

## INTERNATIONAL PATENT LAW CONFLICTS WITH THE RIGHT OF ACCESS TO MEDICINES AND HEALTHCARE: KEY ASPECTS

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This article is dedicated to the legal conflicts between international patent law and the right of access to medicines and healthcare. This article discusses the problem above under the light of the framework of the international agreements, mainly WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and Doha Declaration on the TRIPS agreement and public health. As we know, patents give exclusive rights to the inventors to use their innovations for a long period of time. This limits the ability of public to get easy access to medications, consequently to indispensable healthcare. It is undoubtable that the quality of life and the healthcare of the public is an absolute priority. On the contrary, the expropriation of patent rights, inadequate compensation of damages for issuing the compulsory licensing may have irreversible consequences for the states. Foreign investor may file claims against the governmental authorities to ad hoc or permanent arbitral institutions.

**Key words:** *access to medicines, public health, TRIPS agreement, Doha Declaration, pharmaceutical patent disputes, compulsory licensing, foreign investment, patent law*

Patents are one of the leading legal tools of intellectual property rights protection. As Bruce Lehman described “*patents are exclusive property right in intangible creations of the human mind.*”<sup>1</sup> To put it differently, after the innovation is registered by governmental authorities, the inventor may protect his invention from using it without his permission. In other words, the inventor can use his innovative product like any other property.

Recent years there is an endless political, social and legal debate on the conflict between patent law and the right to access to medications. Some scholars and politicians state that the pharmaceutical manufacturers who are holding the patent rights monopolies on the drugs and leads the pricing policy for life-essential medications.<sup>2</sup> In contrast, the business world representatives and key players of financial markets insist that compulsory licensing of drugs is nothing but expropriation of intellectual property rights of pharmaceutical sector.

This article discusses the problem as mentioned above under the light of the framework of the international agreements, mainly WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and Doha Declaration on the TRIPS agreement and public health. We will present both sides opinion and will argue the statement that protection of intellectual

<sup>1</sup> Bruce Lehman, The Pharmaceutical Industry and the Patent System, International Intellectual Property Institute, {2003} 2 <[https://users.wfu.edu/mcfallta/DIR0/pharma\\_patents.pdf](https://users.wfu.edu/mcfallta/DIR0/pharma_patents.pdf)> accessed 18 December 2019

<sup>2</sup> Dean Baker, End Patent Monopolies on Drugs, The New York Times, (New York, 10 January 2016) <<https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/end-patent-monopolies-on-drugs>> accessed 21 December, 2019

rights of investors downstream the rights of the public to the highest attainable standard of health.

As it was mentioned patents are essential for every innovative activity, no matter the region or the country. Patent protection of pharmaceutical products is especially important, as the drug producing process may be easily replicated and disarrange the investments in clinical testing and scientific research.<sup>3</sup>

The main international treaty that regulates relations between WTO member states regarding the protection of the intellectual property rights is TRIPS Agreement. Before 1994 TRIPS Agreement none of developing countries has an adequate system to protect international intellectual property rights. When the TRIPS Agreement entered into force the developing countries were able to regulate the public health problems slightly interference from the intellectual property rights.<sup>4</sup>

TRIPS Agreement aims to “*reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade*”<sup>5</sup>

As can be seen from TRIPS Agreement, the patents are temporary, and they are valid for twenty years from the date the inventor files his patent application.<sup>6</sup> It is obvious, that after TRIPS Agreement entered into force in 1995, majority of emerging countries faced the difficulties to reconcile the policy and technology of the intellectual property rights.<sup>7</sup> New regulation and policy undoubtedly benefited the financial markets and entire economy of developing countries. But still, there are arguable aspects of this question, especially regulations concerning the public health protection. As it was mentioned above, patents give exclusive rights of the inventors to use their innovations for twenty years. After the period of twenty years, the exclusive patent rights become generic and open for public use. But in particular cases, TRIPS Agreement grant the governmental authorities with the right to use the patent rights without permission of patent holder. In other words, according to the Article 27 (2) “*members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law*”<sup>8</sup>

