WHY UKRAINE NEEDS

A PATENT REFORM FOR MEDICINAL PRODUCTS

“The idea of a better-ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death”

Indira Gandhi
World Health Assembly, 1982

INTRODUCTION

The stringent system of patent rights protection for pharmaceutical products in Ukraine poses significant barriers to the accessibility of pharmaceuticals for people, as it does not allow cheaper generic medicines that hold a therapeutic effect identical to patented medicines to the market and curtails the opportunities for a national pharmaceutical industry to develop.

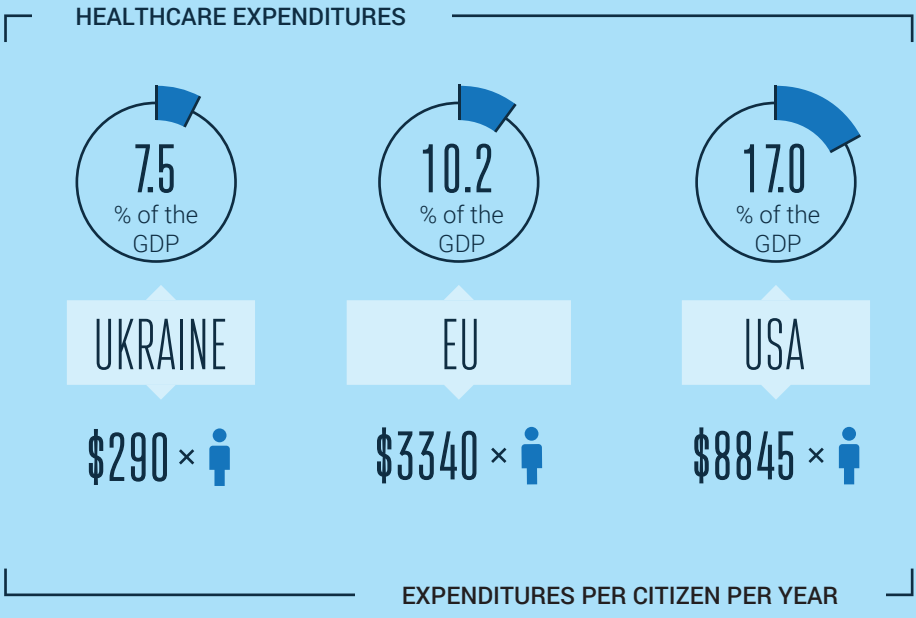
A government's balanced approach to the protection of patent rights for medications by using the public health flexibilities of the WTO TRIPS Agreement will improve access to medicines and further the development of the national pharmaceutical industry. However, this approach would require the Parliament and the government, in particular, the Ministry of Health of Ukraine and the Ministry of Economic Development and Trade to take a stronger stance.

Implementing this approach will require an intellectual property rights reform in pharmaceutical industry and healthcare. Introducing the respective amendments to the Law of Ukraine «On Protection of Rights to Inventions and Useful Designs», the Law of Ukraine «On Pharmaceuticals», the Customs Code of Ukraine, the Criminal Code of Ukraine and a number of respective bylaws.

REASONS FOR THE REFORM

As we know, healthcare funding in Ukraine is quite scarce, in particular, in 2012, public healthcare expenditures were equal to 7.5% of the GDP, that is about $290 per capita, while the average indicator in the EU is 10.2% of the GDP or $3,340 per capita, including the Czech Republic — $1,411, Poland — $859, Bulgaria —$520 and Romania —$468. In the United States this indicator is 17% of the GDP or $8,845 per capita.

GOVERNMENT HEALTHCARE FUNDING



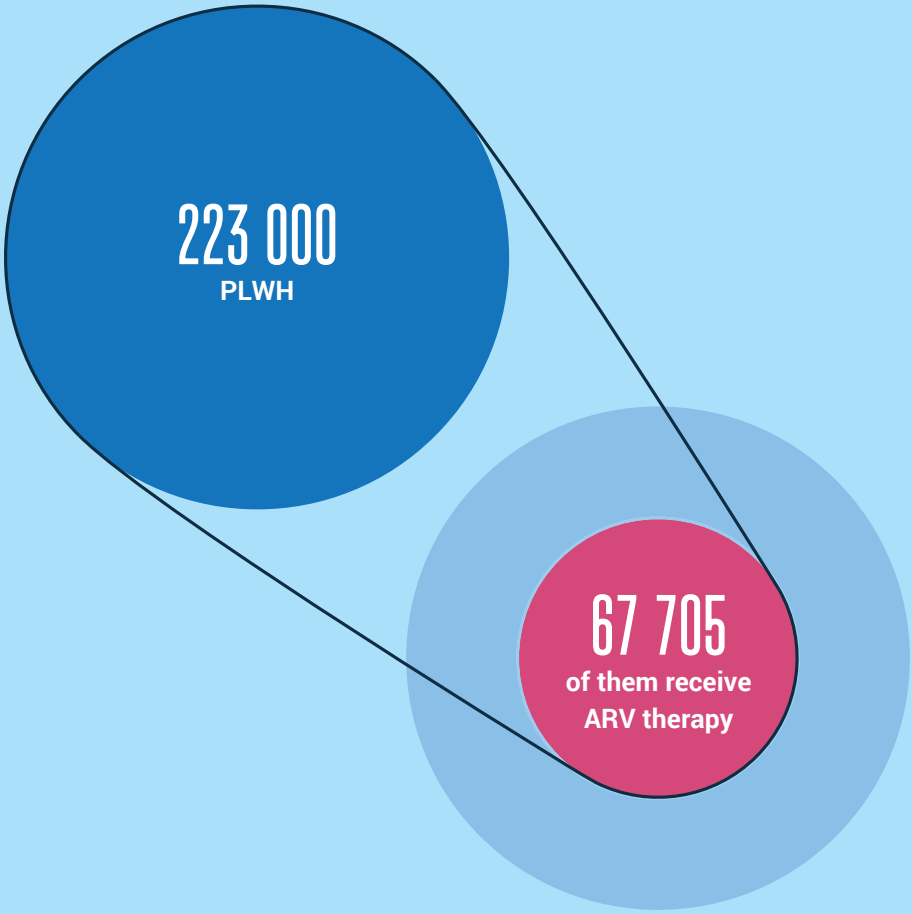
Despite the fact that the number of newly detected HIV cases in the world is decreasing, in Eastern Europe and Central Asia (EECA), the number is still growing at an alarming rate. From 2001 to 2012, the number of people living with HIV increased from 970,000 to 1,500,000. Meanwhile, AIDS-related mortality increased by 21% between 2001 and 2011. The Russian Federation and Ukraine, two EECA countries with the largest population, account for 90% of the new HIV cases. Access to HIV treatment in the EECA countries is low. Only about 21% of people needing ARV therapy actually receive it[1]. The prices on the majority of ARV medicines in the region are significantly higher than the average prices set by the WHO and the Global Fund to Fight AIDS, Tuberculosis and Malaria (hereinafter — the Global Fund). This refers also to the first line medicines, the prices on which dropped considerably during the last decade.

