

## The impact of the legal regime of intellectual property protection in the pharmaceutical market

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### ABSTRACT

**Introduction:** the functioning of the healthcare industry in any country is impossible without providing enough medicines for patient care. This problem can best be resolved only when the majority of drugs, especially vital, will be made at national plants (industry). In this context, competition from generic drugs is the most optimal strategy to reduce drug's prices.

**Aim:** the paper should examine how the legal regime of intellectual property affects the availability of medicines for people and identify ways of supporting breakthrough inventions and counter «unreal innovations».

**Materials and methods:** for the purpose of study were generalized information from the scientific journals of medical and legal perspective, monographs by using a set of scientific methods. Namely under systematic approach have been analyzed the problems of pharmaceutical market, ways of producing generic and original drugs. Comparative legal method was useful for learning features of flexible mechanisms of the TRIPS Agreement and market regulation of medicines in the world.

**Results:** based on the research was found that developed countries with strong pharmaceutical industry are interested in maximizing the protection of intellectual property rights, including importing countries. Flexible mechanisms of the TRIPS Agreement can be useful for developing countries.

**Conclusions:** thus, successful development of pharmaceutical industry and health care should be accompanied by the following measures: - improvement of public health must be recognized as a main task of government policy; - substantial state support aimed at increasing the availability of drugs in the domestic market and the strengthening of export potential; - decrease patent protection of medicines and stimulate market launch of generic copies.

**Key words:** pharmaceutical preparations, pharmaceutical market, intellectual property, patents, invention.

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### INTRODUCTION

The functioning of the healthcare industry in any country is impossible without providing enough medicines for patient care. In other words, medical institutions and citizens should be provided with affordable and quality medicines. This problem can best be resolved only when the majority of drugs, especially vital, will be made at national plants (industry).

The researchers write that the health is a fundamental human right and essential medicines are required to maintain it. Therefore it is morally unjust and unethical to compromise access to medicines for commercial interests. Pharmaceutical companies actually use patents to stifle competition, increase price and create monopolies. Thus they make thrice the profit of other companies and have remained the most profitable business in USA since 1982. Generic competition is the best strategy of lowering drug prices. Anti-retrovirals (ARV) prices reduced from \$ 10,000 to 136 USD per patient per year with supply of generics from India [1].

Globalization (opening of the borders) complicated processes of manufacturing and trade, when many economies faced the problem that domestic production became unprofitable versus imports. Although a competitive advantage in trading gained

through various ways, in XX-XXI centuries intellectual property began to play an important role. Scientists say that innovation is the key driver in the modern economy [2].

International agreements governing these relations, above all, protect the interests of developed countries that produce innovative products. Accession to TRIPS in 1995 however has changed the whole scenario. To mitigate the potential negative effect of drug patents such as increase in drugs price, certain flexibilities have been provided in TRIPS which have been utilized by the member countries [2]. However, these agreements contain so-called flexible mechanisms aimed at protecting the interests of underdeveloped countries. These countries mainly import medicines and reduce the legal protection of intellectual property. The TRIPS agreement also leaves space to deal with the national level issues and process of executing TRIPS obligations [3].

### AIM

The paper should examine how the legal regime of intellectual property affects availability of medicines for people and identify ways of supporting breakthrough inventions and counter «unreal innovations».

## MATERIALS AND METHODS

Globalization has turned the world into a global village of interdependent countries linked by multilateral agreements like the «Trade Related aspects of Intellectual Property rights (TRIPS) agreement» of the World Trade Organizations (WTO). However, there is concern in Low Income Countries and Low-Medium Income Countries that this agreement may further reduce the people's access to much needed essential drugs. This may ultimately increase morbidity and mortality indices and will worsen their health and economic status and lead to under-development [1].