Moreover, as it is mentioned within TRIPS Agreement principles, the

<sup>3</sup> William N. Monte (2016) Compulsory licensing of patents, Information & Communications Technology Law, 25:3, 247-271, DOI: 10.1080/13600834.2016.1230928 <<https://0-www-tandfonline-com.wam.city.ac.uk/doi/pdf/10.1080/13600834.2016.1230928?needAccess=true>> accessed 27 December 2019

<sup>4</sup> Frederick M. Abbott and Jerome H Reichman, The Doha Round’s Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions, Journal of International Economic Law 10(04), 927 <<http://ssrn.com/abstract=1025593>> accessed 29 December 2019

<sup>5</sup> Agreement on Trade-Related Aspects of Intellectual Property, {1994}, Annex 1C

<sup>6</sup> Ibid. Article 33

<sup>7</sup> Margaret Chon, Intellectual Property and the Development Divide, 27 CARDOZO L. REV. 2821 (2006). <<https://digitalcommons.law.seattleu.edu/faculty/558>> accessed 21 December, 2019

<sup>8</sup> TRIPS Agreement Article 27 (2)

member states may create their legislation in the framework of public health, nutrition and other public interest's protection.<sup>9</sup>

In this contrast, many politicians and civil society representatives raised the problem of patented medications, which are highly priced and sometimes unaffordable for the public, especially in the developing countries.<sup>10</sup>

At the same time, there is a problem of so-called Parallel trade of medications. Oliver Morgan, a journalist of The Guardian, reports, that pharmaceutical manufacturer practicing in buying cheap pills and re-exporting them more expansively.<sup>11</sup> This practice raises the prices of medications artificially and may cause a shortage of medications. In the long run, people in less developed EU countries struggle with different diseases as a result of the Parallel pharmaceutical trade organized by the UK, Holland and Germany pharmaceutical private sector. Pharmaceutical companies buy the same drugs at a lower price in Spain or Greece and re-sell them at a higher price in the UK.<sup>12</sup>

Under those circumstances, a new wave of objections raised in the UK. As Sarah Boseley, journalist of The Guardian mentioned in her article; the UK government should urgently interfere and regulate the price policy of the pharmaceutical companies, as it can extend the lives of thousands.<sup>13</sup> Boseley states that people simply die all over the world, facing unreasonably high prices of medications, henceforth the government should react as the NHS system is unable to resolve the situation.<sup>14</sup> Correspondingly, the solution of the problem with NHS system, which is unable to provide the public with life-essential medications are supposed to rely on pharmaceutical companies. In fact, there is a precedential case of compulsory licensing on AIDS drugs in Brazil. Brazilian authorities issued a compulsory license on a drug that is a life essential for 75,000 people, and according to the state health authorities will decrease the price of it until twenty-four million USD.<sup>15</sup> It is notable that, before the compulsory licensing issued, Brazilian authorities negotiated with drug producing company and decreased the costs of the medication. But still the problem of provision it to the public was not solved.

According to the TRIPS Agreement, there are some exceptions to exclusive rights of inventors which “*do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner*”<sup>16</sup>. Consequently, the TRIPS The agreement provides the member states with the authorization to create in their national legislation a

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<sup>9</sup> Ibid. Article 8

<sup>10</sup> Kenan Malik, Big Pharma Can Only See the Benefit of R&D for Wealthy Markets, The Guardian, (London 5<sup>th</sup> of May 2019) <<https://www.theguardian.com/commentisfree/2019/may/05/big-pharma-can-only-see-the-benefit-of-r-and-d-for-rich-markets>> accessed 22 December 2019

<sup>11</sup> Oliver Morgan, Parallel Trade in Drugs Puts EU Patients at Risk, The Guardian (London 29<sup>th</sup> June 2008) <<https://www.theguardian.com/business/2008/jun/29/pharmaceuticals>> accessed 23 December 2019

<sup>12</sup> Ibid

<sup>13</sup> Sarah Boseley, Calls for actions on patients denied 100,000 GBP cystic fibrosis drug, The Guardian (London 3<sup>rd</sup> of February, 2019) <<https://www.theguardian.com/society/2005/sep/12/socialcare.politics>> accessed 22 December, 2019

<sup>14</sup> Ibid.

