REPORT

on the legal analysis of TRIPS-plus provisions in Ukraine

ITPC
INTERNATIONAL TREATMENT PREPAREDNESS COALITION

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INTRODUCTION

One of the driving mechanisms for innovation is an effective legal system that provides for appropriate instruments for innovators' rights protection. The world community has already developed a large number of ways to safeguard and protect such rights. One of the most complex rights protection systems is related to innovations in the healthcare.

Despite the large number of researches and ideas in this area, the problem of choosing the most appropriate regime for balancing the pharmaceutical companies' interests with the interests of society is more relevant than ever, especially for developing countries.

The study explores three mechanisms aimed at strengthening the protection of originator's rights, namely extending the term of patent protection as compensation for delays in the regulatory procedure, patent linkage and data exclusivity.

Such mechanisms belong to the so-called TRIPS-plus provisions that contribute to longer and more robust protection of originator's rights. There are many discussions about health effects of such regimes.

Research object:
Legislation of Ukraine, foreign legislation, reports of international governmental and non-governmental organizations dealing with public health, intellectual property, etc., international experience in regulating data exclusivity and patent protection regimes.

Purpose:
To form the most appropriate model for balancing data exclusivity regimes, patent linkage and extending the patent protection period for Ukraine based on international experience.

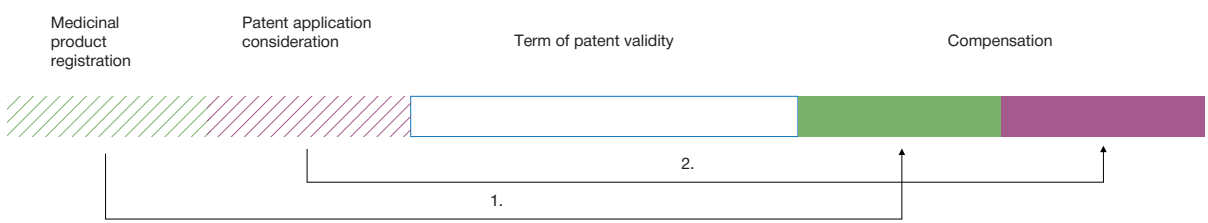
Issues:
- Legal framework for patent term extension in pharmaceutics and opportunities for limiting the regime in the public health sector.
- Legal framework for patent linkage in pharmaceutics and opportunities for limiting the regime in the public health sector.
- Legal framework for data exclusivity and opportunities for limiting the regime in the public health sector.

LEGAL FRAMEWORK FOR PATENT TERM EXTENSION IN PHARMACEUTICS AND OPPORTUNITIES FOR LIMITING THE REGIME IN THE PUBLIC HEALTH SECTOR

The nature of the regime

Patenting is the most direct way of monopolizing pharmaceuticals. A longer term of patent protection means a longer market monopoly, and hence less competition. Therefore, pharmaceutical companies are using all means to extend the life of a patent.

2 prerequisites for patent term extension:



One of available mechanisms is a compensation for marketing authorisation procedure provided for medicinal products. Since authorisation is a legally defined imperative prerequisite for the subsequent use of a medicine, a manufacturer loses part of the effective protection period due to the duration of such a procedure. In particular, the authorisation procedure may last up to 8-10 years depending on the country.

The WTO, explaining the necessity for supplementary patent protection related to delays in the regulatory procedure, states: "The effective period of patent protection for inventions of new chemical entities is much less than the full 20 years, because a large part of that period will have expired before marketing approval is obtained from the public health regulatory bodies. For this reason, most of the major developed countries have introduced systems whereby an extended period of protection can be obtained to compensate, at least in part, for this loss of the effective period of protection." [1]

The process of patenting itself may be long and in some countries may reach up to 8 - 10 years[2]. At the same time, the laws of some countries provide for the possibility of extending the term of protection for time delays by the patent authority ("patent term adjustment"). Examples of such mechanisms will be mentioned in the following sections.

Thus, the idea behind extending patent term protection is to compensate for the time taken for authorisation procedures, which is beyond the applicant's control. During an extended term of protection the patent owner shall enjoy the same amount of rights as before the expiry of the patent, unless otherwise provided by legislation.
From the manufacturer's perspective the purpose of patent term extension is obvious and involves achieving commercial goals.

However, when the need to preserve life and health of the people is on the scales along with commercial interests (especially in the least developed countries), the issue of extending the patent term raises a lot of questions and criticisms.

Patent term extension is considered as one of so-called TRIPS-plus provisions, which limit the scope of the freedoms provided by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Initially, the issue of patent term extension to compensate for regulatory delays in the marketing of new pharmaceutical products was raised in the Uruguay Round negotiations. At the same time, the TRIPS Agreement itself does not contain an obligation to implement such a mechanism.

Article 33 of the TRIPS Agreement stipulates that the available term of protection must expire no earlier than 20 years from the date of filing the patent application. However, there are no provisions for extending this term.

The principle of voluntary introduction of patent term extension is often declared in the international documents.[3] However, in practice such provisions are usually implemented into laws under pressure from developed countries.

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[1] https://www.wto.org/english/tratop_e/trips_e/pharma_ato186_e.htm#fntext1
[2] PhRMA. SPECIAL 301 SUBMISSION 2014. Costa Rica Experience.
[3] In the Doha Declaration; the 2008 WHO Global Strategy and Action Plan on Public Health, Innovation and Intellectual Property; in 2011 the United Nations Political Declaration on HIV / AIDS, etc.

Thus, the USA, concluding free trade agreements (FTAs), insists on patent term extension provision referring to the fact that Article 33 of the TRIPS Agreement establishes only a minimum term of protection. In their opinion, countries may and should introduce longer term of a patent aiming to preserve and encourage more foreign investments in the pharmaceutical sector.

Some free trade agreements require that automatic patent term extension was granted based on its extension in another country. For example, Article 14.8 (7) of the United States-Bahrain FTA stipulates that in case when a Party provides for the grant of a patent on the basis of a patent granted in another territory, that Party, at the request of the patent owner, shall extend the term of a patent by a period equal to the period of the extension, if any, provided in respect of the patent granted by such other territory.

It is worth mentioning that such a rigid position of the United States in bilateral or multilateral negotiations does not always correspond to the official position embodied in the documents. Thus, for example, it was explicitly stated in the 2007 New Trade Policy that the patent term extension is voluntary.

Nevertheless, the obligation on patent term extension is actively imposed upon developing countries through the relevant Free Trade Agreements, the Trans-Pacific Partnership Agreement (Articles 18.46, 18.48)[4]. It is also mentioned in the annual Special 301 Submission Report of the Pharmaceutical Research and Manufacturers of America of the USA (PhRMA)[5] as a flaw of legal systems that do not provide for such a provision.

The similar situation is with bilateral and multilateral agreements concluded between the European Union and developing countries. In particular, the EU also insists on the introduction of patent term extension provision in the partner states legislations. At the same time, it seems that the EU position is less stringent than the position of the USA, since the patent term extension provision is often worded as right not obligation. For example, Article 230 of the Trade Agreement between the European Union and its Member States, of the one part, and Colombia and Peru, of the other part, states that with respect to any pharmaceutical product that is covered by a patent, each Party may [note, not obliged], in accordance with its domestic legislation, make available a mechanism to compensate the patent owner for unreasonable curtailment of the effective patent term resulting from the first marketing approval of that product in that Party.[6]

The similar thing happened in the negotiations between the EU and India regarding the Free Trade Agreement. The position of the EU was as follows: "The Free Trade Agreement will not require India to introduce patent term extension, especially taking into account that, according to preliminary information, marketing approvals in India are provided promptly. Although this issue was initially proposed for discussion in the negotiations, the EU decided not to insist"[7].

[4] https://medium.com/the-trans-pacific-partnership/intellectual-property-3479efdc7adf#.udlvy6kzw
[5] http://www.phrma.org/sites/default/files/pdf/2014-special-301-submission.pdf
[6] http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=OJ:L:2012:354:FULL&from=EN
[7] http://trade.ec.europa.eu/doclib/docs/2013/april/tradoc_150989.pdf; http://trade.ec.europa.eu/doclib/docs/2010/may/tradoc_146191.pdf

Regardless of the fact that the patent term extension provision is actively lobbied by developed countries, it may be the subject of substantial concessions due to specific circumstances and the extent to which the position of the other country is justified.

Such experience could be useful for Ukraine, which also has more than strong arguments to discuss the issue rather than blindly implement European practice.

The position of the developed countries takes into account the interests of pharmaceutical companies to maintain a long-term monopoly on their inventions, but it does not always correspond to the realities of less developed countries, where the problem of treatment accessibility is acute.

Pros and cons of the regime according to the findings of international governmental and non-governmental organisations

Many different views have been expressed for and against the introduction of patent term extension in the pharmaceutical sector. However, there is no consensus and currently it is quite unlikely to reach one.

In particular, if in developed countries patent term extension may not have a significant impact on public health due to favourable conditions of access to treatment, such a mechanism may, on the contrary, be crucial in less developed countries. Therefore, the issue must be considered in the context of specific conditions, the level of country's development and the accessability of pharmaceuticals for the average consumer.

Some specific arguments for and against the extension of the patent term are as follows.

"Some argue that patent term extension prevents pharmaceuticals from entering the market, as it delays introduction of generics. Others believe that patent term extension has a positive influence on public health, since it supports and stimulates innovations in pharmaceutics and, as a result, increases access to medicine, and has a positive effect on public health in the long term." [8]

Such a summarized position of WHO, WIPO and WTO generally reflects, on the one hand, the motives of generic pharmaceuticals companies and the population, which requires lower prices for existing pharmaceuticals, and, on the other hand, the position of major pharmaceutical companies interested in preserving their monopoly.

Other WHO researchers state that enhanced patent protection encourages innovation: "The 2005 study points out that stronger patent protection encourages companies to launch new drugs more quickly." [9]

Thus, pharmaceutical corporations and those advocating their views, in most cases, appeal to promoting innovation by extending the term of patent protection, but for obvious reasons, they do not mention their desire to earn extra profit from extending patent monopoly.

A different view about the impact of patent term extension on innovation was expressed in the study conducted in the USA following the amendments to the law in 1984, which, among other things, introduced a patent term extension mechanism. Assessing the impact of the 1984 Innovation Act, the Congressional Budget Office stated:

"overall, it appears that the incentives for drug companies to innovate have remained intact ..." [10]

In other words, this study did not establish any increase in the contribution of manufacturers to research work in connection with granting them extended patent protection. However, in the same study, the conclusion stated as follows:

"Still, those extensions played an important role in protecting the returns from drug companies' research and development. Without them, the rise in generic market share since 1984 would have dramatically lowered the expected returns from marketing a drug and might have caused the pharmaceutical industry to reduce its investment in R&D. In that case, a successful innovator drug would have been likely to lose over 40 percent of its market to generic competitors just after reaching its peak year in sales."