In a decade, the number of PLWH in the EECA countries increased by 54%, and AIDS-related mortality surged by 21%

Currently more than 223,000 people live with HIV[2] in Ukraine. Despite the fact that the National HIV/AIDS Program funded by the government and the Global Fund launched over 10 years ago, most of the PLWH are still not provided with necessary treatment[3].

[1] UNAIDS, 90-90-90 An Ambitious Treatment Target to Help End the AIDS, 2014., p. 9
[2] As of the beginning of 2015 based on the GARPR Ukraine data
ucdc.gov.ua/uploads/documents/ab1ccb/3c54bc491a41b37b8bb8625d29037e1d.pdf
[3] Based on the data of the State Enterprise «Ukrainian Center of the Socially Dangerous Diseases Control of the MoH of Ukraine» Information about the number of people receiving ARV-therapy as of December 1, 2015.

223,000 PEOPLE LIVE WITH HIV, AMONG THEM ONLY 30% RECEIVE ARV THERAPY



DRUG PATENTS KEEP PRICES HIGH

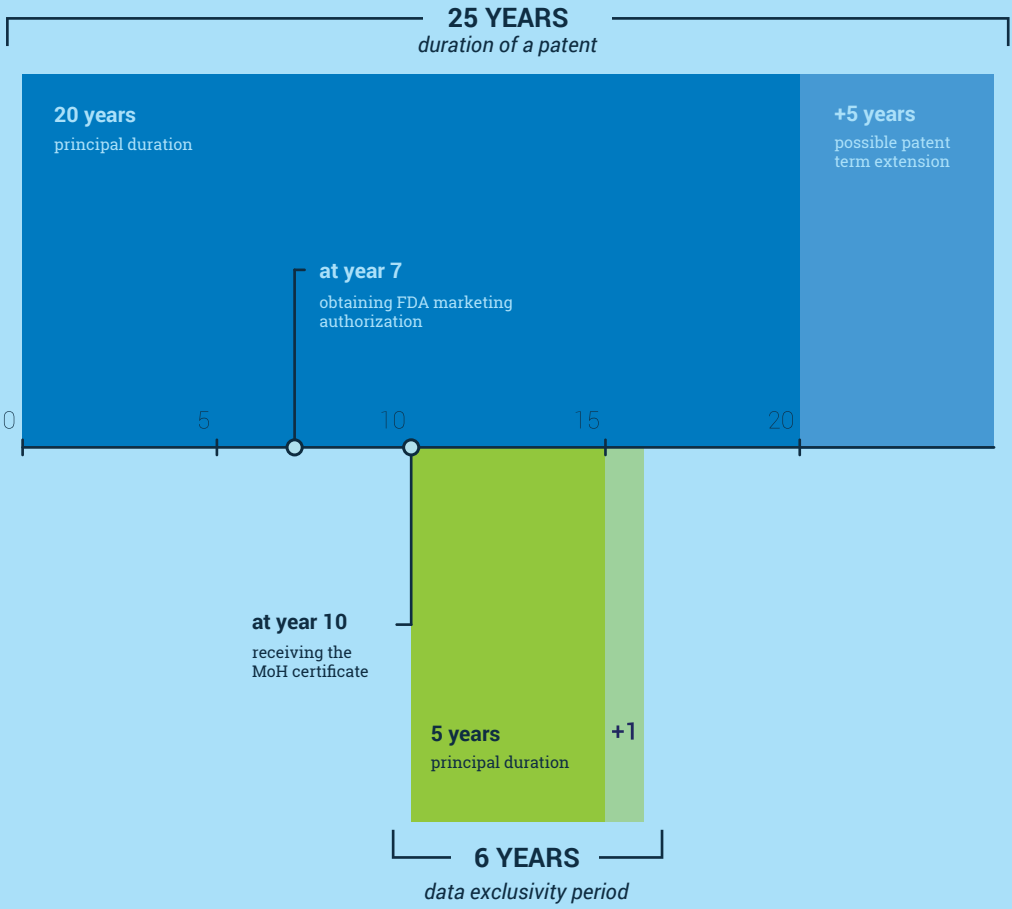
In order to fully provide the patients with the essential medicines, it is necessary to increase access to cheaper pharmaceuticals. Both patents and regulatory barriers, such as excessively complicated registration and licensing requirements, prevent generic medicines[4] from entering the market. Despite all the progress achieved with regard to the compulsory licensing system[5], patent barriers do exist. As a result, even first line ARV medicines in Ukraine are still patented and relatively expensive (such as lopinavir/ritonavir, tenofovir/emtricitabine, efavirenz).

First line ARV medicines are still patented in Ukraine

There is a widespread practice when the manufacturers of brand medicines prevent competition by evergreening[6] patents. Ukrainian law also allows a five-year extension on the term of patent. The data exclusivity regime (5+1 year) also blocks generics[7] from entering the market.

[4] A generic drug a medicine having the same quantitative and qualitative composition of the active ingredients and the same dosage form as the reference drug; the generic is equivalent to the reference medicine as evidences by appropriate studies. See section 2 of the Order of the MoH dated August 26, 2005 No. 426 «On approval of the review procedure of drug registration materials submitted for state registration (re-registration), and review of the materials on amending the registration materials within the registration certificate validity term».
[5] Approval of the Resolution of the Cabinet of Ministers No. 877 dated December 4, 2013 and amendments to the Law of Ukraine «On Amending Art. 9 of the Law of Ukraine 'On Pharmaceuticals» dated November 3, 2011, N 3998-VI.
[6] The practice of «evergreening» is when the manufacturer introduces minor modifications to the already known substance to extend the patent protection of the drug beyond the legally approved term (20 years).
[7] See Art.9 of the Law of Ukraine «On Pharmaceuticals».