<sup>15</sup> BRAZIL ISSUES COMPULSORY LICENCE FOR AIDS DRUG <<http://www.ictsd.org/brazil-issues-compulsory-licence-for-aids-drug>> accessed 21 December 2019

<sup>16</sup> TRIPS Agreement Article 30

system of compulsory licensing. Still, it should also be based on the respect of the inventor's best interests. Accordingly, the member states are not allowed just to expropriate the exclusive patent rights of the financial corporations, reasoning that process as a benefit for the public. What are the criteria of limitation of exclusive patent rights on TRIPS Agreement and are they interpreted in good faith? TRIPS Agreement member states also may exclude from patentability "*in diagnostic, therapeutic and surgical methods for the treatment of humans or animals*" also "*plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes*"<sup>17</sup>

The theory of excluding the patentability in favour of the public was the cornerstone of the political campaign of Labour Party in the UK for the 2019 general elections. Jeremy Corbyn, the leader of the Labour Party and the candidate for the Prime Minister in UK general elections 2019, outlined a radical new national health system policy, based on public ownership.<sup>18</sup> With this intention, Corbyn suggested creating a system, which would allow the UK to produce cheap drugs identical to the high-priced medications. In particular, the UK can make a similar version of Orkambi, which is still unaffordable for NHS, as the American producing manufacturer aimed unreasoned high profits.<sup>19</sup> At the same time, Christina Walker, a publisher of The Guardian, argued that intellectual property rights are not absolute and they need to be balanced with the health rights of the public sector.<sup>20</sup> Also in this political brief analytical review, the World Trade Organization is presented as a safeguard institution for the private pharmaceutical companies and their exclusive patent rights. The main idea is that the governmental authorities can issue government use license, so preventing the patent monopoly and make the life essential drugs affordable for the public.<sup>21</sup>

The official results of the UK general elections 2019 showed that this policy did not meet the expectations of the public. The Labour Party made the worst results since 1935 general elections, won 203 seats at the Parliament or 32,2 percent of the votes.<sup>22</sup> Consequently, the results of the elections states, that civil society realized the irreversible consequences of patent rights expropriation.

It is also vital to analyze the political and even legal nature of compulsory licensing, especially on pharmaceutical products. The first remarks regarding compulsory licensing can be found in US Copyright Act of 1909. Also, Article 13<sup>th</sup> of Berne Convention for the Protection of Literary and Artistic Works states "*the possible limitations of the right of recording of musical words and*

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<sup>17</sup> TRIPS Agreement Article 27 (3) (a) and (b)

<sup>18</sup> Sarah Boseley, Labour pledges to break patents and offer latest drugs on NHS, The Guardian (London 24<sup>th</sup> September, 2019) <<https://www.theguardian.com/politics/2019/sep/24/labour-pledges-to-break-patents-and-offer-latest-drugs-on-nhs>> accessed 26 December 2019

<sup>19</sup> Ibid.

<sup>20</sup> Christina Walker, My son's life depends on this cystic fibrosis drug. And ministers stand in the way, The Guardian, (London 5<sup>th</sup> February 2019) <https://www.theguardian.com/commentisfree/2019/feb/04/save-lives-cystic-fibrosis-orkambi-nhs> accessed 26 December 2019

<sup>21</sup> Ibid.