Today there are the following dominant trends in the global pharmaceutical market: (1) reducing the share of the branded drugs in the total world market and expiration of patents on them. It will lead the entry of generic products and lower prices on them; (2) reducing the cost of drugs in the United States and increased demand on medicines in emerging markets; (3) a new drugs that will create entirely new possibilities of drug exposure, will appear at the market. For example, this is medication for the treatment of multiple sclerosis, metastatic melanoma, the vaccine against prostate cancer and certainly a biosimilars; (4) more active using of utility medicaments, in particular generic. For example, in Japan, where the market for many years had an absolute advantage of branded drugs, in recent years the state policy is the transfer of 40% of the population in the generic drugs. This is due to the fact that health care around the world fall into a vicious circle: the higher health care costs lead the greater life expectancy; the greater life expectancy - the higher health care costs; (5) the growing concentration of pharmaceutical companies; (6) the deepening of specialization of the pharmaceutical business (marketing, production and wholesale); (7) active application of the flexible mechanisms of the WTO by the importing countries, import substitution of strategically important medicines, vital and essential medicines, medical products and equipment.

As you know, the crisis in public health, especially in the field of HIV, tuberculosis and malaria, has led to the adoption of the 2001 WHO Ministerial Council Declaration on the TRIPS Agreement and Public Health (Doha Declaration). The Doha Declaration reaffirmed that the TRIPS Agreement contains flexibilities that could be used by member countries to increase access to medicines.

Enforcing patent rights and enticing developing countries to make TRIP-plus agreements will worsen their health and economic status and lead to under-development. This is not the aim of globalization which promises trade liberalization and technology transfer. Countries should be able to use TRIPS flexibilities and adapt patent laws according to national realities without fear of sanctions. It is surprising that developed countries like the USA will grant aid through PEPFAR and Global Fund and still encourage loss of human capital through unaffordable essential drugs, this can only perpetuate the poverty cycle [1].

We can not agree with the opinion of prof. A. Pearman: «All production has its own specifics, but some have even more than others, and pharmaceuticals just refer to this category» [4]. This strategically important technology sector can be characterized by a high level of income and a limited number of participants. The development of new drugs is impossible without considerable

investments, often a significant portion of these costs reimburse the government or insurance companies. In addition, countries try to endeavor to maintain the possibility to influence on the functioning of the pharmaceutical market in order to ensure the competitiveness of domestic producers.

As you know, medicines are supported for the treatment or prevention of diseases, pregnancy prevention, rehabilitation, correction or changes in physiological functions in humans, and is the subject of a thorough public control at all stages of their market turnover. The pharmaceutical market can be characterized by the following features: significant investments in research and development; a wide range of products; long cycle developments; high research intensity; inelastic demand, its dependence on epidemics and natural disasters; monopolistic tendencies in the market; the sole need of mankind to maintain health, increase life expectancy; similarities in different countries of the dynamics and prevalence of major diseases.

A special place occupies the problem of legal protection of intellectual property rights, which were used in the creation of medicines. A special regime of intellectual property rights ensures the protection of the commercial interests of developers and investors.

The TRIPS Agreement covers seven forms of intellectual property, namely, patent, copyright, trademark, industrial design, geographical indication, lay out design of integrated circuit, and protection of undisclosed information or trade secrets. Pharmaceutical patents can be classified under the following categories: (1) Drug compound patents; (2) Formulation / composition Patents; (3) Synergistic combination Patents; (4) Technology Patents; (5) Polymorph Patents; (6) Biotechnology patents; (7) Process patents [5].

Patenting system as the most common and effective means of legal protection of innovative facilities in respect of pharmaceutical products is controversial. The Pharma industry is one of the most intense «knowledge driven» sectors. Pharmaceutical research is very costly and unpredictable in nature [5].

On the one hand, monopolists maximize their profits by significantly raising the price of the product, because of economic and legal nature of patenting. The profitability of the difference in prices and production costs are high, despite the fact that the high prices reduces the number of buyers. This is because the full development and clinical trials of new drug cost an average of \$ 1 billion USA [6]. Complete series of synthesis, testing and release new drug to the market is nearly 10 – 16 years.

On the other hand, patent owners often abuse by exclusive rights: - among 50 - 60 drugs that appear at the market, two-thirds of them are aimed at people who does not suffer from the most common diseases; - along with the increasing complexity of technology and the simplification of their use, especially noticeable improvements of attractiveness of medicines; - new generation of effective drugs which are intended for treating of diseases of mass, so-called «blockbuster» appear less and less, while pharmaceutical companies bring to the market for 2 - 3 drugs to replace drugs, the validity of patents on which have expired [7]; - for patented medicines are set high prices, making modern and effective drugs available for the vast majority. For example, in 2001 the US wholesale price for popular drug «Prozac» company «Pfizer» has fallen from

\$ 240 USA to less than \$ 5 USA during 6 months since the end of the patent [8].

