobit ne može biti iznad prava na zdravlje! <https://www.dw.com/sr/treba-li-uvesti-prisilne-licence-za-vaccine/a-56498483>
8. Potential WTO TRIPS Waiver and COVID-19 Updated September 13, 2021 <https://crsreports.congress.gov/product/pdf/IF/IF11858>.

9. ROBIN J. 2011, Patents and pharmaceuticals - a paper given on 29th November at the Presentation of the Directorate General of Competitions preliminary report of the pharma sector inquiry, www.europa.eu/.../pharmaceuticals/jacobs.pdf.
10. SARABOH, TESANKIC, 2009, Uslovi za sticanje, kriterijumi patentibilnosti.
11. VLASKOVIĆ, B., 1989, Patentna zaštita pronalazaka iz oblasti hemije, Pronalazastvo, Beograd.
12. WTO-Intellectual property, TRIPS and public health, <http://www.wto.org/english/trips /pharm-patent-e-htm>.
13. ŽIVKOVIC V., 2008, Patenti i investicije, Beograd.