<sup>22</sup> <https://www.bbc.co.uk/news/election/2019/results> accessed 26 December 2019

any words pertaining.”<sup>23</sup>

The World Trade Organization defines compulsory license as: “for patents: when the authorities license companies or individuals other than the patent owner to use the rights of the patent – to make, use, sell or import a product under patent (i.e. a patented product or a product made by a patented process) – without the permission of the patent owner”.<sup>24</sup>

The first significant dispute between pharmaceutical companies and the state took place in South Africa in February 1998. South African Pharmaceutical Manufacturers Association and 39 leading drug-producing companies blamed the government in violations against the constitution and the TRIPS Agreement.<sup>25</sup> South African authorities tried to provide essential medication breaking constitutional principles and even international treaties. The legal procedure of this case was intertwined with various political actions, even with diplomatic pressure from US governmental bodies and European Union different bodies. The main consequence of this particular case was the flexibility of the TRIPS Agreement. Though TRIPS Agreement reflects the question of public priorities towards patented rights, but still there were unclear sides of their limits. It was obvious that TRIPS Agreement needed to be clarified.

From above mention point of view, the crucial legal document on compulsory licensing of medications is WTO ministerial declaration on public health (Doha declaration) adopted in Doha, Qatar, in 2001 November. The Doha declaration affirmed the sovereign right of all member states to issue compulsory licensing for protection of health rights of the public.<sup>26</sup> The main idea of the Doha declaration is the gravity of the public health problems in emerging countries<sup>27</sup>. Even so, the Doha declaration also recognizes the importance of intellectual rights protection as the guarantee of new medicine development.<sup>28</sup> We also need to state that the Doha declaration is not a legally binding international document (soft law).

On this condition, we can state, that the Doha declaration is granting the WTO member states with the right to create a national legal framework and to issue compulsory licensing to protect the health of the public. Henceforth, the according to the Doha declaration every member state may “remove” the exclu-

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<sup>23</sup> “Each country of the Union may impose for itself reservations and conditions on the exclusive right granted to the author of a musical work and to the author of any words, the recording of which together with the musical work has already been authorized by the latter, to authorize the sound recording of that musical work, together with such words, if any; but all such reservations and conditions shall apply only in the countries which have imposed them and shall not, in any circumstances, be prejudicial to the rights of these authors to obtain equitable remuneration which, in the absence of agreement, shall be fixed by competent authority.” Berne Convention for the Protection of Literary and Artistic Works, World [1886], Article 13 (1)

<sup>24</sup> Compulsory licensing of pharmaceuticals and TRIPS, World Trade Organization <[https://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_faq\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm)> accessed 23 December 2019

<sup>25</sup> 1998: Big Pharma versus Nelson Mandela, Médecins Sans Frontières (20 February 1998) <<https://www.msfaccess.org/1998-big-pharma-versus-nelson-mandela>> accessed 27 December 2019

<sup>26</sup> Ellen F.M. ‘t Hoen, Hans V. Hogerzeil, Jonathan D. Quick and Hiiti B. Sillo, A quiet revolution in global public health: The World Health Organization’s Prequalification of Medicines Programme, Journal of Public Health Policy, (Macmillan Publishers Ltd, 16 January 2016) <[https://www.msh.org/sites/msh.org/files/whopqp\\_jphp\\_15jan14.pdf](https://www.msh.org/sites/msh.org/files/whopqp_jphp_15jan14.pdf)> accessed 29 December 2019

<sup>27</sup> Declaration on the TRIPS agreement and the public health, WTO MINISTERIAL [2001], Article 1

<sup>28</sup> Ibid. Article 3

sive rights of the inventors imposing the governmental decision. Also, the compulsory licensing may be forced by the national courts. The patent rights may even be revoked and used directly by the governmental authorities themselves. As it was mentioned above, Brazil issued compulsory licensing in 2006 referring to the increasing problem of unaffordable pricing on AIDS drug efavirenz, produced by Merck.<sup>29</sup> Consequently, the Brazilian government provided the public with much-needed medicine through the revocation of private company patent rights. Given these points, we can state that the Brazilian government did not give the investor a prompt and adequate compensation for all investments, human and financial resources. Overall, other cases of issuing the compulsory licensing will be discussed.