[8] Promoting access to medical technologies and innovation. WHO, WIPO, WTO, 2013.
[9] Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry, Paper prepared for WHO, 2005.
[10] Congressional Research Service Report RL30756, Patent Law and Its Application to the Pharmaceutical Industry:
An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 (The Hatch-Waxman Act), January 10, 2005

The European Commission, substantiating the necessity for the inclusion of the patent term extension in the legislation of EU's partner countries, explains this as follows:

"Extending patent term protection is a mechanism aimed at solving the problem of delays in considering applications for obtaining marketing approvals. (...) extension of the patent term is intended to restore the effective period of protection lost because of the regulatory procedure, in connection with which the term "renewal of the patent" is more appropriate for "extending of the patent". [11]

In the Regulation 469/2009 concerning the supplementary protection certificate for medicinal products, the following arguments are in favour of the procedure for extending patent term protection: "this mechanism is intended to restore the balance between investments and profits in the pharmaceutical sector, which, in connection with over-regulation, remains on average 8-11 years to benefit from the patent for a new medicine. The supplementary protection certificate aims at restoring competitiveness."

Doctors Without Borders (Médecins Sans Frontières, MSF) draws attention to the negative side of extending the patent term in their address to the Congress on the terms of the Trans-Pacific Partnership Agreement (TPP)[12]:

"The most concerning provisions of the Agreement are the extension of the patent term after 20 years of protection, when the patent office exceeds certain processing period and when the patent owner claims delays in the regulatory procedure. Adjustment of the patent term significantly delays the market entry of generic pharmaceuticals. (...) By expanding the pharmaceutical companies' monopoly, the terms of the TPP agreement restrict generic medicine competition and thus prices soar beyond the reach of the country - both here [in the US] and transferring this system to 11 other TPP countries and those that can join later, including countries with low incomes, where resources are limited, and most citizens are forced to buy pharmaceuticals at their own expense".

The World Health Organization is commenting on the similar provisions of the Free Trade Agreement:

"The current trend in the Free Trade Agreements is, among other things, a requirement for developing countries to introduce into their legislations a patent term extension condition due to delays in the regulatory procedure, both in the field of medicine approval and in obtaining a patent. Such an approach has significant negative consequences for public health. The persuasion of the US that such innovations will not interfere with the implementation of the TRIPS provisions in public health sector does not provide adequate answers to questions that arise."[13]

Doctors Without Borders draws attention to additional negativity of the mechanism in connection with patent processing delays, describing the situation in Brazil:

[11] http://trade.ec.europa.eu/doclib/docs/2013/april/tradoc_150989.pdf
[12] https://www.doctorswithoutborders.org/sites/usa/files/us_tpp_public_health_letter_12_april_2016_updated_18_april.pdf
[13] "The use of TRIPS flexibilities by developing countries: can they promote access to pharmaceuticals?", WHO, 2005.

"Extending the patent validity not only prolongs the term of patent protection without need, but also imposes excessive pressure on patent experts, who handle thousands of unsubstantiated applications on receiving of patents from multinational pharmaceutical companies." [14]

UNDP and UNAIDS comment on the potential impact of Free Trade Agreements and, in particular, their patent term extending provisions on public health:

"There is growing evidence that TRIPS-plus provisions may adversely impact medicine prices and consequently, access to treatment. To retain the benefits of TRIPS flexibilities, countries should at least avoid entering into FTAs that contain TRIPS-plus provisions that can affect drugs price or accessability. Where countries have undertaken TRIPS-plus provisions, all efforts should be made to mitigate the negative impact of these provisions on access to treatment by using to the fullest extent possible, remaining public health related flexibilities available." [15]

PhRMA association commented on the state of compliance with intellectual property rights in the pharmaceutical sector and the necessity to extend the term of protection:

"A prerequisite for ensuring that a patent owner can enjoy the commercial benefits of its IP rights to the fullest extent possible is a patent office in each market that grants patents on eligible inventions within a reasonable period of time, and a regulatory approval authority that grants timely marketing approval. However, in some countries (including most developing countries and even developed countries like Canada), there are unreasonable patent or marketing approval backlogs that raise uncertainty as to whether an invention will be protected in a meaningful way at all in that market. These backlogs seriously erode the patent term enjoyed for these inventions and, unlike in the United States, there is no mechanism to extend the patent term to offset any of the delays." [16]

[14] MÉDECINS SANS FRONTI RES ACCESS CAMPAIGN. WHY BRAZIL SHOULD REFORM ITS PATENT LAW AND BOOST MEDICAL INNOVATION TO PROMOTE ACCESS TO PHARMACEUTICALS.
[15] UNDP, UNAIDS "THE POTENTIAL IMPACT OF FREE TRADE AGREEMENTS ON PUBLIC HEALTH", 2012
[16] PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA). SPECIAL 301 SUBMISSION 2014

Regulation in foreign jurisdictions

Jurisdiction	Patent term extension	Legislation
EU countries	Supplementary protection certificate (SPC) may be obtained. • An extension term equals to the period which elapsed between the date on which the application for a basic patent was filed and the date of the first authorisation to place the product on the market in the Community (MA), reduced by a period of 5 years. • The duration of SPC may not exceed 5 years. • The application for a certificate shall be filed within 6 months of the date on which the MA was granted (or a patent was granted, if it comes later). • The certificate may be extended by 6 months only for medicinal products for paediatric use.	Regulation 469/2009 Regulation 1901/2006 (immediately enforceable as law in all member states)
Switzerland **Norway** **Iceland** **Macedonia** **Albania**	SPC obtaining procedure is similar to the procedure under the EU legislation.	
USA	1. Patent Term Extension. The term of a patent shall be extended by the time equal to the regulatory review period for the approved product. The total patent term remaining after obtaining an approval may not exceed 14 years. An application may only be submitted within 60 days beginning on the date the product received marketing approval. 2. Patent Term Adjustment. Patent term may be automatically extended if the period of processing an application at the USPTO exceeds 3 years.	35 U.S.C. § 156 35 U.S.C. § 154
Canada	No patent term extension is provided.	

Jurisdiction	Patent term extension	Legislation
Japan	Patent term may be extended for up to 5 years. • The application for patent term extension is submitted within 3 months from the moment the product received marketing approval.	Patent Act, Art. 67 (2)
China	No patent term extension is provided.	
New Zealand	No patent term extension is provided.	
South Korea	Patent term may be extended for up to 5 years. • The application for patent term extension is submitted within 3 months from the moment the product received marketing approval, but not later than 6 months from the moment of the patent term expiration. It is possible to adjust the patent term due to delays at the patent office, i.e.more than 4 years from the moment of applying for registration, or 3 years from the moment of applying for examination. The application shall be submitted within 3 months from the moment of payment patent issuance fee.	Patent Act Art.89-92(2)
Singapore	Patent term may be extended for up to 5 years. • The period between the date of applying for authorisation and granting an authorisation takes 2 years or more. • The application for patent term extension is submitted within 6 months from the moment a patent or a permission was granted whichever occurs later. The patent term extension is possible due to delays in the processing of a patent application. The extension shall be requested within 6 months from the date the patent was granted.	Patent Act, Art. 36 A
Taiwan	Patent term may be extended for up to 5 years. • The maximum term of extension can be requested only if the regulatory reviewing period exceeds 5 years. • The application shall be submitted within 3 months from the moment the product received marketing approval. In any case, applications for extension are not accepted within the last 6 months of the patent term protection.	Patent Act, Art. 53, 147
Vietnam	No patent term extension is provided.	

Jurisdiction	Patent term extension	Legislation
Australia	Patent term may be extended for up to 5 years. • The term of the extension is equal to the period beginning on the date of the patent application and ending on the earliest first regulatory approval date reduced by 5 years.	Patent Act 1990, Art. 70–79
Israel	Patent term is extended for up to 5 years. Israel also accepts extension of related patents based on patents extension in the USA, Italy, Great Britain, Germany, Spain and France. The patent term after extension should not exceed 14 years from the moment the product received marketing approval in one of abovementioned countries.	Patent Law, Art. 64
Colombia	No patent term extension is provided.	Patent Act Art.89-92(2)
Peru	No patent term extension is provided.	
Brazil	Generally patent term extension is not provided. However, in cases, when the National Institute of Intellectual Property (INPI) unreasonably delays the examination procedure for more than 10 years, the patent term should be 10 years from the moment the patent is granted.	Industrial Property Law, Art. 40
Chile	The patent term may be extended due to the delays in the regulatory review procedure. Unlike other countries, the extension period is not limited. • Requirements: the regulatory review period exceeds 5 years from the moment of applying or 3 years form the moment of initiating the examination, whichever occurs later. • Request for patent term extension is filed to the Court of intellectual property within 6 months from the moment the patent is granted. • Decision is made after hearing the case.	Industrial Property Law, Art. 53bis 2
Georgia	Patent term may be extended for up to 5 years. The application may be submitted within 1 year from the moment the marketing approval is granted.	Patent Law, Art. 5

Jurisdiction	Patent term extension	Legislation
Argentine	No patent term extension is provided.	
Mexico		
Turkey		
India		
Thailand		
The Russian Federation	Patent term extension is provided for the period which elapsed between the date of filing a patent application and the date the product received its first marketing approval reduced by 5 years. The extension term may not exceed 5 years. The applicant is provided with additional patent. The application for patent term extension is filed within 6 months from the moment a patent or a marketing approval was granted whichever occurs later.	The Civil Code of the Russian Federation, Article 1353
Belarus	Procedure is similar to the one in the Russian Federation.	Civil Code of the Republic of Belarus, Article 1002
Indonesia	No patent term extension is provided.	
The Republic of South Africa	No patent term extension is provided.	
Morocco	The term of extension is equal to the number of days that have elapsed from the specified date of the marketing approval to the actual date it was granted. The extension term may not exceed 2.5 years. The application may be submitted within 3 months from the moment the patent is granted. In case of patent term extension, the certificate shall be granted.	Law on the Protection of Intellectual Property, Art. 17.3 – 17.6

Jurisdiction	Patent term extension	Legislation
Moldova	SPC may be obtained. Patent term extension is possible for the period which elapsed between the date of filing a patent application and the date the product received its first marketing approval reduced by 5 years. The extension term may not exceed 5 years. The application for patent term extension is submitted within 6 months from the moment a patent or a marketing approval is granted whichever occurs later.	Law on the Protection of Inventions, Art. 69–72
Liechtenstein	Patents and supplementary protection certificates of Switzerland are recognized in Liechtenstein. Liechtenstein does not provide any certificates.	Treaty between Switzerland and the Principality of Liechtenstein
The UAE	No patent term extension is provided.	
Egypt	No patent term extension is provided.	

Balancing the regime with public health

National legislation allows patent term extension under certain conditions, and determines the mechanisms of balancing such a regime with public interests.

Bolar provision

Patent term extension is often considered along side so-called “Bolar provision”, or “early working exception”. Its main idea is that the invention may be used during the patent term for research and testing in order to obtain a marketing approval. Such use does not require the consent of the patent owner and accordingly does not constitute a violation of rights.

Bolar provision facilitates the fastest possible market entry of the generic after the expiration of the patent. Otherwise, we would have a situation when the originator retains actual market monopoly even after the expiration of the patent.

Many countries have incorporated Bolar provision in their laws, although its scope varies, sometimes quite substantially, from country to country.

In the European Union, the scope of Bolar is stipulated in Directive 2001/83/EC. In particular, Article 10 (6) states that conducting the necessary studies and trials shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.