DRUG PATENT VALIDITY TERMS IN UKRAINE



*FDA is similar to the Ukrainian SE "State Expert Center of the MoH of Ukraine"

**There are initiatives to extend the data exclusivity period to 10 years, as in the EU

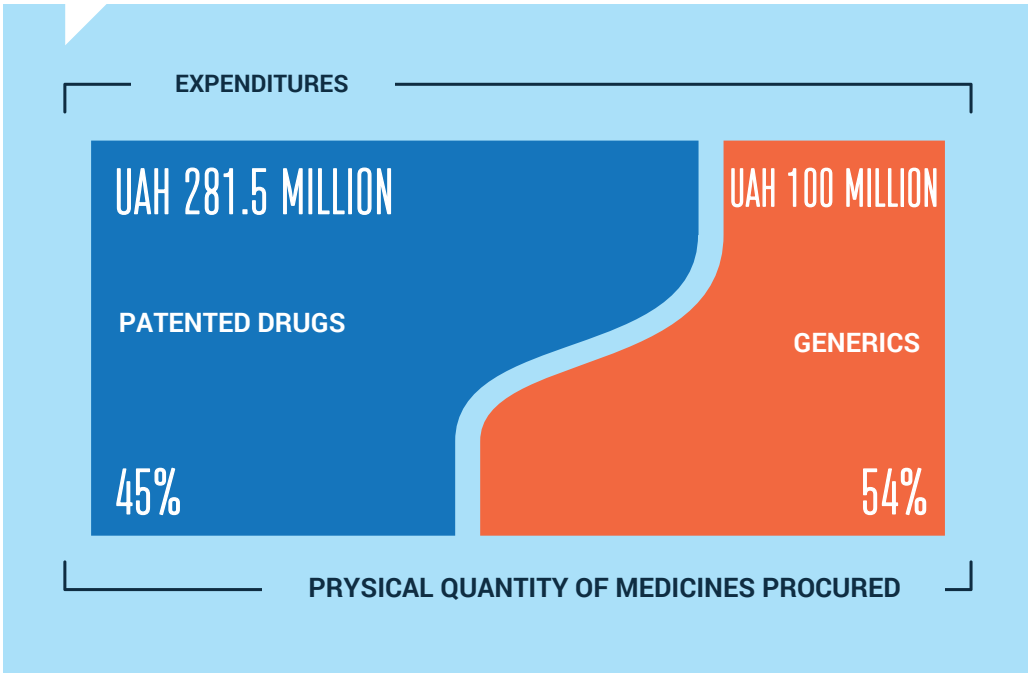
Under these conditions it is extremely important to carry out efficient policies aimed at decreasing the cost of medicines. The key factor to significantly reduce drug prices is the competition from generic medicines. Generic medicines are cheaper than big brand medicines, however, the quality is usually equal.

Studies show that the generics have the same therapeutic effect as brand medicines. For example, the results of 38 published clinical trials comparing generic cardiovascular drugs with their branded equivalents were evaluated. These studies did not provide any evidence that big brand cardiovascular drugs were more efficient than their generic equivalents[8].

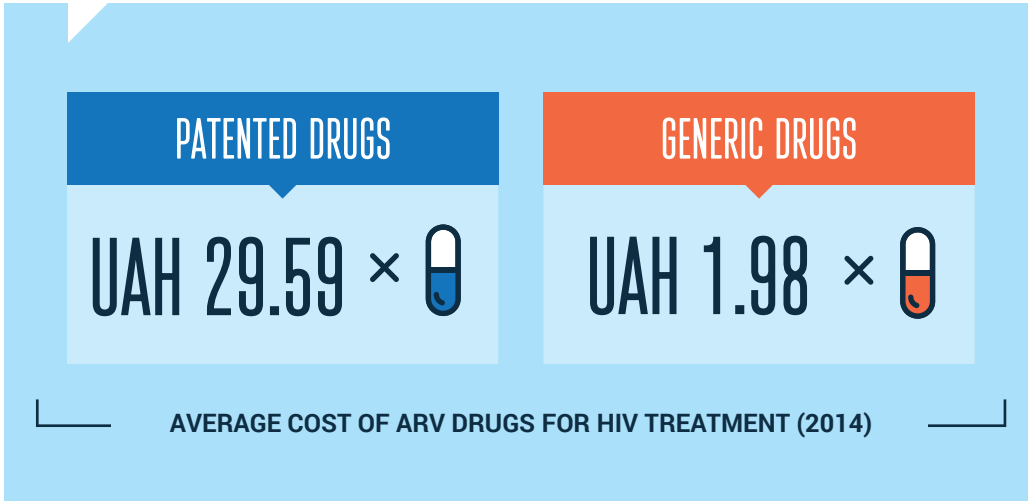
However, there is a significant price difference between generic and big brand medicines. On average, the price of a generic medicine is 80-85% lower than the big brand medicine on the US market[9]. In 2010 alone, the use of generics in the US saved $158 billion, which is, on average $3 billion weekly[10].

In Ukraine generic antiretrovirals are several times cheaper than their reference patented versions and they are used to larger extent, if we compare «in kind» volumes. For example, in the total cost of ARV medicines procured in 2014 (UAH 383 million) the patented medicines accounted for UAH 281.5 million, while their quantity in kind (tablets, ml of solutions) was 44% of the total volume of the supply; at the same time, antiretrovirals not covered by valid patents cost UAH 100 million and accounted for 54% of their physical quantity.

[8] Davit et al. Comparing generic and innovator drugs: a review of 12 years of bioequivalence data from the United States Food and Drug Administration. Ann Pharmacother. 2009;43(10):1583-97 // ncbi.nlm.nih.gov/pubmed/19776300
[9] Facts about Generic Drugs, US Food and Drugs Administration
fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm#_ftnref3
[10] Savings. An Economic Analysis of Generic Drug Usage in the U.S., GPhA, September 2011 //
gphaonline.org/media/cms/IMSStudyAug2012WEB.pdf



Moreover, the average cost of generic ARV medicines for HIV treatment in Ukraine in 2014 was UAH 1.92 per tablet, while the average cost of patented ARV medicines was UAH 29.59 per tablet. That is, the patented ARV medicine cost 15 times more on average. This correlation is very likely to apply to the entire pharmaceutical market of Ukraine.



If we compare the cost of medicines procured by the Ministry of Health of Ukraine, the average cost of medicines without competition (UAH 4,592 per unit)[11], which exceeds by 6.5 times the average cost of medicines registered under more than one trademark (UAH 700 per unit)[12]. That's why competition is a major factor in making the medicines more affordable.