Compulsory licensing on pharmaceutical products also was implemented in Thailand. Up to the present time, the health insurance system is smouldering and the national population of the country struggling against the healthcare costs. Though Thailand domestic legislation regulated the obligation of the state to provide essential life drugs to the patients, still there was a substantial lack of medications affordable for the public. Generally speaking, the authorities of Thailand issued compulsory licensing on HIV/AIDS drugs in November 2006. Consequently, the policy of producing cheap generic versions of patented drugs was encouraged.<sup>30</sup> The main argument put in was the Doha declaration and also the TRIPS that allow issuing compulsory licensing in “emergency cases and public uses.”<sup>31</sup> The production and also import of generic copies of the drugs, surly faced active critical reviews from the patent holders, especially from the Merck, US pharmaceutical key player. Mainly, the patent holders stated that the Thai government did not arrange a proper negotiation process and did nothing to decrease the prices of the medications. Given these points, it was more acceptable to expropriate the exclusive rights of the pharmaceutical sector instead to negotiate for the lower rates.<sup>32</sup> The compulsory licensing of several drugs in Thailand did not solve the problems with pricing policy and essential medications access. Thousands of people still suffer from the lack of much-needed medicine and healthcare in Thailand. Thereupon, it is the result of wrong management of the field and classified approach on the drug providing policy.<sup>33</sup> In the political analytical articles, published in The Wall Journal, Thai governmental authorities were described as “*patent hooligans*” and blamed in attacking the property of inventors.<sup>34</sup>

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<sup>29</sup> BRAZIL ISSUES COMPULSORY LICENCE FOR AIDS DRUG

<sup>30</sup> Thailand Issues Compulsory Licence for Patented AIDS Drug, International Center for Trade and Sustainable Development, (Bridges, 13 December 2006) <<https://www.ictsd.org/bridges-news/bridges/news/thailand-issues-compulsory-licence-for-patented-aids-drug>> accessed 26 December 2019

<sup>31</sup> TRIPS Agreement, Article 31 (b)

<sup>32</sup> Thailand Authorises Generic Production of Two More Patented Drugs International Center for Trade and Sustainable Development, (Bridges, 31 December 2007) <<http://www.ictsd.org/bridges-news/bridges/news/thailand-authorises-generic-production-of-two-more-patented-drugs>> accessed 26 December 2019

<sup>33</sup> Jared S. Hopkins, Generic-Drug Approvals Soar, But Patients Still Go Without, The Wall Street Journal, (19 November 2019) <<https://www.wsj.com/articles/many-generic-drugs-havent-hit-market-hindering-cost-control-efforts-11574198448?mod=searchresults&page=1&pos=2>> accessed 27 December 2019

<sup>34</sup> Bangkok’s Drug War Goes Global, The Wall Street Journal, (7 March 2007) 3

The Doha declaration had a significant impact also on the public health system of Malaysia. The authorities of Malaysia granted a compulsory license on the groundbreaking hepatitis C drugs to produce a generic alternative to patented ones.<sup>35</sup> Starting from 2001 Malaysian government negotiated with deferent pharmaceutical companies to engage them in the price reducing policy. As a result of unsuccessful negotiations, the compulsory licenses issued.

The other developing country experienced the parallel trade of drugs and compulsory licensing of pharmaceutical products is Kenya. According to Kenya Property Act 2001 the government issued compulsory licensing to produce life essential drugs more cheaply than patented medication imported from developed countries.<sup>36</sup> Surly, the pharmaceuticals protested to protect their patented rights. The case was resolved six years after, in favour of the Government of Kenya. After all, Kenya started to produce generic drugs for HIV/AIDS patents with affordable prices. Given this points, the governmental authorities provided cheap drugs approximately to 270,000 to 300,000 patients.<sup>37</sup> The pharmaceutical companies announced about “wild” expropriation of their property rights and started the procedure of financial compensation of the damaged.