Despite the existence of such a provision in the Directive, its implementation by the EU Member States differs. For example, in Belgium, the Netherlands, and Sweden this provision is limited to the purpose of obtaining authorisation to place the product on the market within the EU, while in Germany - both within the EU, the European Economic Area, and beyond. The laws of India, the Philippines, establish a similar wide-ranging exception. In Israel, the Bolar exemption applies both to obtaining an internal permission to place the product on the market and a permission in another country that also recognizes Bolar.

There are countries that do not have a clearly defined Bolar provision but allow experimental and scientific research, which is a similar mechanism.

For example, a patent legislation of Japan, does not contain a Bolar provision, but similar exception was established by courts in course of interpretation of the provision on experimental research (judgment of the Supreme Court of Japan of 16.04.1999).

Patent term extension requirements

Safeguards guaranteeing balance of the patent term extension with public interests are a limited time of using this right, and a statutory procedure of extension.

Clear requirements help to prevent abuse of patent rights and establish objective basis for regulating body decision.

Thus, the EC Regulation 469/2009 concerning the supplementary protection certificate sets the following terms for obtaining it:

(a) the product is protected by a basic patent in force;
(b) a valid authorisation to place the product on the market as a medicinal product has been granted;
(c) the product has not already been the subject of a certificate;
(d) the authorisation referred to in point (b) is the first auth¬orisation to place the product on the market as a medicinal product.

In addition, the applicant has a limited 6-month period to initiate obtaining a certificate, unless he/she is deprived of such a right. In such case both society and interested generic pharmaceuticals companies can calculate the patent expiration date and be aware that it will not be subsequently extended for an indefinite period of time.

Other than that, the legislation of a number of countries stipulates the procedure for establishing a "groundless delay" in the regulatory procedure as a basis for patent term extension. In such cases, the extension term is determined not automatically, but calculated with due consideration of a groundless delay.

Thus, for example, the legislation of Singapore defines clear terms for processing documents by the Patent Office, and defines actions that do not belong to groundless delays in the procedure. For example, such delays do not include a waiting period (from the moment of sending notification to an applicant to the receipt of a response from the latter).

A similar approach is applicable in South Korea.

Legislation of Chile also defines which actions do not fall within "groundless delays", namely filing of objections or any injunction in respect of the application filed; the time required to obtain reports or other procedures with national or international bodies; actions or inactions of an applicant.

Besides, in Chile, the court decides on patent term extension after verifying whether delay was groundless. The parties are entitled to exchange statements; the regulator should explain the reasons of delay.

Opposing the grant of an extension or cancellation of such extension

This mechanism of balancing the regime with public interest is common in the jurisdictions allowing patent term extension.

For instance, under the laws of Israel, any person may oppose to the authority the grant of extension within 3 months from the date the notification on possible extension was published. Opposition may be filed on any ground that constitute a reason to dismiss patent term extension application.

Legislation of Australia sets following grounds for opposition: the application for extension of the patent (section 70) and the form and timing of the application (section 71) have not met the requirements of the law. An opposition may be filed by the Minister or by any third person. If it is based on grounds not specified by law (Articles 70-71 of the Patents Act), it will not be considered.

At the same time, Article 19 (2) of the EU Regulation concerning the supplementary protection certificate excludes the procedure for opposition to the granting of a certificate.

However, as practice shows, national regulators of the EU Member States may take into account the explanations of third parties when deciding on the extension.

For example, the UK Intellectual Property Office explains that although it is not allowed to oppose issuance of a certificate, an expert will consider any written observations filed by a third party prior to the issuance of a certificate.[17]

In accordance with the EU Regulation, any person may file a request for invalidation of the SPC to a relevant national patent office.

The grounds for invalidation of the SPC, in accordance with Article 15 of the Regulation, are as follows: the SPC was granted contrary to the provisions of Article 3; the basic patent has lapsed before its lawful term expires; the basic patent was revoked or limited to the extent that the product would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.

Limited period of patent term extension

The regulations of most countries define limited period of patent term extension. Usually it does not exceed 5 years. Thus, in most cases, the patent term may not be extended if the period between the date of filing the patent application and the first permission is less than 5 years. This rule is stipulated in the EU Regulation (EC) No 469/2009 as well as in many national laws.

Moreover, the mentioned Regulation sets forth that in any case, the maximum term of effective patent protection cannot exceed 15 years (the remaining patent term + supplementary protection certificate).

The United States approach to limiting this period is slightly different, and involves setting a maximum limit of 14 years, which is determined by adding the period remaining after the permission, to the number of days spent on the regulatory procedure. If the calculated period exceeds 14 years, it is reduced accordingly to the maximum limit.

[17] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/309167/spctext.pdf

The Chilean legislative approach is significantly different from the generally accepted approach on the matter, i.e. the period of possible extension is not limited.

Restriction of subject matter eligible for patent term extension

The Regulation concerning the supplementary protection certificate and the practice of its application by the European Court of Justice provides grounds for distinguishing certain approaches to the interpretation of the product eligible for patent term extension, namely:

- it is not permitted to obtain a certificate for active ingredients which are not specified in the claims of the basic patent;
- if a patent claims that a product is composed of two active ingredients but makes no claim to one of those active ingredients individually, a certificate cannot be granted on the basis of such a patent for the one active ingredient considered separately;
- a certificate may be issued for a combination of two active ingredients that correspond to those in the claims of the patent, when the medicinal product for which a market authorization (MA) is obtained contains not only this combination of the two active ingredients but also other active ingredients;
- at the same time, the MA for a product that comprises the combination of two active ingredients specified in the patent claims, may be regarded as the first MA for that "product" as a medicinal product within the meaning of Article 3(d) of the Regulation.

Informing the generic pharmaceuticals companies about the patent protection term.

The so-called Orange Book is an example of such informing. It contains data on current patents, their validity, extension terms, and expiration of patents.

The Food and Drug Administration of the United States administers such a database.

The impact of the regime on the access to pharmaceuticals

Prospective and retrospective studies indicate that TRIPS-plus provisions, including patent term extension, constitute a significant threat to the access to treatment and have significant adverse health effects in developing countries.

The study conducted by Oxfam International provides the following indicators of the possible impact in case of introduction of patent term extension into the legislation of developing countries[18]:

[18] https://www.oxfam.org/sites/www.oxfam.org/files/file_attachments/bp-trading-away-access-pharmaceuticals-290914-en.pdf

Free trade agreement	Source	Impact on public health
EU – Colombia	IFARMA prospective study commissioned by Health Action International (HAI) Europe	By 2030, patent term extension could increase expenditure on medicines in Colombia by nearly $280 million.
USA – Thailand	University of Bangkok, prospective impact study	A macro-economic model measuring the impact of data exclusivity and patent extension proposals forecasted that all scenarios demonstrated a negative impact on the pharmaceutical market and access to medicines. Medicines prices would increase by 32 percent and the domestic pharmaceutical market would contract of $3.3 million by 2027.

The study conducted by Health Action International on the assessment of the possible impact of trade agreements between the EU and the Andean countries (such as Peru and Colombia) provides the following indicators. [19].

Free trade agreement	Source	Impact on public health
The EU – Peru	IFARMA. Impact of the EU – Andean Trade Agreement on Access to Medicines in Peru, 2009	Introductions of two measures - data exclusivity and supplementary protection certificates would increase pharmaceutical costs in Peru by USD 459 million in 2025 and total costs growth by USD 1267 million in the same year. Drugs consumption is expected to be reduced due to 11% increase in the number of patented active ingredients that in turn will increase prices for drugs by 26%. Patent term extension for 4 years due to implementation of supplementary protection certificates may cause an increase in pharmaceutical costs by USD 159 million or reduce consumption by 9% in 2025.
The EU – Colombia	IFARMA.Impact of the EU – Andean Trade Agreement on Access to Medicines in Columbia. June 2009	Introduction of two mentioned measures, including patent term extension, will increase pharmaceutical costs by USD 756 million in 2025. The reduction of consumptions will be caused by 8% increase of number of products protected by patents that in turn will lead to 16% increase in prices.

The study on the impact of patent term extension due to conclusion of the FTA between Thailand and the United States shows the following impact on drugs accessibility.

Free trade agreement	Source	Impact on public health
The USA – Thailand	UNDP, UNAIDS "THE POTENTIAL IMPACT OF FREE TRADE AGREEMENTS ON PUBLIC HEALTH", 2012	It is expected that pharmaceuticals prices will raise by 32%; the cost of pharmaceuticals will raise to USD 11,191 million; the domestic pharmaceutical industry will lose USD 3,370 million during the next 20 years.

The following assessment is made in regards to the market of South Korea due to conclusion of the FTA with the United States:

"A three-year patent extension would cost the National Health Insurance Corporation USD 529 million and a four-year extension would cost USD 757 million as proposed in the Free Trade Agreement."[20]

On the other hand, there are studies that indicate that a weak patent protection regime, including lack of adequate compensation for a lengthy regulatory procedure, reduces manufacturer's interest in the market and thus people are deprived of access to new pharmaceuticals.

WTO study on the issue contains the following conclusions:[21]

- Countries with weak IPRs and aggressive price regulation may face substantial delays in the introduction of new pharmaceuticals;

- Notwithstanding treaty obligations to provide patent protection for pharmaceutical products, innovator companies are still struggling to obtain market exclusivity in countries such as Brazil, China, and India. One of the consequences of the policy choices underlying these market outcomes are weakened incentives for any firm to incur the costs of launching a new drug in these countries. These weakened incentives to launch new drugs in "unfriendly markets" are clearly visible as less than two-thirds of the new drugs in the sample were commercially available in Brazil, China and India.

This position is denied by the International Commission on Intellectual Property Rights. In its opinion, the incentives of pharmaceutical companies to R&D are not dependent on the strong or weak IPR system in developing countries. A strong IPR system, including extended patent term, is often shown as the price that a developing country has to pay to encourage the development of new pharmaceuticals and vaccines by pharmaceutical companies. Nevertheless, empirical studies do not substantiate the validity of this statement. In the Commission's view, low demand, rather than IPR system, is a determining factor in such countries.[22]

[19] http://haieurope.org/wp-content/uploads/2012/01/Sep-2011-European-Union-Andean-Community-Trade-Agreements-Intellectual-Property-Public-Health.pdf
[20] US FTA may cost drug industry $1.2 billion: govt, Hankyoreh, 17 October 2006
[21] Economics of TRIPS and Public health. Jayashree Watal WTO Secretariat, 02.11.2012
[22] Commission on IPR, 2002 Page 39.

Statutory regulation under Ukrainian legislation and its implementation

Pursuant to paragraph 3 part 4 Article 6 of the Law of Ukraine “On Protection of Rights to Inventions and Utility Models”, the patent term for an invention is 20 years from the filing date of the application.

According to paragraph 5 part 4 article 6 of the Law, patent term for medicinal invention, requiring marketing authorisation, may be extended at the request of the patent owner for a period which elapsed between the date on which the patent application was filed and the date of marketing authorisation but not more than for 5 years. The fee is charged for lodging the application.