One of the ways to increase competition from generic medicines is a more balanced approach from the government in granting and protecting drug patents[13]. Considering that the national pharmaceutical industry mostly produces generic medicines, this approach will facilitate the development of national production[14]. Moreover, increased competition from generic suppliers would facilitate drug price reduction and budget savings.

According to the survey carried out by Prescribing Analytics, the UK National Health Service (NHS) could have saved up to £1 million ($1.6 million) if doctors had opted for their cheaper, but not less efficient generic copies[15].

For example, potential savings from procuring antiretroviral medicines for HIV/AIDS treatment by the Ministry of Health of Ukraine, L.V. Gromashevsky Institute of Epidemiology and Infectious Diseases and the program of the Global Fund to Fight AIDS, Tuberculosis and Malaria in Ukraine could have amounted to UAH 128.6

[11]The substances under international non-proprietary names (INN) under which only a medicine from one manufacturer is registered in Ukraine.
[12]The prices for 310 accepted proposals were compared on the basis of MoH procurement procedure in 2014 under centralized programs.
[13]A drug patent authorizes the patent owner (a pharmaceutical company) to prohibit importation and manufacturing of the medicines which use patent-protected invention.
[14]According to the WHO report (Local production for access to medical products: developing a framework to improve public health, 2011, pg. 58) the countries, depending on the national pharmaceutical industry development level, may select different level of intellectual property rights protection to ensure maximum access for their domestic manufacturers to the existing pharmaceutical technologies and know-how by limiting the applicability of exclusive rights to medicines.
[15]Based on BBC News: Richard Anderson. Pharmaceutical industry gets high on fat profits bbc.co.uk/ukrainian/business/2014/11/141110_pharmaceutical_industry_dk?ocid=socialflow_twitter

million or 33.6% of the total procurement expenditures volume in 2014. If patented branded medicines could be substituted with their generic versions available on global markets. With the average price of the most widespread treatment regimes (TDF+FTC+EFV, AZT+3TC+EFV) being UAH 2815.98, such savings could support the treatment for 45 671 new patients.

STATE EXPENDITURES FOR ANTIRETROVIRALS IN 2014, POTENTIAL SAVINGS

UAH 383.1 MILLION

COST OF PROCURED ARV DRUGS

UAH 254.1 MILLION/67%

PRICE IF GENERIC VERSIONS WERE PROCURED

UAH 128.6 MILLION/33%

POTENTIAL SAVINGS

This amount could allow initiating treatment for additional 45 600 patients.

PATENTED ARV DRUGS AND THEIR GENERIC VERSIONS: POTENTIAL SAVINGS IN 2014

International non-proprietary name	Number of patients which need the treatment with this medicine	Percentage of expenditures for this medicine in the total ARV budget	Procurement price of the medicine ($/tablet)	Potential generic price ($/tablet)	Potential savings from procurement of generics ($/year)
Lopinavir/ritonavir 200/50 mg	25 649	47,5 %	$ 0,39 AbbVie	$0.2 Aurobindo, Global Fund, Belarus 2012	$ 5 111 357,53
Tenofovir/Emtricitabine /Efavirenz 300/200/600 mg	6 210	10,6 %	$ 1,65 Merck Sharp & Dohme	$0.49 Aurobindo, Global Fund, Moldova 2013	$ 1 466 392,44
Abacavir 300 mg	7 133	9,48 %	$ 0,39 Glaxo Smithkline	$0.19 Aurobindo, Global Fund, Georgia 2013	$ 980 497,25
Darunavir 600 mg	207	3,94 %	$ 7,32 Janssen	$ 1,50 Hetero, Medecins Sans Frontieres, 2014	$ 643 632,84
Raltegravir 400 mg	97	1,95 %	$ 8,63 Merck Sharp & Dohme	$ 2,40 Hetero, Medicins Sains Frontieres, 2014	$ 267 460
Etravirin 100 mg	21	0,45 %	$ 3,24 Janssen	$ 0,3 Janssen, Medicins Sains Frontieres, 2014	$ 104 615,28

DUBIOUS BENEFITS OF DRUG PATENTING IN UKRAINE

As we know, the patents are issued to facilitate innovations and R&D. However, patent protection itself does not ensure research and development progress in the pharmaceutical industry and at times, may even hinder innovation.

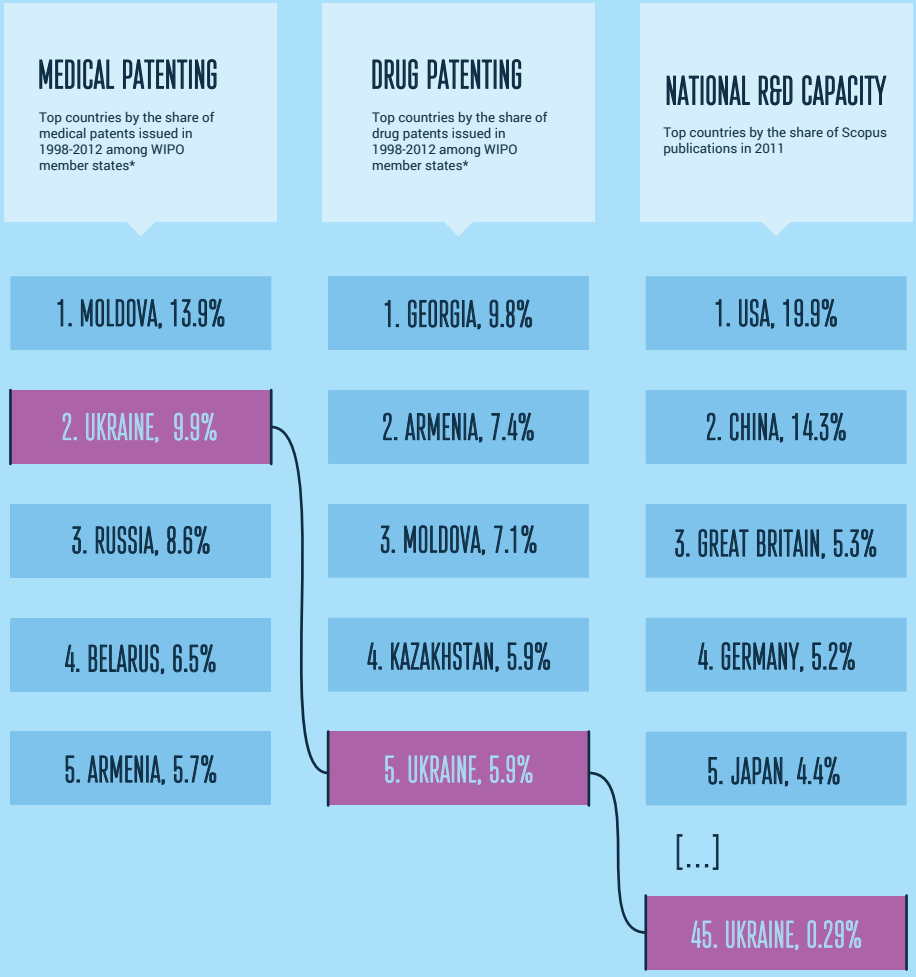
According to the data of the World Intellectual Property Organization (WIPO), Ukraine is the second in the world by the percentage of patents issued in medical technologies (9.91%) and the fifth in the pharmaceutical industry (5.54%) of the total number of patents issued in all technology spheres in 1998-2012[16].