Strong intellectual property rights protection checks imitations while simultaneously attempt to strengthening the ownership of the innovation. It also has a positive effect on economic growth by increasing the average duration of monopoly on power of goods and an increase in the average price of goods in the economy [9]. But clearly we can not agree with this statement: strong intellectual property protection satisfies the interests of exporters of innovations contrary to the interests of importers.

According to this, we should pay attention to the main flexible mechanisms of the TRIPS Agreement. Namely, regulation of the sphere of patent protection, legal regimes of data exclusivity and parallel imports, additional conservation certificate, compulsory licensing etc.

In the TRIPS Agreement attached the general principle of total patent protection according to which patent protection can obtain an invention in any field of technology that goes for products and processes. Certainly it has certain exceptions. According to Art. 27 of the TRIPS Agreement all inventions regardless of the field of technology would be eligible for protection [10].

By this time many states used a limited list of pharmaceutical and biotechnological inventions that could be patented, because the importer of innovation is always beneficial to establish maximum simplified intellectual property and vice versa. Now the task is no less important because of the problem of «evergreen patenting».

India laws are the most effective to combat the world's «evergreen patenting».

Section 3 of the Indian Patent Act 1970 has a list of the objects that can not be considered as «invention» and therefore it is impossible to obtain a patent on them. Firstly, section 3 (d), even before the amendments of 2005, excluded the possibility to obtain a patent for an existing drug, which new actions or new uses have been identified. Therefore, new ways to use old products can not be patented in India. Secondly, section 3 (d) clearly decides that the opening of the new forms of existing drugs is not an invention, excepting the situations when the effectiveness of the drug is significantly higher than the previously known substances. Thirdly, Section 3 (e) states that it is impossible to obtain a patent for an impurity, if it is only necessary to connect the properties of the components. Interestingly, India has also made changes in the definition of inventive step, to make it more stringent. Section 2 (1) (ja) requires the bearer of the patent to show that the invention has a technical advantage or economic importance, or a combination of both. The Patent Law also includes procedural safeguards to prevent unjustified patenting and allows any person to protest the patent.

Also, there are several ways how to challenge a patent after its issuance. Firstly, contesting of the patent may be filed within one year from the date of granting of the patent. Secondly, the procedure for cancellation of the patent can be started at any time after its issuance. Thus, the Indian patent law contains some leverages to prevent unjustified patenting. It shows how strictly the Indian Patent Office applies the patent standards to protect public health from the harmful effects of unwarranted patents.

So, India has used flexibilities such as compulsory license grant provision during health crisis; scope to redefine standards for patentability and Section 3(d) antiever-greening provision that restricts patenting on incremental innovation. Section 3(d) In order to safeguard the interest of the public and to maintain a balance for the accessibility of life saving drugs to patients (public goods), The Indian Patents Act, 1970 (amended) has stipulated various provisions (exceptions) making patentable subject matter non-patentable. That is why Pharma giants are not in favor of Section 3(d) and argue that Section 3(d) stands in the way of innovation [2].

That is why Pharma giants are not in favor of Section 3 (d) and argue that Section 3 (d) stands in the way of innovation [2]. But we can not agree with this opinion, because pharmaceutical manufacturers get substantial profit, while medicines are inaccessible for most citizens. Also, holders often abuse their patents for as long keeping a monopoly on technology and prevent the emergence of competitors.

Moreover, Indian Medicinal Products Act reduces to almost zero the likelihood that multinational companies will be able to prevent the entry of new drugs on the Indian market. According to Indian law, even if the multinational pharmaceutical companies would not register the drug in the country, India will still be possible to submit its generic version. One of the provisions in the Indian Act allows Indian medicines regulatory agency authorize generic versions of the drugs for trading in confirming their bioequivalence with the drug, that has been already approved. For drugs that have already been presented on the world market, but has not yet been registered by the manufacturer for sale in India, the decision of the Indian regulatory Medicines Agency may be based on the resolution of trade, issued in other countries, defining the level of safety and efficacy. In the past, already there were cases when a generic version of the drug was introduced in India even earlier than the original.