The Law of Ukraine No. 1771-III of 1 June 2000 introduced this provision into the legislation. Prior to that, domestic law did not provide for the possibility of patent term extension for pharmaceuticals.

The procedure of patent term extension is stipulated by the Instruction No. 298 of 13 May 2002, approved by the Ministry of Education and Science.

The Instruction establishes the following main requirements to the application and its consideration procedure (by the Patent Office):

An application must be filed and the fee must be paid no later than 6 months before the expiration of the patent;

An application must contain the name of the patent owner, address, patent application filing date and number, title of an invention;

A certified copy of the marketing authorisation for a medicinal product, and a power of attorney should be provided in case an application is submitted by a representative;

An application is reviewed within 1 month from the date of receipt;

In case of non-compliance with the requirements or justified doubts regarding the reliability of the information contained in the submitted documents, the patent owner shall be notified and/or asked for additional documents;

The patent owner has 2 months to eliminate deficiencies and/or submit additional documents;

A decision to reject patent term extension shall be taken if the petition and the attached documents do not meet the statutory requirements; if the deadline is missed; if the patent is found to be invalid; if the patent is terminated.

The legislation does not set out other requirements either to the patent owner or to the procedure. At the same time, such shallow regulation leaves a number of emerging issues unanswered.

In particular, a specific form of both marketing authorisation and patent claims may not provide a clear understanding that both documents relate to the same product.

In case the regulator reaches an erroneous conclusion and finds that the patent claims correspond to the registered medicine, when it is in fact not true, or if the regulator comes to the opposite false conclusion, it is possible to appeal against such decision in court. The law does not specify another way of responding both by the applicants and by third parties.

An analysis of the case law in appealing the actions of the Patent Office indicates that the difficulties with establishing the conformity of the patent to the marketing authorisation arise.

In addition, the most striking issue in this context is the definition of the patent term.

The formula for calculating the term used in Ukraine does not conform to the generally accepted approach applied in the EU and many other countries.

Thus, a common method for calculating such term is the subtraction of 5 years from the period between a patent application filing date and a marketing authorisation date. If the resulting period makes less than 5 years, extention is not provided. Contrary to this approach, Ukrainian legislation allows the patent term extension regardless of the duration of the authorisation procedure (including if it took less than 5 years).

A fundamentally different approach for extending the patent term is determined by the EU legal system, which Ukrainian legislation should be adjusted. In particular, by signing the Association Agreement with the European Union, Ukraine accepted the obligation to implement supplementary protection certificates in its legislation (Article 220).

Thus, Ukraine should provide additional period for the protection of medicinal products, which is subject to marketing authorisation. This period should be determined as the period from the patent filing date to the date of obtaining marketing authorisation, reduced by five years. In relation to paediatric pharmaceuticals, Ukraine is obliged to provide an additional six-month extension.

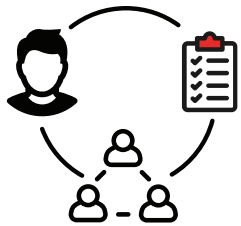
Analysis of Ukrainian case law regarding patent term extension

Number of cases (2014-2016)	Number of decisions in favour of the plaintiff	Number of dismissals and the main grounds	Tendencies
3 2 cases - administrative court proceedings 1 case –commercial court proceeding	1 Patent owner's appeal against the decision concerning refusal of patent term extension for an invention. The Patent Office is required to consider an appeal. Motivation: if the appeal is not compliant with the established requirements, the Patent Office is obliged to send a request for the elimination of non-conformities.	2 Among them: 1 case - (commercial court proceeding). The plaintiff opposed the patent term extension because the patent object is a method of treatment, not a medicinal product. The court, having examined the patent claims, disagreed with the plaintiff and stated "The claims of the invention "The method of treatment …" is multiclaim and characterizes the group of inventions (the process, the method of treatment and the product)". 1 case - (administrative court proceeding). The plaintiff opposed the patent term extension. The court of primary jurisdiction satisfied the claim and cancelled the decision on the following grounds: - patent term extension requires the evidence that the patent relates to a medicinal product, whereas the State Intellectual Property Service did not provide an evidence that an invention is a medicinal product, rather than an active ingredient; - unduly executed power of attorney of the signatory. The Court of Appeal cancelled the decision and dismissed the claim.	the court supports patent owners' positions; the key value is given to the conclusion of Ukrainian Patent Office regarding the active ingredient that might be used in a medicinal product; arbitration is carried out by courts of different jurisdictions (administrative and commercial) due to different approaches to the qualification of legal relationships; contradictory case law regarding the possibility of patent term extension in cases when the subject matter of invention is the process (method); peculiarities of proving the eligibility to file oppositions (the plaintiffs refer to the fact that the contested decision illegally prolongates the monopoly on certain technology, and limits their right to use it in their own medicinal product); patent owner joins the process as a third party to the action on defendant's side; injunctive relief measures are not being taken.

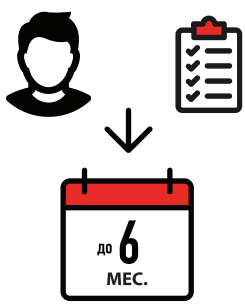
Conclusions and recommendations

National legislation should be in line with the level of development, domestic needs and priorities of the country. At the same time, the system of patent protection should, among other things, pay due regard to public health needs. The provisions on patent term extension enshrined in current legislation of Ukraine and implemented in practice do not correspond to the intended purposes and create room for violation. Such violation becomes possible not only due to an imperfect procedure for patent term extension, but also due to the deficient system of providing patent protection that is used by unscrupulous pharmaceutical companies.

By concluding the Association Agreement, Ukraine has undertaken to review the current approach. The result of the fulfilment of the obligations stipulated by the Association Agreement should be the creation of a separate concept - supplementary protection certificates - that will be issued in case of compliance with a set of specified conditions and fulfilment of all the requirements by the patent owner. The European approach, in general, does not contradict the 20-year patent term, as it stipulates the provision of a separate sui generis right, dependent on the actual authorisation of a medicine, rather than extension of intellectual property right as such. The conditions for granting certificates and the requirements for patent owners may be taken from the practice of the EU and developing countries.



The key issue is the introduction of a rational approach for determining the patent term extension (certificate term), which will be in line with both the interests of the patent owner and the society. Thus, it is expedient to calculate such a term by reducing the period between the date of filing the patent application and the date of marketing authorisation by 5 years, using the EU formula. Thus, if the registration procedure lasts less than 5 years, the patent owner is not entitled to the patent term extension.



It is also advisable to abridge the patent term extension application period. Now the patent owner can enjoy this opportunity during almost 20 years of patent term, namely until 6 months before the patent term expiration. It is important to considerably shorten this period by linking it to obtaining marketing authorisation or a patent whichever occurs later. It is expedient to establish time limit in 6 months from the date of marketing authorisation or a patent.

Such a short filing period will serve the public interests since generics companies will be able to calculate the patent expiration date and, accordingly, prepare a generic release in advance. In addition, marketing authorisation must be the first marketing authorisation for the medicinal product.

It is mandatory to adhere to a number of conditions, the failure of which should lead to the refusal to provide patent term extension:

- a medicinal product is protected by a patent in force;
- a valid marketing authorisation is available;
- marketing authorisation is the first marketing authorisation to place this medicinal product on the market.

In addition, in order to ensure public control over the patent term extension process, it is necessary to provide new legislative framework for opposing a supplementary protection certificate and its invalidation. At the same time, in order to ensure prompt response, an opposition procedure should be available not only through the court, but also through regulatory authority.

In any case, by implementing such approach Ukraine should bear in mind that public interest should take precedence over the interests of patent owners. Moreover, under Article 219 of the Association Agreement, Ukraine declared recognition of the Doha Declaration and committed to ensure its provisions.

LEGAL FRAMEWORK FOR PATENT LINKAGE IN PHARMACEUTICS AND OPPORTUNITIES FOR LIMITING THE REGIME IN THE PUBLIC HEALTH SECTOR

The nature of the regime

The patent linkage regime involves establishing the interdependence of the state authorisation of pharmaceuticals and the observance of the intellectual property right of third parties. Depending on the specific regime of patent linkage (PL), the state authorisation of a medicine may be rejected, if such medicine violates the intellectual property rights of others, or there is a possibility of such violation in the future.

Patent linkage is established in the legislation due to the obligation of applicants, who apply to the competent authority for authorisation of a medicine, to provide documents, including those indicating the existence and nature of patents, patent licenses. It is also enshrined in law through the inclusion of the infringement of third-party intellectual property rights to the list of grounds for a refusal to grant a proper authorisation.

The regulatory authority, which carries out the authorisation of pharmaceuticals, has no right to register it during the validity period of the "competing" patent. Thus, two systems are connected: the protection of intellectual property rights and the quality control of pharmaceuticals that are allowed for distribution and use.

The reason for the introduction of the patent linkage regime was the protection of rights of patent owners throughout the validity period of patents. Sales of a medicine, in which a patented invention/utility model is used, without patent owner's permission constitutes the use of intellectual property object in violation of the owner's patent rights.

Companies that are the rightholders of inventions/utility models in the field of pharmacy, seek to protect them within a period specified by the law of particular country, and to ensure effective prevention of rights violations. From the owner's perspective, the best way to ensure protection is to prevent violations through "interdiction" before entering the market, namely at the stage of authorisation. Patent owners seek the protection of their rights and prevention

of authorisation of generic pharmaceuticals within the full lifetime of their patents. For this purpose, they apply the patent linkage established for authorisation procedures, as well as challenge the marketing authorisation in court on other grounds in the absence of a patent linkage regime.

Patent linkage may be applied in different ways:

- prohibiting the authorisation of pharmaceuticals before the original patent expiry;
- prohibiting the consideration of applications for generic drugs authorisation within the validity of the originator's patent;
- informing the patent owner about applications for authorisation of the generic equivalent of the original drugs.

Patent linkage may provide for a condition to maintain a patent register, which accumulates data on all medicine-related patents, or patents that meet only established criteria, or patents referenced in the registration dossier of the original product.

Scheme of market entry of generic drugs within a patent linkage regime:

Scheme of market entry of generic drugs disregarding a patent linkage regime:

Statutory regulation under Ukrainian legislation

In the Ukrainian legislation, patent linkage system was introduced in 2006 as a result of the adoption of Law No. 2399 of 20.10.2006 "On Amendments to Article 9 of the Law of Ukraine "On Pharmaceuticals". As stated in the explanatory memorandum by the President, who introduced a corresponding legislative initiative, the need for the adoption of the Law corresponds to the need for bringing the Ukrainian legislation into line with the commitments made during the negotiation process on Ukraine's accession to the WTO. Socio-economic and other outlook of the draft law pointed out that it aimed at improving the quality and safety of medicinal products and medical supplies for citizens, as well as establishing fair competition in the Ukrainian pharmaceuticals market. However, it is also worthwhile noting that the project did not in fact envisage any changes that would affect the quality, safety of pharmaceuticals and control of compliance with the relevant standards, while all incentives concerned the strengthening protection of intellectual property, as well as the confidentiality of authorisation information.

This draft law received considerable criticism that pointed to the deterioration of the public access to pharmaceuticals and the complication of the market entry for generics.