Meanwhile, such a large percentage does not seem to match the existing R&D capacities of Ukraine and should be attributed to the imperfection of the national patent system. This point is supported by the Scopus international database showing that in 2011 Ukraine was holding only the 45-th place among 76 countries published in this database. Ukraine's contribution to the total number of publications in this database was 0.29 %. For comparison, for Europe this indicator is 29.8%, for the USA — 19.9%, for China —14.3%, for Japan —4.42 %, for India —3.39 %, and for Russia —1.49%.

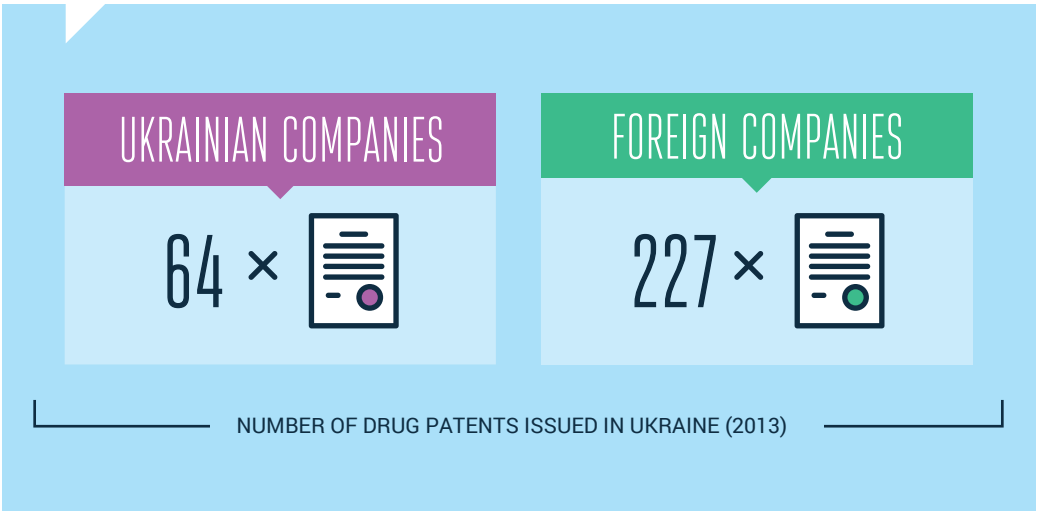
Thus, being at the bottom of international scientific and metric database ratings on global scientific achievements recognition, Ukraine, at the same time, is second after Moldova in the number of patents in the medical field.

[16]According to the statistical data regarding the number of patents issued in medicine, from 1998 to 2012 among the WIPO member countries: Moldova holds the first place with 13.86 %, Ukraine – the second (9.91 %), followed by Russian Federation – 8.55 %, Belarus – 6.51 %, Armenia – 5.74 %. According to the ratio of patents for pharmaceuticals to the total number of patents issued in a country from 1998 to 2012 Ukraine takes the 5-th place: Georgia – 9.78 %, Armenia – 7.38 %, Moldova – 7.08 %, Kazakhstan – 5.94 %, Ukraine – 5.54 %.

MEDICAL PATENTING AND SCIENTIFIC CAPACITY



*World Intellectual Property Organization



Ukrainian society has gone a long way towards recognizing the social value of intellectual property. Instead, in the early 2000-s, the national legal intellectual property doctrine placed inventor's rights above social interests[17]. Intellectual property rights can be seen as absolute, as is seen in case law, which tends to protect the patent rights to medicines. In the majority of cases the patent protection claims for pharmaceutical inventions are satisfied[18].

Meanwhile, the patent system of Ukraine regarding the medicines mostly protects the patent rights of foreign industries. According to the data from the State Intellectual Property Service of Ukraine, in 2009 to 2013 foreign companies obtained on average three times more drug patents than Ukrainian domestic companies. For example, in 2013 national owners obtained 64 drug patents, while foreign companies obtained 227[19].

[17] Oksana Kashyntseva. Human rights and intellectual property rights from the perspective of the modern science ethos // - Intellectual property theory and practice. - 2012. - № 6; Concept development of scientific field «Harmonization of human rights and intellectual property rights in healthcare and pharmaceuticals» // (available in Ukrainian; electronic access: ndiiv.org.ua/en/kontseptsija.html); Yaroslav Iolkin, Intellectual Property Rights and Access to Medicines: Trademark Aspect // Fifth National Congress on Bioethics (September 23-25, 2013, Kyiv).

[18] See Decision of the Commercial Court of the city of Kyiv dated 16.05.2008 in case No. 12/381 [Electronic resource]. – Accessible at:reyestr.court.gov.ua/Review/2803858; Decision of the Commercial Court of the city of Kyiv dated 04.03.2013 in case No. № 39/245 [Electronic resource]. – Accessible at: reyestr.court.gov.ua/Review/29785746; Decision of the Commercial Court of the city of Kyiv dated 16.11.2012 in case No. № 20/155 [Electronic resource]. – Accessible at: reyestr.court.gov.ua/Review/27598546; Decision of the Commercial Court of the city of Kyiv dated 02.04.2012 in case No. 39/247 [Electronic resource]. – Accessible at: reyestr.court.gov.ua/Review/22604176; Resolution of the Commercial Court of the city of Kyiv dated 20.11.2007 in case No. 41/491-A [Electronic resource]. – Accessible at: reyestr.court.gov.ua/Review/1313801

[19] See Annual Report of the SIPS of Ukraine for 2013, sips.gov.ua/i_upload/file/zvit-2013-ua.pdf

Moreover, according to data provided by WIPO for 2013, about 154 patent applications submitted from Ukraine entered the national phase in accordance with the PCT Convention, while 2,280 national phases of international patent applications were initiated in Ukraine under the PCT convention. For comparison, the European countries being home to the largest pharmaceutical companies, Switzerland, Great Britain and France, have the following figures:

Country	International patent applications which reached national phase	International patent applications sent by residents to the national phase globally
Switzerland	75	21 913
Great Britain	2 381	19 020
France	___	28 534
Ukraine	2 280	154

Thus, Ukraine makes practically no use of the international patent system due to a standstill in research and development activities. At the same time, according to a World Bank study, in 2005, there was no correlation between enhanced intellectual property rights protection and attracting foreign investments[20]. Besides that, given the strict protection of intellectual property rights, foreign companies are less motivated to open local offices in a country where the legal system ensures complete absence of competition on the market.