Another cornerstone case in pharmaceutical patent disputes is the Canada v Eli Lilly ICSID case. The federal court of Canada revoked the patents of two medications. The patent holder Eli Lilly company announced about violations against their exclusive patent rights. The company signified the investment that was made in Canada and the approximate amount of their financial damages. Eli Lilly filed a claim against the Canadian authorities to the International Centre for Settlement of Investment Disputes referring to the North American Free Trade Agreement (NAFTA).<sup>38</sup> It is important to mention that Canada v Eli Lilly case is precedential as the pharmaceutical patent issues were discussed in the light of international investment. The Canadian authorities presented counter-arguments referring to their national jurisdiction. In general Eli Lilly company, did not succeed in this investment dispute, had to bear the costs of this arbitral trial. Given those points the Canada v Eli Lilly case did not leave any positive impact on patent right protection and the company was refused to get any adequate compensation for their financial damages.

Another crucial question on pharmaceutical patent protection is the duration of patent validity. Many scholars argue that twenty years of patent duration is a very long period. In other words, some critics offer to reduce validity duration up to three years. First of all, it is important to analyse how the international approach to the patent validity formulated and how it was supported. As it was discussed above, granting the patents is the only way to protect the exclusivity of the inventor. Only if the invention is registered by the governmental

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<sup>35</sup> Catherine Saez, Malaysia Grants Compulsory License for Generic Sofobuvir despite Gilead License, Intellectual Property Watch, (15 September 2019) <<https://www.ip-watch.org/2017/09/15/malaysia-grants-compulsory-licence-generic-sofosbuvir-despite-gilead-licence/>> accessed 27 December 2019

<sup>36</sup> Paul Garwood, Kenya Rejects Bid to Remove Government’s Compulsory Licensing Flexibilities, Intellectual Property Watch, (14 September 2007) <<https://www.ip-watch.org/2007/09/14/kenyan-parliament-rejects-bid-to-remove-governments-compulsory-licensing-option/>> accessed 15 December 2019

<sup>37</sup> Ibid.

<sup>38</sup> Canada v Eli Lilly ICSID [2017] Case No. UNCT/14/2

authorities, the patent holder may protect his financial and all other related rights.

Most importantly, the innovation process, especially in the field of chemicals and pharmaceutical production, is in the particular need of financial investments. The pharmaceutical inventions are intertwined with severe scientific research, high technology, various laboratory testing and tremendous human resources. It is obvious, that the powerful pharmaceutical companies are expecting to get financial benefits from their investments in this specific field of public interest. Given these points, we can state that, if the beneficial period of 20 years may be reduced to seven or three, the investors will choose the alternative field to invest their financial capital. So to sum up, the long term of patent duration is the vital guarantee of pharmaceutical industry development and flow of investments in this life essential field.

On balance, it is urgent to analyze the potential dangers on compulsory licensing of patented pharmaceutical products. As a result, the revocation of the proprietary rights of the inventors parentally may dramatically increase the production of fake medications. While the patent holders are interested in making investigations on the drug market and controlling the imitative medical products manufacturing. Whereas, after changing the exclusive patented drugs into generics, big pharmaceutical companies will defiantly lose their interest in the specific market supervision by using their financial and human resources.

Although the developing countries should have the right to development<sup>39</sup> and correspondingly should have the opportunity to realize it, but still these countries may face difficulties in organizing the manufacturer of pharmaceutical products. The developing countries may not have appropriately equipped high tech laboratories, which are vital for drug production. Lack of well-developed health and medical infrastructure may be dangerous for public health. Under those circumstances, the emerging states may not manage to organize multidimensional scientific research, which is crucial for drug-producing and health-care.

In addition, we can fact, that every new invention in pharmaceutical industry is immediately made available for scientific research community.<sup>40</sup>

The last but not the least, the revocation of the patent rights may stop or decrease capital investments in the pharmaceutical sphere. As long as the pharmaceutical industry will be attractive and profitable for investors, they will continue to invest substantial financial capital for the development of research in this essential field. Equally necessary to mention, that expropriation of patent rights, inadequate compensation of damages for issuing the compulsory licensing may have irreversible consequences for the states. Foreign investor may file claims against the governmental authorities to ad hoc or permanent arbitral institutions. In fact, the majority of such cases are solved in favor of the investors. Accordingly, the arbitration awards usually combined with tremendous financial obligations towards investors, which defiantly affect the economic growth of the country.