In 2010, an attempt[23] to exclude the patent linkage under Art. 9 of the Law of Ukraine "On Pharmaceuticals" was made, however, such change was not reflected in the final version of the Law.

Currently, the legal basis for patent linkage is Article 9 of the Law "On Pharmaceuticals", which states that an applicant submits the following documents for authorisation of medicine:

1. A duly certified copy of a patent or license, which authorises the manufacture and sale of an authorised medicine
2. A document verifying the validity of patent in Ukraine
3. A statement of non-violation of third-party rights protected by a patent or transferred under a license in connection with the authorisation of a medicine

[23] Draft Law "On Amendments to Article 9 of the Law of Ukraine "On Pharmaceuticals"" (on adjusting the order of registration of pharmaceuticals to international standards) No. 7412 dated 02.12.2010 http://w1.c1.rada.gov.ua/pls/zweb2/webproc4_2?id=&pf3516=7412&skl=7

The state authorisation may be rejected in the event that it results in the violation of existing valid economic patent rights, including the manufacture, use and distribution of medicinal products.

The application form to be submitted for state authorisation was approved by the order of the Ministry of Health No. 426 of 26 August 2005. In application, the applicant must indicate whether the medicine is protected by patented invention, utility model or industrial design, applicable in Ukraine, and also fill in information about such patents, in particular, indicate the number, date of issue, date of termination of the patents, and indicate the patents holders. Applicants should also provide information on registered marks for goods and services.

As an attachment to the application form, the applicant adds a letter of guarantee, the form of which is approved by order of the Ministry of Health . In this letter, the applicant guarantees that when applying for the state authorisation of pharmaceuticals the requirements of part 14 of Article 9 of the Law "On Pharmaceuticals" are met, namely third party rights protected by a patent or transferred under a license are not violated in connection with the authorisation of a medicine. By submitting the letter, the applicant confirms the awareness of the possible refusal of the state authorisation of medicine if such authorisation results in the violation of valid economic rights of a patent holder. The legislator imposes responsibility for the authenticity of the data contained in such a letter on the applicant.

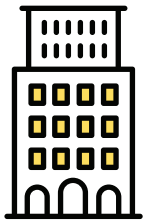
Similar requirements are contained in Clause 3 of the Procedure for State Registration (Re-registration) of Medicinal Products.[25]

In accordance with Clause 6 of Section IV of the Procedure for Conducting Expert Evaluation of Registration Materials Pertinent to Medicinal Products submitted for state registration (authorisation), a medicinal product cannot be recommended for state registration (authorisation) if, in particular, a court decision has come into force stating that such authorisation will result in the violation of economic rights protected by a patent of Ukraine, including the manufacture, use and sales of pharmaceuticals. Copies of the court decision are to be submitted to the Ministry of Health and the Centre.[26]

Consequently, the legislation on authorisation of medicinal products empowers the Ministry of Health to decline the state authorisation on the grounds of intellectual property infringement. Thus, the regulator in the public health sector, who by virtue of one's specialisation has no relation to the intellectual property field, exercises additional powers for the assessment of issues beyond one's competence.

[24]The Procedure for Conducting Expert Evaluation of Registration Materials Pertinent to Medicinal Products, which are Submitted for State Registration (Re-Registration) and Expert Evaluation of Materials about Introduction of Changes to the Registration Materials during the Validity Period of Registration Certificate, approved by the order of the Ministry of Health of Ukraine No. 426 dated 26.08.2005.
[25]The Procedure for State Registration (Re-registration) of Medicinal Products, approved by the Decree of the Cabinet of Ministers of Ukraine No. 376 dated 26.05.2005.
[26] The Procedure for Conducting Expert Evaluation of Registration Materials Pertinent to Medicinal Products, which are Submitted for State Registration (Re-Registration) and Expert Evaluation of Materials about Introduction of Changes to the Registration Materials during the Validity Period of Registration Certificate, approved by the order of the Ministry of Health of Ukraine No. 426 dated 26.08.2005.

Example of infographic:



State Intellectual Property Office

Registration of IP rights

Courts

Establishing a violation of rights

Ministry of Health

Authorisation of pharmaceuticals

Ukrainian Intellectual Property Institute (Ukrpatent)

Expert evaluation of applications for industrial property objects to examine:

- novelty;
- inventive step;
- industrial applicability;
- clearance search for potentially conflicting trademarks;
- misleading, etc

Court experts

Expert evaluation for:

- use of the patent formula in the medicine;
- same or similar trademark examination

State Expert Centre, state enterprise

Expert evaluation of applications for:

- quality;
- safety;
- efficacy;
- examination on violation of IP rights is not carried out no IP expert

A tendency to abuse intellectual property rights while registering the industrial property objects gives grounds to assert that the system of protection of intellectual property rights in Ukraine is not flawless. Patenting minor improvements, constituent elements, variations in drug products, protecting the same medicine with several patents and other cases of abuse of the patent protection system creates a basis for establishing a chain of low-quality patents that blocks the use of other pharmaceuticals.

It should be noted that during the registration procedure of such objects as a utility model and industrial design no substantive examination is carried out (examination of the patentability of the object per se). Thus, the “quality” of such patents is questionable. The abusive practices in industrial design rights (so-called patent trolling) have reached a critical point in Ukraine in recent years. A design patent for visual appearance of the medicinal product, in particular a drug pill design, in the absence of substantive examination is sufficient to obstruct the authorisation of a medicine in Ukraine. The situation regarding the issuance of poor-quality protection documents, namely, for utility models and industrial design, is widely debated and is currently under reform in Ukraine.

In view of the above, the patent linkage regime in Ukraine creates additional grounds for abusive practices and restricts public access to affordable pharmaceuticals.

In practice, in most cases the disputes on patent linkage application are resolved in courts when appealing decisions of the Ministry of Health on the ground of patent rights infringements.

Simultaneously, in some cases courts issue decisions in favour of patent owners for original drugs, having established violations of patent rights and pointing to a patent linkage[27], but in other cases courts claim that the Ministry of Health is not authorised to verify applications with regard to intellectual property rights infringements and generally grants protection on the basis of a positive opinion of the State Expert Centre that examines only the efficiency, safety, and quality of a medicine.[28]

On the one hand, current issues relating to patent legislation as well as shortcomings of judicial protection of intellectual property rights lead to weak predictability of the market entry of generic drugs.

On the other hand, unresolved issues of patent linkage application often mean that the patent linkage de-facto never apply. The marketing authorisation is being granted to the medicinal products, not only generic ones, without any examination in regard to potential intellectual property rights infringement, as long as the Ministry of Health has no opportunity to conduct such assessment by its own means.

This practice hardly has positive impact due to the fact that it creates uncertainty in law enforcement and unpredictability for both new applicants and patent owners.

Consequently, the patent linkage regime requires consideration, detailed regulation and clear recommendations for use by courts and bodies responsible for the registration of pharmaceuticals.

[27] http://www.reyestr.court.gov.ua/Review/18764164
[28] http://www.reyestr.court.gov.ua/Review/23927292

Pros and cons of the regime according to the findings of international governmental and non-governmental organisations

Patent linkage regime and its impact on public health are the subject of analysis of both governmental and non-governmental organisations.

PhRMA Association operates actively in strengthening the protection of intellectual property rights on the results of pharmaceutical research. Continuing to emphasise the importance of developing innovation to ensure the rapid creation of newer and more advanced pharmaceutical products, PhRMA points out the mandatory implementation of the effective protection of intellectual property rights of developers and manufacturers, in particular through the patent linkage regime. PhRMA prepares 301 Report annually with review and recommendations regarding the protection of intellectual property in the field of pharmaceuticals, including the consideration of the introduction of patent linkage regime. In reports of the organisation, patent linkage is defined as a necessary effective mechanism for the enforcement of intellectual property rights, which provides for the early resolving of patent disputes before medicine is actually launched onto the market. Early market entry of product, which, as it might turn out, infringes the patent rights of the originator company, may lead to difficulties in the process of treating patients. PhRMA requires governments to enforce patent linkage in domestic law, since it lacks can culminate in commercial losses for pharmaceutical innovators that cannot be recovered in the future. PhRMA offers different patent linkage regimes for countries with different realities and legal systems.

The policy of the European Federation of Pharmaceutical Industries and Associations (EFPIA) is based on achieving the best possible balance of interests of patients and pharmaceutical companies. Emphasising the importance of ensuring the effective protection of the rights of patent owners, the availability of pharmaceuticals remains in focus. A representative of the federation, Richard Bergstrom, in his speech in 2011, emphasised that:

> patents encourage the activity of pharmaceutical companies, but when patent expires, it is necessary to make every effort to ensure that generics are available as soon as possible at the lowest possible price and to the maximum possible extent. As for pharmaceutical companies, they should accept the expiration of the patent, although this means losing of billions daily[29].

The purpose of the public health system, including the authorisation procedure is to ensure the best level of health of the population, in particular, due to the sufficient access to high-quality and effective pharmaceuticals. The statistical data indicate that the EU situation regarding pharmaceuticals and the public health demonstrates positive dynamics. Consequently, Ukraine must keep up with the implementation of European standards and the EU legislation.

[29] http://www.efpia.eu/topics/innovation/intellectual-property

Issues related to the connection of intellectual property and the availability of pharmaceuticals were also covered by the UN Secretary-General. Taking into account the report of the Global Commission on HIV and Law on intellectual property, it is argued that

> it has also been characterised by a dangerous tendency to equate IP enforcement with drug quality assurance. IP enforcement itself cannot be understood as a measure that enhances public health. Indeed, some of the patent protection measures constitute threat in access to pharmaceuticals. While some counterfeit pharmaceuticals are of substandard quality, the same is true of branded and patented products. The Commission also points out that developing countries should introduce restrictions on the patentability of inventions and utility models in the field of pharmaceuticals, and to include a provision into the patent legislation that allows any person concerned to initiate a patent invalidation (opposition) procedure; include in the domestic legislation the Bolar exemption in a broad version. The most controversial provisions of TRIPS-plus should be abandoned, in particular regarding the patentability of new indications and new forms of already known ingredient, to introduce a strict criterion to the inventive step[30].

A common report by the World Health Organisation, the World Intellectual Property Organisation and the World Trade Organisation on promoting access to medical technologies and innovation also states that

> patents and marketing approval are separate issues. It is irrelevant for the regulatory approval whether a patent is granted[31].