Extremely efficient IP rights protection also leads to a considerable negative balance of IP-related payments. In particular, despite the fact that Ukraine has a positive foreign trade balance in services, when it comes to royalty payments

[20] World Bank, Global Economic Prospects 2005. Washington, 2005, pg. 110
siteresources.worldbank.org/INTGEP2005/Resources/gep2005.pdf

and related services, IP import exceeded IP export by almost 9 times in 2013[21]. According to the World Bank data, in 2014 Ukraine obtained $118 million for using IP rights, while it had paid for the same rights almost five times more, $552 million.

At the same time, in 2014 several pharmaceutical giants, such as Pfizer, Hoffmann-La Roche, AbbVie, Glaxo SmithKline (GSK) and Eli Lilly, obtained profit margin of 20% and more. Pfizer, the biggest global pharmaceutical supplier in terms of revenues, reached a soaring 42% of profitability. In comparison, a wave of indignation hit Great Britain when the national energy regulator publicized the forecast requiring the increase of energy companies' profitability from 4% to 8% during the year[22].

90% of all large pharmaceutical companies sales are generated in developed countries, and only 5-7% of the profits come from sales in the developing countries (low income and middle income countries, Ukraine pertaining to the latter category)[23]. Moreover, 88% of the profits of multinational pharmaceutical companies from the new medicines are obtained in the U.S., the EU and Japan.

In 2012 multinational pharmaceutical companies invested 14.4% of their net revenues in the research and development of the new medicines[24]. However, despite high prices and the profits of pharmaceutical companies, during the last 13 years, we have witnessed a drug innovation crisis, states independent expert

[21] See the structure of export and import by types of services, State Statistics Committee, 2013 ukrstat.gov.ua/operativ/operativ2013/zd/str_eip_kv/str_eip_kv_u/str_eip2013_u.htm
[22] Richard Anderson. Pharmaceutical industry gets high on fat profits bbc.co.uk/ukrainian/business/2014/11/141110_pharmaceutical_industry_dk?ocid=socialflow_twitter
[23] Frederick M. Abbott and Carlos M. Correa, World Trade Organization Accession Agreements: Intellectual Property Issues, Quaker United Nations Office, 2007, p. 36 papers .ssrn.com/sol3/papers.cfm?abstract_id=1915338
[24] See EFPIA report for 2014, efpia.eu/uploads/Figures_2014_Final.pdf pages 4 and 10.

organization Prescrire. According to this research, the majority of new medicines, that is about 1,300 products, are not innovative in any way and do not meet actual healthcare needs. 14% of these medications are worse than existing ones in terms of view of safety and efficacy or do not bring any benefits. 65% do not have any real added therapeutic value, while only 20% of the new medicines are potentially useful. These findings are consistent with the data of many other facilities and research centers[25].

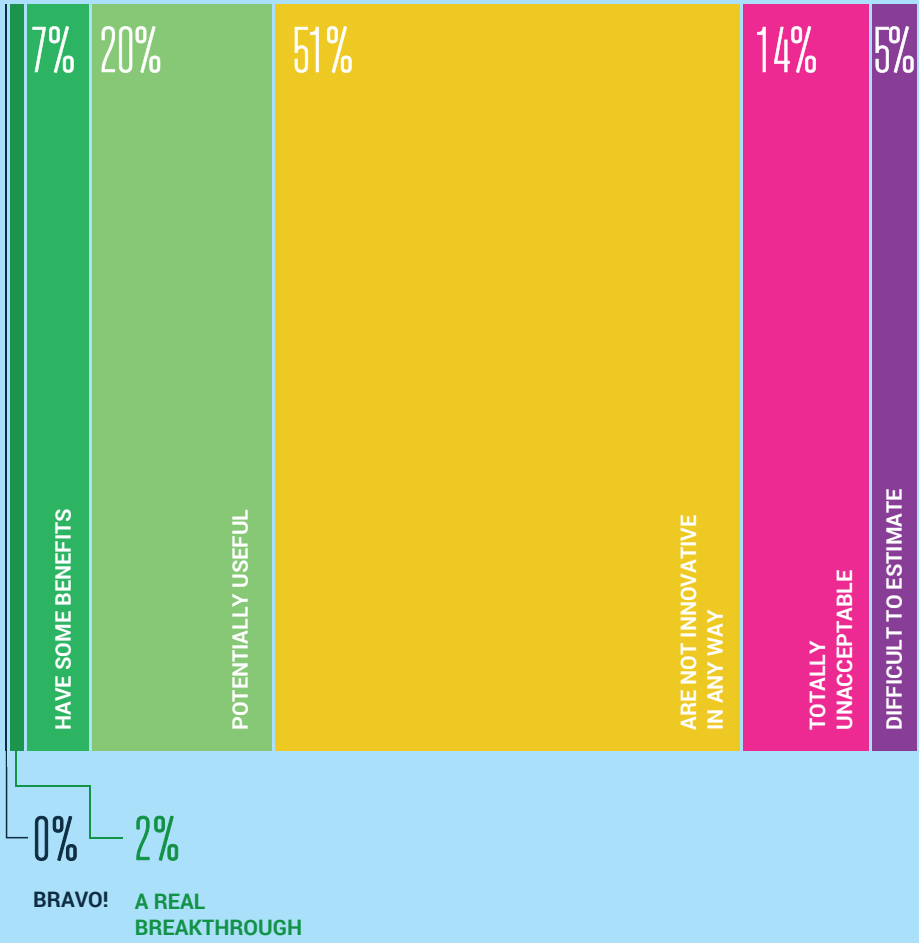
> Most of the new medicines do not meet actual healthcare needs or are not innovative in any way

Thus, a balanced approach from Ukrainian government to the protection of drug patent rights is necessary. The use of TRIPS flexibilities will not significantly affect the incomes of the key pharmaceutical market actors and development of new medicines on the international level.