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<sup>39</sup> UN GA Declaration on the Right to Development 41/128 {1986}

<sup>40</sup> Servier, Mediator information < <https://servier.com/en/news/why-patents-are-necessary-for-the-pharmaceutical-industry/>> accessed 28 December 2019



As it has been noted, drugs produced by patent holders improved the health conditions and even the quality of life for a million people all over the world. If the drugs are not adequately patented, the development of pharmaceutical companies could not be realized. Given these points, we can state that pharmaceutical companies in developed countries, like the USA, Canada, France, Germany and around the world should benefit from reliable protection of intellectual property rights. For this reason, protection of intellectual property rights will ensure their contribution towards science and technological research, which will surely benefit the people both in developing and developed countries.

All things considered, we can state that the quality of life and the health-care of the public is an absolute priority. Every human being should have the right to get immediate health protection and essential life medication. Instant access to drugs is an undivided part of the right of health. This principle was first noted in the Constitution of the World Health Organization in 1946.<sup>41</sup>

But at the same time, it is essential to mention, that the protection of the right to health is the absolute obligation of the State and its governmental authorities. As it can be seen from the Constitution of the World Health Organization “*governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures.*”<sup>42</sup>

Even so, the states cannot transfer their obligation of health protection of the public to the private pharmaceutical companies. The compulsory licensing without adequate compensation of all financial damages is nothing but expropriation of the patented property. As it was mentioned above the reliable protection of intellectual property rights of pharmaceutical companies is the only effective way to decrease the development of drug production. As it was discussed in this coursework, the invention of new pharmaceutical products is directly connected with the level of intellectual property protection. To summarize, the private company should be secure in the protection of the capital investments made for the production of the pharmaceutical goods.

For this reason, the reduction of patent validity up to three or even seven years, will not resolve the conflict between intellectual property rights and access to medicine. The governmental authorities should find an alternative solution against violations of the intellectual property rights. In the long run, especially developing countries may provide the public with life essential drugs and healthcare through implementation of flexible health insurance system. Developed health insurance system will guarantee the access to the adequate healthcare and life essential medication. Another vital instrument of the realization of the right to the health is the creation of strong antimonopoly native legislation. In fact, it may help to ensure that drug producing companies will keep their exclusive intellectual property rights, but still in accordance with respect to

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<sup>41</sup> “*The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.*” World Health Organization Constitution {1946} < <https://www.who.int/about/who-we-are/constitution> > accessed 29 December, 2019

<sup>42</sup> Ibid.

other role players of the pharmaceutical market. The strict antimonopoly legislation and policy will protect the society from unreasonable or artificial prices of the pharmaceutical products. In December 2019, the parliament of the Russian Federation accepted new law regarding the regulation of prices in the pharmaceutical market. According to the new policy, if the pharmaceutical companies must be involved in the administrative procedure if the locally produced drugs are higher in price as the alternatives in the international markets.<sup>43</sup> The aim of this new law is to reduce the prices of life essential drugs.

In the final analysis, we can state that balancing the free access to drugs with the effective protection of the Intellectual property rights is the only way to provide sufficient healthcare to the public.