In June 2016, the United Nations Development Program (UNDP) announced signing of agreement with Macleods Pharmaceuticals Ltd. for the supply of moxifloxacin to Ukraine, a generic medicine used only for the treatment of tuberculosis. The unpatented medicine costs 50 cents per pill (while the cost of its patented equivalent is nearly three thousand US dollars). This medicine will provide access to treatment for a much larger number of patients throughout Ukraine, as significant saving of the state budget, initially allocated for the purchase of patented medicine, will allow the purchase of an additional amount of antituberculosis drugs. The UNDP organisation notes that

> it is important to carefully align the human right to treatment with the rules of trade in order to provide treatment for the maximum number of patients at the lowest cost.[32]

[30] http://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/56547292e4b0e74bc872ee41/1448374930129/ACCESS-TO-PHARMACEUTICALS-THE-ROLE-OF-INTELLECTUAL-PROPERTY-LAW-AND-POLICY-1+%281%29.pdf

[31] Promoting access to medical technologies and innovation. The World Health Organization, the World Intellectual Property Organization and the World Trade Organization, 2012. http://www.wipo.int/edocs/pubdocs/ru/wipo_pub_628.pdf

[32] http://www.ua.undp.org/content/ukraine/uk/home/presscenter/articles/2016/06/-1.html

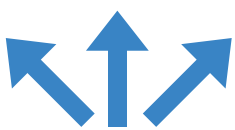
According to the report of the European Generic Pharmaceuticals Association, governments are urged not to include the patent linkage regime in domestic legislation as it causes the delays and blockage of generic pharmaceuticals market entry, and obstruct the development of competitive and sustainable market environments.[33]

Pros

- Effective protection of intellectual property rights of patent owners;
- Enforcement of property rights and sufficient funding of patent owners to cover costs and continue R&D activities.

Cons

- Complications of generic pharmaceuticals market entry;
- Delaying the authorisation procedure of medicinal products;
- Procedural imperfection of the system of medicinal products authorisation. It establishes an additional obligation and scope of responsibility for the authority without involving the necessary specialists in the field of the intellectual property and therefore indicates the need for additional examinations;
- The unification of two essentially different fields and the unification of various competences in one authority;
- Uncertainty in the issuance of compulsory licenses;
- Disadvantages of patent system (issuance of patents for objects that do not meet the requirements of patentability, issuance of patents without substantive examination) that directly affects the registration procedures and market access of generic pharmaceuticals.



Opportunities

- Promotes the innovative activity of medicinal products developers;
- Allows financing of more extensive development of new medicinal products of higher quality.

Danger

- Stable high level of prices for medicinal products in comparison with foreign countries;
- Complicated access to medicinal products that have vital importance to those who need them;
- The impossibility of providing with pharmaceuticals to a wide range of people with very high rates of morbidity (for instance, HIV/AIDS, tuberculosis, oncological diseases). Rejection of authorisation due to improperly issued patents and lengthy procedure of patent invalidation.

[33] How to Increase Patient Access to Generic Pharmaceuticals in European Healthcare Systems. A Report by the EGA Health Economics Committee, 2009

Legal regulation in foreign jurisdictions

No.	Jurisdiction	Patent linkage regime	Regulation
1.	European Union	The patent linkage is not applicable. The application of patent linkage as a dependence of the decision to grant marketing authorisation to the generic pharmaceuticals on patent protection of originator's product is the violation of the EU legislation.	Directive 2004/27/EC Directive 2001/83/EC
2.	Switzerland	The patent linkage is not applicable. Under the legislation of Switzerland, applying for marketing authorisation of a medicinal product does not constitute a violation of patent rights, as it is not a commercial use of a patent. The patent validity and patent rights are not related to obtaining marketing authorisation in Switzerland or in another country, and therefore the patent linkage regime cannot be applied.	Art. 9 §1c Patent Act
3.	USA	The original conception of patent linkage is based on the legislation on authorisation of pharmaceuticals adopted by the USA. The modern legislation is formed based on a compromise introduced by the Hatch-Waxman act that provides protection of patents included in a special list (Orange book). The patent linkage regime is applied to protection of rights to the patents listed in Orange book. While applying for marketing authorisation, generic pharmaceuticals company informs and guarantees the patent owner that his/her rights will not be violated during the term of patent protection. If a patent owner considers that his/her rights will be violated due to the authorisation, he/she may sue to court, in this case, the authorisation process automatically terminates. If the court finds that the patent is not valid or there is no violation of the patent owner's rights, the marketing authorisation may be granted from the date of a court decision or introduction of a settlement agreement.	Drug Price Competition and Patent Term Restoration Act of 1984 (21 U. S. C. § 355 (2006) Hatch-Waxman act
4.	Canada	The patent linkage is applied through the notification system of patent owner and suspension of the authorisation procedure of generic pharmaceuticals. Data about patents is filed together with an application for authorisation of a medicinal product. If generic pharmaceuticals contain an object patented by a third person, the patent owner must be informed about such application and shall respond regarding the potential infringement of his/her patent rights. If the applicant agrees that the patent is used indeed, the marketing authorisation of generic medicine and its market entry is possible from the date of patent expiration. In other case, the applicant can respond and indicate one of the following reasons: no patent rights violation; a claim that there is a connection between generic pharmaceuticals and patent is erroneous; the patent expired; the patent is invalid. The patent owner is provided with an opportunity to bring a claim to court with the requirement to prohibit the Minister to grant authorisation to these generic pharmaceuticals within 45 days. If the court decides that there has been no violation of patent rights, the patent owner should reimburse losses to the generic's applicant.	Patented Medicines (Notice of Compliance) Regulations

5.	Japan	The patent linkage is not applicable. In accordance with the patent legislation of Japan, an application for marketing authorisation does not constitute a violation of patent rights.	
6.	China	The applicant should provide information on patent and rights for it (the applicant is the patent owner or was granted with a license). The applicant also submits a warranty statement stating that he/she does not infringe patent rights, unless he is the owner of the patent. If the applicant is not the patent owner, he/she can file an application for authorisation only within 2 last months of the patent validity term.	Provisions for Drug Registration
7.	South Korea	The patent linkage is applied to patents that were included to the Green list (the register of originators patents with valid marketing authorisations). Information is not included to the register automatically. The patent owner should fill the application within 30 days from the moment of marketing authorisation. Generic pharmaceuticals may obtain marketing authorisation provided that a patent for reference medicinal product is available, if: - patent expired; - generic pharmaceuticals will be manufactured after patent expiration; - the patent owner rejected the prohibition of marketing authorisation; - there is a court decision, according to which a medicine is not covered by the patent or that a patent is invalid; - pharmaceuticals are not connected with a patent from the Green list; - the patent expired or generic pharmaceuticals do not violate the rights deriving from such patent. The patent owner must be notified of the application for authorisation of a generic medicine within 7 days from the day of such an application. The legislation does not provide for the consequences of failure to inform the patent owner by the applicant, however data exclusivity of generic pharmaceuticals (the beginning of the period during which other generic pharmaceuticals cannot enter the market) is defined from the date of notification of the patent owner, if it was made after the expiration of a 7-day period. The patent owner may demand suspension of sales (not the registration procedure) of generic pharmaceuticals from the Ministry for up to 12 months. Disputes arising during the authorisation of medicinal products concerning patent rights are resolved in a special patent linkage confirmation tribunal, which operates within the Ministry.	Pharmaceutical Affairs Act of Korea
8.	Singapore	Patent linkage is established according to the requirements of the Free Trade Agreement with the USA. Having submitted an application for authorisation of a medicinal product, the applicant should provide information on patents that protect medicinal products and mention whether the patent belongs to the applicant or third parties. If the patent belongs to another person, the applicant should provide the permission for its use or evidence of its expiration. The patent owner must be informed about submitted application on authorisation of generic pharmaceuticals. The patent owner has the time to appeal to court or the authority that grants patents for the protection of patent rights that have been violated in connection with such submission. The marketing authorisation of generic pharmaceuticals may be provided if the patent owner applied for protection of his/her rights to the relevant authorities and received no order or decision within the established period.	Pharmaceuticals Act, 12A

9.	Taiwan	The patent linkage was established recently in connection with signing of the Trans-Pacific Partnership Agreement. The majority of domestic companies of Taiwan produce unpatented medicinal products or pharmaceuticals patents for which have expired. Generic pharmaceuticals companies used to be able to use the registration dossier to prepare for the release of generic pharmaceuticals, including to obtain a distribution permission before the patent expiration for the originator product. However, the distribution may be implemented only after the expiration of patent. The introduction of a patent linkage caused a wave of disappointment, including from representatives of the Pharmaceutical Administration, the Patent Office and others, which claimed that this system would be difficult to implement due to insufficient expertise on the matter. In accordance with an agreed mechanism of a patent linkage, the list of patents for originator products, rights to which are protected upon registration, was established. The authorisation of generic pharmaceuticals is suspended up to 18 months (such term is shorter than in the USA, however is also subject to criticism). The average duration of the patent disputes in Taiwan is 11-13 months. In addition, the exclusivity regime for the first generic medicine is introduced, according to which other generic pharmaceuticals companies cannot obtain authorisation within 180 days after the initial market entry.	Taiwan patent act Controlled Drugs Act
10.	Vietnam	The patent linkage is partially applicable. Generic pharmaceuticals companies may submit applications regarding marketing authorisation not earlier than two years before the expiry of the originator patent. Besides, the applicant should provide evidence regarding the confirmation of the patent expiration date and substantiate filing of an application before the term expiration.	Article 13.3 Circular 44/2014/TT-BYT
11.	Indonesia	Indonesia established the patent linkage regime. Health Protection Agency requires from applicants the provision of the patent search results from the Patent Office regarding the medicine submitted in order to verify that it is not covered by a third-party patent. The agency does not examine the report in details if it meets the criteria: - the patent for a reference medicinal product (active ingredient) was not overlooked; - if the complete explanation is provided reasoning that the medicinal product applied for marketing authorisation is not covered by any of these patents and the rights are not violated.	Decree of the Head of the National Agency of Drug and Food Control
12.	Thailand	A patent linkage regime is not established. Authorisation procedure for pharmaceuticals and patents rights protection belong to different fields and are applied separately. Introduction of the patent regime in the national legislation is actively discussed in connection with the participation of Thailand in Trans-Pacific Partnership Agreement. The PhRMA Organisation is actively opposed to the unsettled regime, insisting on consolidation of the patent linkage at the legislative level. As the organisation emphasises, the only mechanism to protect patent rights is the protection of rights in court, which is time-consuming and entails substantial expenses and losses.	
13.	Turkey	The patent linkage is not applicable. Submission of an application for authorisation of a medicinal product and obtaining marketing authorisation do not constitute the violation of patent owner's rights.	