We should mention some legal measures of how to extend patent protection (extra security certificate).

The products designed to protect health, may be subject to administrative procedure for permission before they can be released on the market. Therefore, the amount of time that passes from the filing date of the patent to obtaining permission on producing the first product on the market, can reduce the period of effective protection under the patent. In this regard, there is a need to provide additional protection for original medicines. As you know, clinical trials and registration of medicines can last for years and even if patents were obtained in the initial stages of preparations, the term of their action often comes to an end when the product only appears on the market.

Typically, the institute of additional security certificate establishes in legislation as follows: «A further period of protection for a medicinal protection product which is protected by a patent and which has been subject to an administrative authorisation procedure, the period that elapses between the filing of the application for a patent and the first authorisation to place the product on their respective market, as defined for that purpose by the relevant legislation, may shorten the period of effective protection under the patent. This sets the maximum length of the extension, for example, from 5 to 15 years».

Also laws of different countries provide an additional six-month extension of the period of patent protection if pediatric studies were performed relating to medicinal products, the results of which are reflected in the information about the product.

In this context, it should be considered an exception to the purpose of the introduction of generic medicines on the market. Art. 33 of the TRIPS Agreement stipulates that the term of the patent protection should not end before the expiration of twenty years from the filing date for a patent. For manufacturers of generics and patients who expect cheap essential medicines, it is important to bring medicines on the market as soon as possible after the 20 year period of patent protection. According to this number of developed countries, such as Canada, enshrined in law so-called «Bolar exception» that allows the use of a patented invention for the purpose of registering generic to the actual expiration of the patent, without the need to obtain the permission of the patent owner.

## RESULTS END DISCUSSION

Highly developed countries with a strong pharmaceutical industry are interested in maximum protection of intellectual property rights, including in countries of import. Developing countries should use flexible mechanisms of the TRIPS Agreement to provide citizens with affordable medicines and encourage investors in localization their companies in the state.

TRIPS Agreement provides the following exceptions to exclusive rights: (1) state has the right to take measures which are necessary to protect public health and nutrition in sectors of vital importance to their socio-economic and technological development, if such measures are consistent with the TRIPS Agreement; (2) state has the right to establish limited exceptions to the exclusive rights granted by a patent, if such exceptions will not significantly conflict with a normal exploitation of the patent and cause significant harm to the legitimate interests of the patent owner, taking into account the interests of third parties; (3) state has the right to prevent the patenting of inventions, the prohibition of commercial use of which is necessary for protection of public order or public morality, public life or health of humans, animals or plants or to prevent significant damage of environment; (4) state has the right not to recognize patentable diagnostic, therapeutic, surgical methods of treatment of animals and humans.

Thus, as a reason for the free use of the patented invention we can add its application to meet the immediate needs of the public by producing substances drugs, list of which would be approved by the government. It is also possible to prohibit the patenting of medicines for certain groups of essential disease.

Aim of the «Bolar exception» is to complete the regulatory approval for the use of a generic product before the patent expires, and also production and introduction of generic drugs into the market on the day of expiry of the patent. This exception meets the requirements of the WTO and applies to both domestic producers and importers.

## CONCLUSIONS

Therefore, the successful development of the pharmaceutical industry should be accompanied by the following measures:

1) Ensure social orientation of the state because the right to life includes the right to health. It obliges the State to improve the public health, which must be the highest priority for the government as it relates to the very physical existence of society.

2) Ensure substantial public support, both aimed at improving the availability of medicines in the domestic market, and increasing the country's export potential. We can distinguish such measures of state support: - government return entitles funds spent on the implementation of GMP and other international quality control standards (modernization of fixed assets); - compensation of cost for the promotion of products abroad; - support of national producers; - providing preferential loans (guaranteed by the government) for pharmaceutical organizations implementing investment projects on creation, reconstruction and technical re-equipment of production facilities; - exemption technologies, components and spare parts which use for building national production equipment from import customs, duties and VAT; - implementation of programs that offer affordable medicines by enhancing the public order; - providing the system of subsidies and benefits for those companies that successfully export medicines to other countries.

Such public support should be allocated solely on the basis of competition, rather than advance specific manual «promising» companies. The following pharmaceutical relations are attractive for investors: biotechnology, genetic engineering, new vaccines, improvement of the method of application of medicines, medical equipment.