**ԱՆԻ ՄԻՄՈՆՅԱՆ – Միջազգային արտոնագրային իրավունքը հակասության մեջ է մտնում դեղերի և առողջապահության հասանելիության իրավունքի հետ. հիմնական ասպեկտներ** – Հոդվածում վեր են հանվում միջազգային արտոնագրային իրավունքի և առողջապահության ու դեղամիջոցների հասանելիության իրավունքի հակասությունները՝ մի շարք միջազգային իրավական փաստաթղթերի լույսի ներքո: Այդ փաստաթղթերի շարքին առաջին հերթին դասվում է Առևտրի միջազգային կազմակերպության կողմից 1994 թվականին ընդունված Մտավոր սեփականության իրավունքների առևտրային ասպեկտների վերաբերյալ համաձայնագիրը կամ ԹԸԻՓՍ համաձայնագիրը, Դոհայի հանրային առողջության մասին 2001 թվականի համաձայնագիրը և միջազգային իրավական այլ համաձայնագրեր: Ինչպես հայտնի է, մտավոր սեփականության արտոնագրերը գյուտերի հեղինակներին տալիս են իրենց հայտնագործությունների երկարաժամկետ բացառիկ օգտագործման հնարավորություն՝ դրանով իսկ սահմանափակելով այդ հայտնագործության արդյունքներին հանրության ազատ հասանելիությունը: Հաշվի առնելով այն հանգամանքը, որ մտավոր սեփականության ներպետական և միջազգային իրավունքով պաշտպանվող հայտնագործությունները հաճախ առնչվում են հանրության կյանքի, առողջապահության ու դեղամիջոցների հասանելիության իրավունքների (որոնք անվերապահորեն յուրաքանչյուր պետության համար բացարձակ առաջնահերթություն են) սահմանափակմանը, հարց է առաջանում՝ արդյո՞ք պետությունները կարող են զրկել կամ նվազեցնել հայտնագործողների արտոնագրային իրավունքները: Հեղինակը վերլուծել է նշված հարցերի վերաբերյալ մի շարք երկրների փորձը, ինչպես նաև ներկայացրել է միջազգային արտոնագրային իրավունքների սահմանափակման հնարավոր վտանգավոր հետևանքները:

**Բանալի բառեր** – արտոնագրային իրավունք, դեղամիջոցների հասանելիության իրավունք, ԹԸԻՓՍ համաձայնագիր, Դոհայի համաձայնագիր, օտարերկրյա ներդրողներ, դեղագործական արտոնագրային վեճեր, պարտադիր արտոնագրում

<sup>43</sup> [https://www.1tv.ru/news/2019-12-16/377500-dmitriy\\_medvedev\\_podpisa\\_postanovlenie\\_o\\_snizhenii\\_tsen\\_na\\_zhiznenno\\_vazhnye\\_lekarstva](https://www.1tv.ru/news/2019-12-16/377500-dmitriy_medvedev_podpisa_postanovlenie_o_snizhenii_tsen_na_zhiznenno_vazhnye_lekarstva)

**АНИ СИМОНЯН – *Международное патентное право вступает в противоречие с правом доступа к лекарствам и здравоохранению: ключевые аспекты.*** – Научная статья посвящена анализу юридического конфликта между международным патентным правом и правом на свободный доступ к медикаментам и здравоохранению в свете ряда международных правовых документов. В числе этих документов в первую очередь проанализировано соглашение по торговым аспектам прав интеллектуальной собственности, или соглашения ТРИПС, принятого в ходе Уругвайского раунда генерального соглашения по тарифам и торговле в 1994-ом году Всемирной торговой организацией. В работе проанализирована также Дохинская конвенция о здравоохранении 2001-го года.

Как известно, патентные права дают их владельцу возможность долговременного исключительного использования их изобретений, тем самым ограничивая доступ общественности к использованию этих изобретений.

Принимая во внимание тот факт, что изобретения, которые защищены международным правом интеллектуальной собственности, часто касаются права на здравоохранение и права на свободный доступ к медикаментам (эти права являются абсолютным приоритетом для любого государства), возникает вопрос, может ли государство лишить или ограничить изобретателя патентных прав.

Автором представлен международный правовой опыт разных государств по ограничению международных патентных прав, а также показаны возможные негативные последствия ограничения международных патентных прав.

**Ключевые слова:** *соглашение ТРИПС, Дохинская конвенция, принудительное лицензирование, патентные права, право на доступ к медикаментам, право на здравоохранение, фармацевтические патентные споры, международные инвесторы*