According to the World Bank data, Ukraine is a developing country, thus, the use of international flexibilities in the field of intellectual property is justified.

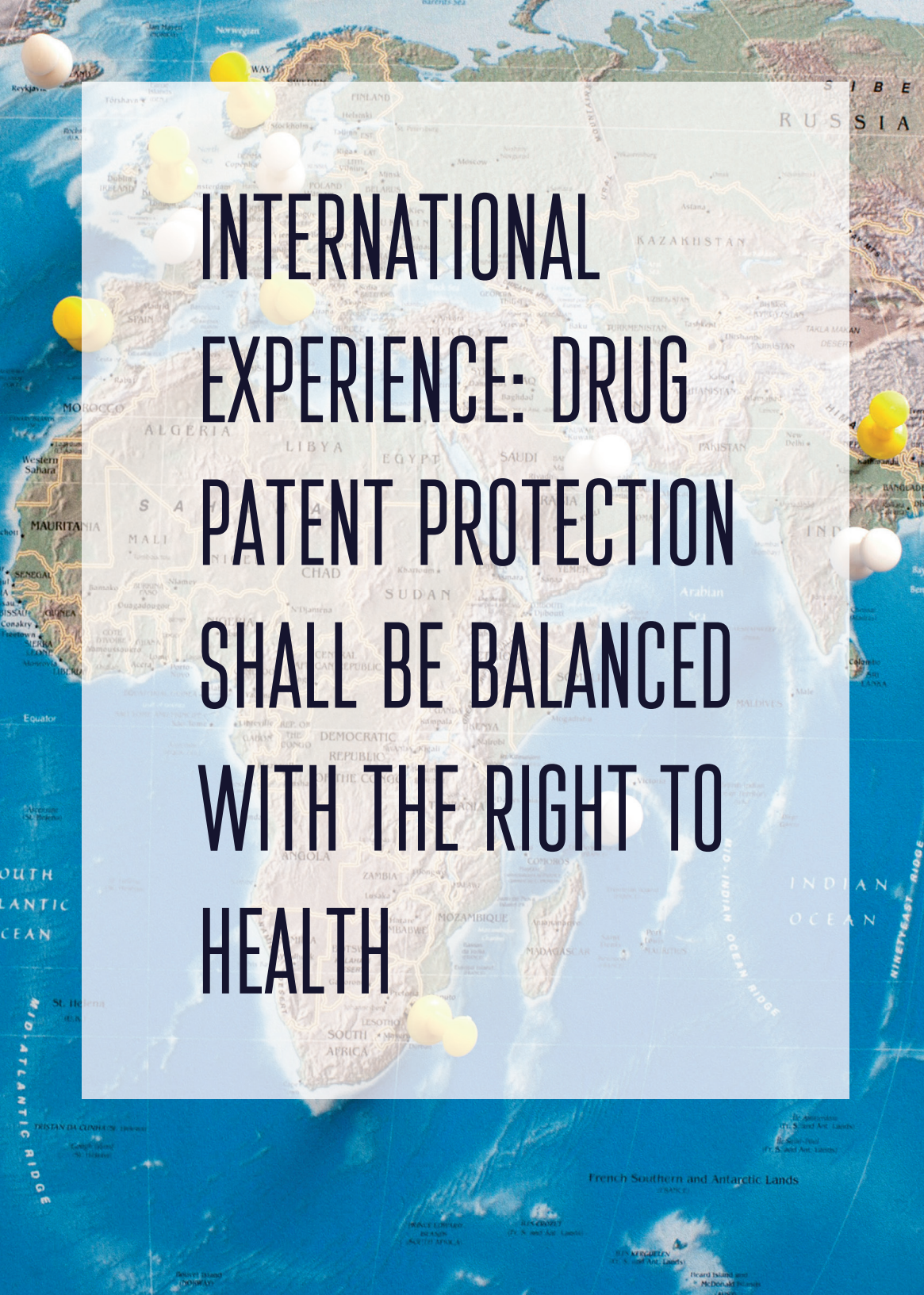
[25] According to Teresa Alves, Prescrire tacd-ip.org/archives/1252

EFFICACY LEVEL OF THE NEW MEDICINES



According to the Prescrire rating for 1345 new medicines which emerged between 2000 and 2013

tacd.org/wp-content/uploads/2014/11/EU-Parliament-12-November-2014-TA-version-finale-Teresa-Alves.pdf


INTERNATIONAL EXPERIENCE: DRUG PATENT PROTECTION SHALL BE BALANCED WITH THE RIGHT TO HEALTH

“The developed countries, having taken full advantage of the Paris Convention provisions to strengthen the innovative capacities of their pharmaceutical companies, are now denying the same privileges to the developing countries. This is morally unwarranted in a civilized society”.

K. Balasubrabanyam. Access to Medicines: Patents, Prices and Public Policy — Consumer Perspectives

The countries which used WTO TRIPS flexibilities and considerably simplified the bureaucratic mechanisms to allow generic pharmaceutical manufacturers to enter the market have managed to significantly decrease their expenditures on essential medicines.

MALTA

The Maltese government managed to provide incentives to pharmaceutical companies in order for them to balance their pricing policy by:
- Establishing legislative guarantees of recognizing the registration dossiers of EU member states;
- Introducing privileged conditions for establishment of the pharmaceutical companies' representative offices and national subsidiaries;
- Ensuring the absence of patent linkage between the registration of a drug and a patent for it.

* Electronic access:
justiceservices.gov.mt/LOM.aspx

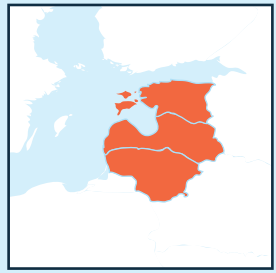
** Electronic access:
ccmalta.com/pharmaceutical-biotech

The countries that at least declared the necessity and readiness to use international IP legislation flexibilities managed to obtain a price reduction from pharmaceutical companies.

LATVIA, LITHUANIA, ESTONIA

In the Baltic countries the patients who have to take lifetime ARV therapy receive compensation from pharmaceutical companies.

Pharmaceutical companies were forced to offer such financial privileges due to efforts from the community and the government's political will to issue compulsory licenses.



Based on the materials of the workshop "Intellectual property, human rights and access to medicines", Open Society Institute. – September 14-18, 2009, Kyiv

The main directions of a greater-balanced approach towards patent rights protection in pharmaceutical field in developing countries would be implementation of a patent reform and compulsory licensing.