14.	Belarus	The applicant is required to provide information about existing patents for medicinal product and their validity, as well as non-violation letter that the intellectual property rights of third parties are respected. In case of submission of inaccurate information in the registration dossier, the state registration certificate of a medicinal product may be suspended for up to 6 months. During this period, the applicant should eliminate the grounds for suspending the certificate and provide confirmation to the Ministry of Health. If the applicant fails to do so, the certificate is cancelled.	The Act of the Republic of Belarus "On medicinal products"
15.	The Russian Federation	Submission of an application for authorisation does not constitute patent owner's rights violation but the publication of information that generic pharmaceuticals are registered and ready for sale (in advertising, news, etc.) poses a threat of violation of rights and is not allowed in practice. To protect rights, the patent owner should prove the feasibility of treat of infringement of patent rights and high probability of a direct violation in the short term. The violation of intellectual property rights in generic pharmaceuticals is the reason for cancellation of medicinal product registration.	Federal Law of the Russian Federation "On medicine circulation"
16.	Mexico	Provisions on the patent linkage are incorporated into the legislation. Mexican Institute of Intellectual Property maintains a register of pharmaceutical patents and publishes it twice a year. During the authorisation of a medicinal product, the applicant should provide information about patents relating to medicinal product and the rights for them (for example, licensing agreements). The authority that grants authorisations to medicinal products is supported by the Institute of Intellectual Property and provides materials for a 10-day technical examination aimed to determine whether patent rights will be violated if generic pharmaceuticals are distributed. Generic pharmaceuticals companies have rights to use patent objects for research, testing, and clinical examinations during the last three years before the patent expiration. This provision was declared unconstitutional by a decision of the Constitutional Court, because it does not allow the patent owner to take part and submit his/her arguments when granting authorisations to generic pharmaceuticals. As a result, the patent linkage regime in Mexico has not been dismissed; instead, the patent owner can participate in the examination of the registration dossier of generic pharmaceuticals, making his/her case for the authorisation.	Health Law Regulations Industrial Property Regulations
17.	Moldova	The patent linkage is not applicable.	
18.	Georgia	The patent linkage is not applicable.	
19.	Egypt	The patent linkage is not applicable.	
20.	Israel	The patent linkage is not applicable. The usage of an invention for research (trials) with the purpose of obtaining marketing authorisation is not considered as the usage of invention that violates patent owner's rights. Thus, two conditions should be met: 1) actions aimed at obtaining the authorisation should relate to issuance of an authorisation in Israel or in another country where a similar patent protection expulsion applies; 2) none of the products obtained as a result of such use is not used during the patent validity or after its expiration for any purpose other than obtaining an authorisation.	54 A Patents Law

21.	Morocco	The country joined WTO, and the patent linkage regime is applicable. Morocco issues patents for pharmaceutical or medical inventions, generic pharmaceuticals are prohibited until patent expiration. A special authority resolves disputes concerning respective violations of patent rights.	Code of the Medicine and Pharmacy, Law on the protection of intellectual property
22.	The UAE	The patent linkage regime is applied. The applicant cannot obtain a marketing authorisation for a medicine that violates the rights to granted and valid patents. The applicant provides information about related patents and the regulatory authority consults with the Patent Office regarding the potential violation of intellectual property rights as the result of authorisation. If during the inspection it is found that the violation of rights protected by the patent might occur, the authority may either refuse to grant authorisation or postpone the decision and issuance of MA until the patent expiration.	Ministry of Health Decree 404
23.	Colombia	The patent linkage is not applicable. National Institute of Pharmacy and Nutrition publishes on its website the data identifying the applicant, as well as main information about the product for which the application for authorisation has been submitted. Information is published within 5 days after the submission.	Decree 733
24.	Peru	The patent linkage is not applicable. The regime was discussed during negotiations on free trade with the USA, but it was not implemented at the national level.	
25.	Chile	The patent linkage is not applicable. Chile shall include the patent linkage regime in the national legislation due to execution of the Free Trade Agreement with the USA. Amendments to the patent law were drafted in 2012, including the provisions on the patent linkage, which, in particular, introduced a register of patents protecting medicinal products and inspection for violations of patent rights during the authorisation of pharmaceuticals. However, consideration and adoption of these changes was suspended.	
26.	Brazil	A separate regime of patent linkage is not applicable. Patents in the field of pharmacy are issued based on preliminary positive conclusion of the National Agency of Health. Information about patents is submitted together with all documents for state authorisation of a medicinal product.	Resolution No. 2, of 23 February 2015 Resolution No. 60/2014.
27.	Argentina	The patent linkage is not applicable. The applicant may obtain the marketing authorisation for a medicinal product before the patent expiry, but the product cannot enter the market during this term.	
28.	Saudi Arabia	The applicant may submit documents for obtaining marketing authorisation for generic pharmaceuticals only during the last two years of the patent validity.	Circular Letter No. 7448

Balancing the regime with public health

The mechanism for applying patent linkage may vary from country to country and include different options for mitigating this regime.

1. When conducting authorisation of a medicine, the possibility of violation is considered only with respect to those patents that are included in a special list. This approach applies, for example, in the US, Canada, and South Korea. At the same time, patents in pharmaceutical industry are not included in the list automatically – it is possible to establish different criteria for them:

- relation to an authorised medicine (patents to which there is a reference in the authorisation materials to originator product);
- time criterion (patents are registered within a certain period, for example, 30 days);
- qualitative criterion for the patents (only patents for inventions or patents for the main invention, while "patents for improvement" cannot be registered; other advanced criteria for patentability ("drastic innovations");
- an exclusion concerning the registration of patents for pharmaceuticals for deadly diseases (limited list of illnesses in the case of an epidemic).

Balancing the regime by using such methods is stipulated in the legislation of Australia, Canada, Singapore, the USA and others. For instance, in Australia, the patent linkage regime is balanced by a system of fines and compensations for the unfair suspension of the authorisation of a generic medicine from the patent owner. The requirement for the patent holder to compensate the damage caused to the public health system by delaying the market entry of the generic involves payment of significant amounts and constitutes an effective restraining mechanism against misconduct of patent owners.

2. Under the patent linkage regime, the authority that grants marketing authorisations for the medicine may immediately reject or suspend authorisation if a violation of intellectual property rights is revealed. Suspension may be limited to: a) a certain term specified by legislation, b) the term for settling the dispute between applicant and patent owner. In the first case, the term is provided for submitting an explanation by the applicant or for proving the violation by the patent owner. If the procedure provides for the possibility of resolving a dispute at the stage of authorisation of a medicine, the suspension may be established:

- for a period of dispute resolution by a particular body (chamber, tribunal, arbitration) which operates under the jurisdiction of an authority which carries out state authorisation of pharmaceuticals;
- in case of appeal to court, examination of the authorisation materials and issuance of a permission is suspended pending a court decision or before issuance of a court decision on suspension of the examination/ prohibition of the issuance of a marketing authorisation until the end of trial proceeding. At the same time, the patent owner is given a specific period for lodging an action in court and, if the claim is not filed within this period, the consideration of the authorisation documents is renewed.

3. Legislation may set a specific term before the expiration of the originator patent starting from which generic pharmaceuticals companies can file medicine authorisation documents, for instance, in such countries as Saudi Arabia, China, and Vietnam. This period is determined based on the average period during which the marketing authorisation for the medicine and, accordingly, the permission are valid. For example, if the process of obtaining marketing authorisation for a medicine in the country takes 6 months from the date of filing an application, then generic pharmaceuticals companies can apply for authorisation not earlier than during the last 6 months of the patent validity. Thus, the rights of the patent owners are not violated because the permission is not granted earlier than the date of patent expiry, and therefore it minimises the possibility of violation of the patent rights; on the other hand, the rights of generic pharmaceuticals companies are taken into account as they obtain marketing authorisation in advance and do not spend extra time on authorisation after the expiration of the patent protection.

4. The easiest way to mitigate the patent linkage regime is to postpone the decision on a generic medicine till the expiration of the patent protection, which means that the medicine is examined for compliance with the quality, safety, and efficacy criteria in the standard regime, but the applicant is granted a marketing permission only from a specific date. In this case, in some countries marketing authorisation of a generic medicine may be granted without the right to distribute, advertise, offer, etc. This allows to start the distribution of the generic medicine the day after patent expiration, but originators companies are opponents to this regime because it is difficult to make sure that the generics do not enter on the market before the specified time.

5. Patent linkage is implemented through the system of notifications. Upon receipt of an application for authorisation of a generic medicine, when the period of patent validity for originator product has not yet expired, the receiving body shall send a notification to the patent owner providing the information on the generic medicine and the contact details of an applicant. In this case, the consideration of application is not terminated, and the authorisation for a generic may be granted before the patent expiration. The patent owner may also be notified of the results of consideration of the registration dossier and granting/refusal of marketing authorisation for the generic pharmaceuticals companies. In this case, the patent owner will be able to track the violation of patent rights in advertising or selling a generic product before the expiration of a patent and appeal for the protection of one's rights to generic pharmaceuticals companies or to court.

6. Mechanism of additional assessment of inventions by the regulatory body on health issues at the stage of obtaining a patent can also be considered a balancing mechanism. A patent is issued subject to a positive conclusion from such an authority (Brazil). Simultaneously, patents for pharmaceutical inventions are subject to advanced requirements, in particular, they must demonstrate special significance and effectiveness (e.g. in India). Such a mechanism is intended to minimise the number of low-quality patents, particularly, patents for minor improvements, and prevent the unfair exercise of the patent linkage regime. A similar provision is also stipulated in the legislation of Ukraine. However, due to the absence of a procedure for additional assessment of inventions in the Ministry of Health and lack of intellectual property experts in the Ministry of Health, this provision does not apply.

7. The possibilities of balancing the patent linking regime should be considered in conjunction with the Bolar provisions – patent protection exemptions that allow the use of a patented invention for research, testing in order to obtain a marketing authorisation.

The application of the Bolar provisions has already been considered as a way of balancing in the previous section. The Bolar provisions differ from country to country in the area of patent protection exceptions granted to generic pharmaceuticals companies: in some countries, the use of the invention in scientific research are not considered to be a violation of the patent rights, some countries do not consider it as violation in conducting researches, testing, and preparation of documentation to obtain a marketing permission, while in other countries, the Bolar provisions also cover authorisation procedures.

Bolar and the patent linkage regime may coincide when it comes to the widest version of the Bolar exemption regime, which encompasses not only preparation, but also obtaining a marketing authorisation for a medicine. In this case, the broadest version of the Bolar provision in the legislation cancels the patent linkage regime.

However, the consolidation of narrower Bolar provisions also promotes the rapid entry of generics on the market. The Bolar provisions allow generic pharmaceuticals companies to conduct the necessary research, trials and preparation for authorisation, without which cancellation or mitigation of the patent linkage regime would make no sense and no noticeable result.

The impact of the regime on the access to pharmaceuticals

As of 2015:
- 37.6 million people in the world live with HIV;
- 2.1 million became newly infected within a year;
- 1.1 million died from AIDS within a year.

According to various estimates, 70% of people living with HIV are residents of middle-income countries. The success of the global fight against HIV depends on the intensity of measures aimed at increasing access to pharmaceuticals in these regions[34].

In addition to its obligations to protect intellectual property rights, Ukraine has also signed the UNGASS Declaration[35] , recognising that the lack of affordable pharmaceuticals and their effective delivery structure in the healthcare system obstructs the fight against HIV/AIDS, especially for people with low incomes. In pursuit of the goals set forth in the Declaration, Ukraine should make efforts to provide pharmaceuticals at a low price for all those in need[36].

Due to the patent linkage application, the market entry of generic pharmaceuticals is substantially limited. The creation of unwarranted barriers to generic pharmaceuticals is indicated, in particular, in the reports of Doctors Without Borders[37].

Postponing the market entry of generic pharmaceuticals through the patent linkage regime affects the price level:
- for generic pharmaceuticals;
- for originator products and other generic, biosimilar;
- of medicines for state procurement.

The absence of cheaper analogue

Patent linkage is one of the key barriers to generic medicine availability since it postpones the market entry or completely blocks the market entry of generic pharmaceuticals. Therefore, the public access to affordable treatment with the use of generic pharmaceuticals is unfairly limited.