It should pay attention to the common problems of the developing countries, for example: - national pharmaceutical manufacturers find more profitable investments in marketing and sales, rather than the development of new effective drugs; - pharmaceutical manufacturers invest no more than 1 – 2 % of their revenue (in the USA and Western Europe – 10 – 15 %) in research and development; - pharmaceutical industry depends on import of substances, although some countries have national chemical industry, scientific and educational sphere; - there is practically no training of highly qualified personnel for modern pharmaceutical industry and scientific research; - there are no developed mechanisms for the transfer of intellectual property, obtained for the budget, including public research institutes, small innovative firms. These participants ensure subsequent commercialization of new knowledge etc.

The level of public sector involvement should be increased and should not be limited to initiating basic research and development but should continue up to the stage of commercializing the drugs. Capacity will need to be built in the public sector. Some research institutes like Nigeria's NIPRD need to be upgraded and get better funded to ensure cost-effectiveness. There should be increase in research grants given to researchers and institution; this can be raised from both public and private sources. This should be given through an equitable and transparent system. Corporate organizations should be made to contribute to R&D efforts and tax credits can be received for these. Individuals in countries with low drug taxes can be made to pay special R&D taxes [1].

3) Establish centers of biological products development, as the prospect to take a leading position on the market of biogenerics has substantial economic conditions: the cost of treatment per

patient with some biologics estimates in the hundreds of thousands of dollars per year. For example, the cost of the annual rate of the drug «Avastin», which is used in the treatment of collateral cancer is \$ 100,000 USA. Output of some of these drugs under patent protection in the coming years will bring considerable profits to companies that will be able to re-create them in the form of biogenerics.

4) Compensate customer's expenses (30 – 50 %) on the organization of clinical trials on the territory of Ukraine.

5) Decrease patent protection of medicines and stimulate market launch of generic copies.

6) It is necessary to provide high price competitiveness (availability) of the national pharmaceutical products using the low cost of labor, the reduction of energy prices and taxes. That is, in general, would improve the investment climate, exploit the potential of the internal market (the economic aspect) and the protection of public health.

## REFERENCES

1. Kolawole A., Patent rights and essential medicines in developing countries: is access compromised for innovation in Nigeria, *Journal of Medicine and Medical Sciences*, 3 (3) (2012) 130 – 134.
2. Shalini A., Rekha C., Section 3(d): Implications and Key Concerns For Pharmaceutical Sector, *Journal of Intellectual Property Rights*, 21 (2016) 16 – 26.
3. Nair G., Impact of TRIPS on the Indian pharmaceutical industry, *Journal of Intellectual Property Rights*, 13 (8) (2008) 432 – 431.
4. Permand G., EU pharmaceuticals regulation: The politics of policy-making, Manchester: Manchester University Press, 2006.
5. Vipin M., Patenting of Pharmaceuticals: An Indian Perspective, *International Journal of Drug Development & Research*, 4 (3) (2012) 27 – 34.
6. DiMasi J., Hansen R., Grabowski H., Assessing Claims about the Cost of New Drug Development: A Critique of the Public Citizen and TV Alliance Report, Tufts Center for the Study of Drug Development, Tufts University (2004) 20 [http://cssd.tufts.edu/files/.../assessing\\_claims.pdf](http://cssd.tufts.edu/files/.../assessing_claims.pdf).
7. Pharma 2020, The vision: Which path will you take, PricewaterhouseCoopers (2007) <http://pwc.com/gx/en/pharma-life-sciences/pharma-2020.html>.
8. Vernon R., International investment and international trade in the product cycle, *The Quarterly Journal of Economics*, 80 (2) (1966) 190 – 207.
9. Nazura A., Rohimi S., Pardis M., Ahmad A., Protecting R&D Inventions through Intellectual Property Rights, *Journal of Intellectual Property Rights*, 21 (2016) 110 – 116.
10. Kochhar S., Institutions and capacity building for the evolution of intellectual property rights regime in India: V - Analysis of review of TRIPS Agreement and R&D prospect in Indian agriculture under IPR regime, *Journal of Intellectual Property Rights*, 13 (5) (2008) 536 – 547.

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