Pharmaceutical companies often receive unmerited patents

Patent reform in the pharmaceutical field is the establishment of mechanisms that would establish a balance between protecting rights to inventions and the best interest of the public (for example, the mechanisms which would ensure granting only high quality patents to truly innovative medicines).

PATENT REFORM

The history of developed countries demonstrates that a «loose» or balanced patent regime can be more acceptable for developing countries. For example, the Netherlands cancelled the validity of chemical patents for 47 years (1869-1970) in order for for the country to be able to freely imitate German inventions[26]. A retrospective review of establishing rigid healthcare monopolies via IP mechanisms shows that such developed countries as France, Germany, Italy, Japan, Sweden and Switzerland firmly opposed the necessity to implement drug patenting provisions in their national legislation until their national pharmaceutical industries achieved a respective competitive level. Thus, France started patenting medicines in 1960, Germany — in 1968, Switzerland — in 1977, Italy and Sweden — in 1978[27].

Similarly, the Asian economies in 1960s-1980s supported imitation and reverse engineering. For example, when South Korea introduced patents in 1961, their validity term was limited to 12 years and they were not applicable to nutritional technologies, pharmaceutical industry and chemical industry. India, having the third largest pharmaceutical industry in the world, was compelled to introduce patent protection of drugs only in 2005 because of WTO regulations.

Therefore, many developed countries used simplified protection systems, often violating the patent rights of other countries[28].

Because of the excessive workload at patent offices, understaffing and low requirements for patents, pharmaceutical companies obtain patent monopolies, which do not actually comply to the universally acceptable patentability standards — novelty and innovation level. Patent reforms initiated in 2013 in Brazil and South Africa are an attempt undertaken by their national governments to solve

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[26] Adam b. Jaffe and Josh lerner, Innovation and Its Discontents – How our Broken Patent System is Endangering Innovation and Progress, and What to Do About it, princeton, 2004, стор. 86-90.
[27] Великобритания, Gowers Review of Intellectual Property, report by the government of the United Kingdom, 2006, стор. 59
gov.uk/government/uploads/system/uploads/attachment_data/file/228849/0118404830.pdf
[28] Brazil's Patent Reform: Innovation Towards National Competitiveness, 2013, стор. 225
infojustice.org/wp-content/uploads/2013/09/Brazilian_Patent_Reform.pdf

the problem of balancing the public health safeguarding with the patent rights protection.

In particular, Brazil relied on the following key arguments to support patent reform: non-residents were the main group to benefit from patent system functioning (75-80% of the patent applications were submitted by the non-residents); considerable decrease in the number of technology transfer agreements in pharmaceutical industry; the number of international patent applications submitted by the country's residents remained the same (0.3%) during 10 years of a strict patent protection regime; the budget deficit on foreign payments under IP rights increased by 36 times from 1993 to 2012 – from $86 million to $3.1 billion[29].

It should be noted that in the opinion of international experts the provisions suggested by South African and Brazilian patent reforms fully comply to the international standards, including the WTO TRIPS agreement, the Doha Declaration on the TRIPS Agreement and Public Health, and are supported by the international organizations, including WIPO, WTO, UNDP, UNAIDS, WHO[30].

[29] Ibid., pg 226-228.
[30] Brook Baker. US Pharma Bares its Fangs – South Africa Patent Law Reform and Access to Medicine at Risk Yet Again, 18 January 2014 infojustice.org/archives/31986

COMPULSORY LICENSING

Compulsory licensing implies granting governmental authorization to the third party to use intellectual property without the patent owner's consent and subject to payment of remuneration to the owner. International practice shows that compulsory licensing is an effective measure to create conditions for the rapid growth of the competition, which results in lowering price for a particular medicine.

> Licensing is an effective tool for fostering competition

It is a widespread practice, especially in the European countries. For instance, during antitrust investigations the government of Italy has granted a compulsory license to the combination of antibiotics imipenem+cilastatin (2005), medicine for migraine headache treatment - sumatriptan succinate (2006), and medicine for prostate cancer treatment – finasteride (2007).

INTERNATIONAL COMPULSORY LICENSING EXPERIENCE

THAILAND/2006-2008

Due to the use of compulsory licenses the price of ARV medicine Efavirenz decreased sevenfold. Prices on Docetaxel decreased by 24 times, while prices on Letrosol decreased by 70 times.

BRAZIL/2007

The local manufacturing of a generic antiretroviral drug - Efavirenz began. This allowed to decrease its cost from $1.56 to $0.45 per tablet. Thus, the country managed to save $237 million in 5 years.

ECUADOR/2009

By importing an Indian generic clone of Lopinavir/Ritonavir, an antiretroviral drug, the country managed to save $150,000.

DIRECTIONS AND WAYS OF PATENT LEGISLATION REFORM

The following actions may be taken by the Parliament and the government of Ukraine to ensure more balanced approach to protection of the drug patent rights

1. **Introducing more stringent patentability criteria for pharmaceutical inventions** — increasing invention level standards, strict application of absolute novelty and invention level criteria in order to prevent granting patents for drugs that are not innovative and to facilitate innovation.

2. **A ban on patents for new forms of substances which do not enhance their therapeutic efficacy** — a ban on patents for new uses of known substances, preclusion of the possibility to patent diagnostic and therapeutic treatment methods.

3. **Implementing pre-grant and post-grant patent opposition procedures within Ukrpatent** — enabling third parties to provide their arguments against granting a patent.

4. **Limiting the extention of patent duration** for more than 20 years regarding socially essential medicines.

5. **Implementation of non-commercial use within public health purposes, also known as governmental use** — the mechanism similar to compulsory licensing but it is more simplified. It is a less restrictive type of permission to use the invention without the consent of the inventor.

6. **Simplifying the procedure of the Cabinet of Ministers of Ukraine authorization to use the patented invention** (compulsory license) according to the Resolution No. 877 dated December 4, 2013 to increase the chances for this mechanism application.

7. **Limiting the applicability of registration data exclusivity** regimes and patent/registration linkage as set forth by Art. 9 of the Law of Ukraine «On Pharmaceuticals».

8. **Implementing the mechanism of approving a drug patent granting decision with a health care authority** (following the Brazilian lead).

9. **Implementation of the Bolar regulatory exclusion provision** — exclusion from patent protection allowing generic pharmaceutical manufacturers to prepare to the state registration of generic drugs before a patent expires (facilitates early market entry of the generics).

10. **Ensuring the possibility of parallel importation** — implementation of international or regional exhaustion regime enabling to import the originator drugs from other countries where they are sold at a lower price.

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