Stable public health systems are formed with well-balanced policies that increase the use of generic pharmaceuticals. It makes sense not only because of moderate prices for generic pharmaceuticals, which undoubtedly saves money of both the patients and the budget, but also because generic pharmaceuticals provide long-term access to cost-effective treatment while generating savings in excess of at 40 billion euro annually in Europe[38]. In the case of applying a patent linkage and postponing market entry of generic medicine by one year, the same amount should be paid from the state budget or at the expense of patients.

[34]http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_31-ru.pdf?ua=1
[35]The document is of a recommendatory nature for the parties who have agreed to follow the principles enshrined therein.
[36]Committee on Economic Cultural and Social Rights, General Comment 14, paragraphs 11-12.
[37]Doctors Without Borders/Médecins Sans Frontières (MSF) Campaign for Access to Essential Pharmaceuticals TPP Issue Brief - September 2011.
[38]IGES based on IMS (2015) Value of Generic Pharmaceuticals. Study Report for the European Generic Pharmaceuticals Association. Berlin, 2015. http://www.pharmaceuticalsforeurope.com/wp-content/uploads/2016/03/IGES_Study_Report_final_05-10-2015.pdf

Within the framework of analysis of the implementation of provisions of agreement between Canada and the European Union, the calculations of the economic consequences of delaying the market entry of generic pharmaceuticals were carried out: while extending the period of exclusivity of the manufacturer on the market for 382 days, the costs increase by 850 million dollars a year, which is 7% of the total annual expenditures on the patented pharmaceuticals[39].

Negative impact on competition

Experts from the European Generic Pharmaceuticals Association point out that the patent linkage does not contribute to the existence of competitive market. The companies - the patent originators - use the patent linkage regime in the strategy of life-long preservation of the market position and the rights to manufacture and distribution of pharmaceuticals. Governments should carefully monitor such activities in order to prevent undesirable market takeovers. The market entry of generic pharmaceuticals creates competition on the market, which leads to lower prices for all similar pharmaceuticals and promotes innovation and the creation of new value-added pharmaceuticals, which is confirmed by studies of the European Commission's pharmaceutical sector[40].

According to the European Commission pharmaceutical sector, average market prices for generic pharmaceuticals in Europe decrease by almost 20% within the first year following the market entry of generic medicine, and by 25% within the second year. In case of certain pharmaceuticals, the decrease may be higher, as in the case of RAMIPRIL in German market, where average prices fell by 74% five years after the expiration of the patent[41].

Without the use of a patent linkage, the rapid entry of generic pharmaceuticals on the market can have a significant effect on its market environment. The share of generic pharmaceuticals on the market, where there are no patented originator drugs, is 7% in Greece and 81% in Germany[42], while the share of biosimilars in the non-patent market is 2% in Belgium, 71% in Germany and 100% in Hungary[43]. When applying the patent linkage regime, the patent owner extends his/her monopoly, which is reflected in the price. It should be noted that the use of a patent linkage with exclusivity regime of the first generic medicine does not contribute to the intensive development of competition and the rapid drop in prices for pharmaceuticals.

A differentiated approach to analysing the state of competition for the market after the market entry of generic pharmaceuticals was developed by the American company, IMS. Under this approach, the market of pharmaceuticals is divided into 4 sectors: pharmaceuticals with valid patent, on the one hand, and three sectors of non-patent market: generic pharmaceuticals, originator drugs with expired patent validity, and pharmaceuticals that were never protected by patents. In 2014, all pharmaceuticals of non-patent market accounted for 92% of the market share in quantitative equivalents, but only 47% of the market share in price equivalent (on average in European countries). The market share varies considerably between countries. At the same time, the share of pharmaceuticals never protected by the patent in the Eastern European countries was the largest: Poland and Romania (88% each), Slovakia (82%), the Czech Republic (81%), followed by the Netherlands (78%), Germany (77%). The lowest rates are in Belgium (47%) and Greece (49%)[44].

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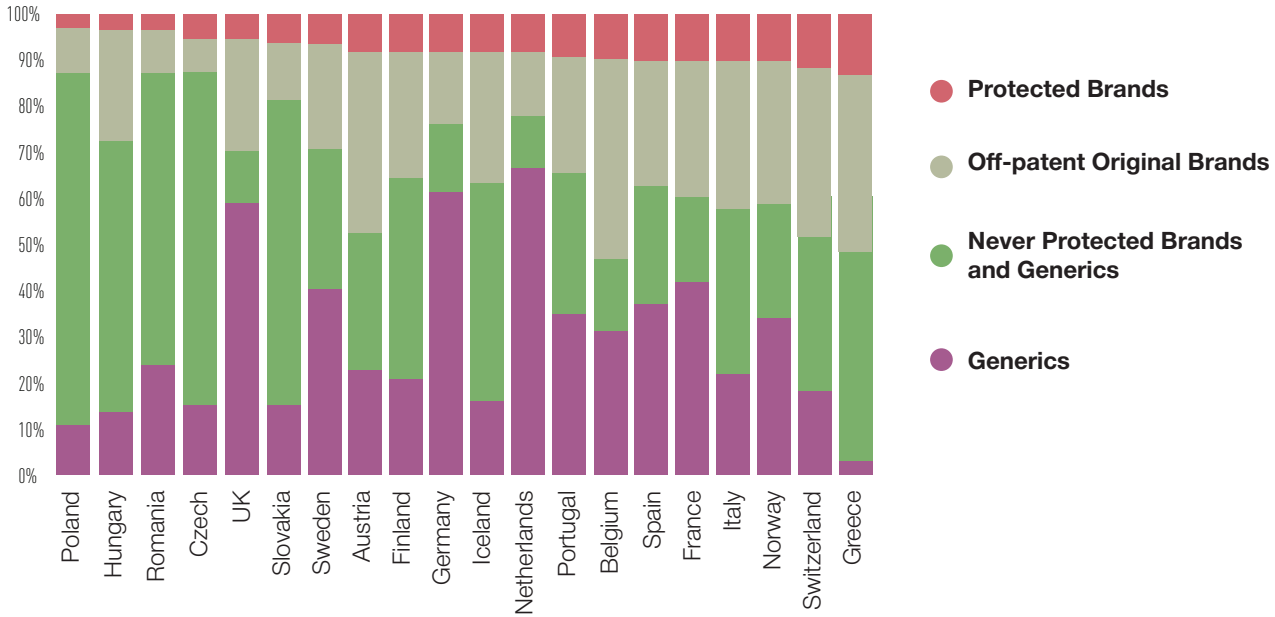
[39]Joel Lexchin and Marc-André Gagnon. CETA and Pharmaceuticals. Impact of trade agreement between Europe and Canada on the cost of patented drugs, 2013.
[40]EGA Contribution to the Public Consultation Process Initiated by the European Commission on The Future of Pharmaceuticals for Human Use in Europe, 2007.
[41]How to Increase Patient Access to Generic Pharmaceuticals in European Healthcare Systems. A Report by the EGA Health Economics Committee, 2009
[42]IGES. Value of generic pharmaceuticals. Study Report for the European Generic Pharmaceuticals Association. [Internet] 2015 Oct 05. Available from: http://www.progenerika.de/wp-content/uploads/2015/11/IGES-Study-Report_Value-of-Generics_Oktober- 2015.pdf
[43]IMS Health. The Impact of Biosimilar Competition. November 2015. [Internet]. Available from:http://ec.europa.eu/DocsRoom/documents/14547/attachments/1/translations/en/renditions/native
[44] IGES based on IMS (2015) Value of Generic Pharmaceuticals. Study Report for the European Generic Pharmaceuticals Association. Berlin, 2015. http://www.pharmaceuticalsforeurope.com/wp-content/uploads/2016/03/IGES_Study_Report_final_05-10-2015.pdf

The structure of pharmaceuticals market in the EU makes it clear that a policy that fosters competition in the pharmaceutical sector, which in particular involves the non-application of patent linkage, helps to avoid monopoly, broadens the share of available pharmaceuticals and gives a right to choose.

The European Union insists that all members of the Union shall avoid linkage between patent protection and procedures for obtaining marketing authorisation.

In Portugal, laws allowing the use of patent linkages and blocking the authorisation of pharmaceuticals were in force for some time in the past. Pharmaceutical companies have substantially abused these laws in order to maintain a monopoly on the market. Appeals against decisions of regulatory bodies in court were widespread in response to issuing permissions for the sale of generic pharmaceuticals. For example, only in 2007 about 70 cases were initiated against a regulatory body that carries out authorisation of pharmaceuticals and authorises the sale of pharmaceuticals on the market.

Protected and Off-Patent Market Share in European countries, 2014



The situation with patent linkage and market access of generic pharmaceuticals was almost catastrophic, which drew the attention of the European Commission. Portugal received a warning from the European Commission, which pointed out the failure to ensure the functioning of an effective system of interaction between the patent protection system and the regulation of the market entry of pharmaceuticals, as well as shortcomings in judicial resolutions of relevant issues. Because of applying the patent linkage regime, about 830 generic pharmaceuticals were denied access to the market. According to specialists, another regime in the legislation could save 45-65 million euros only for the national budget. In 2011, the Parliament unanimously supported the draft law 62/2011, according to which issuance of marketing authorisation cannot be considered as a violation of intellectual property rights arising from a patent. Moreover, in Portugal, by the same law, disputes between manufacturers of originators and generic pharmaceuticals companies were passed to a special arbitration on mandatory basis. Such a decision, however, caused the negative reaction of representatives of all parties in the pharmaceutical sector.

The postponement of the market entry is related not only to patent linkage, since in many countries, after obtaining a marketing authorisation, the manufacturer should also receive a price and compensation confirmation. Thus, the possibility of access to affordable pharmaceuticals is further delayed. The table below shows the average number of days of delay of the market entry of pharmaceuticals after obtaining marketing authorisation in Europe[45]:

Austria	180	Luxembourg	180
Belgium	120	Netherlands	45
Bulgaria	120	Poland	180
Croatia	360	Portugal	111
Czech Republic	180	Romania	270
Denmark	14	Slovakia	270
Estonia	180	Slovenia	180
France	75	Spain	150
Ireland	45	Sweden	30
Italy	135	Turkey	180
Latvia	240		

[45]According to the European Generic Pharmaceuticals Association EGA Market Review 2007.

Patent linkage regime is included in some free trade agreements between countries. The number of proofs of the harmful effect of this regime on the public health is increasing[46]. In particular, according to UNDP, such a negative effect is observed in Ukraine[47].

The patent linkage in the US contains a number of regulations for balancing the interests of different parties. Particularly, such a regime provides for a delay for appeal of the patent owner to the court, the possibility for a generic company to seek invalidation of an originator patent in court and, thus, obtain authorisation for a generic medicine, while the first generic medicine is granted the exclusivity right for 180 days. Since the patent linkage regime has been used long ago in the USA, it is possible to track the results of its implementation. According to the empirical studies[48], introduction of a patent linkage did not catalyse a significant leap of innovation in pharmaceutical industry but the number of disputes in court in this area increased significantly.Because of an exclusivity period (6 months) of the first generic, the manufacturer is given an opportunity to return litigation costs[49].

Almost in all countries, the patent linkage provisions do not appear naturally in the light of the circumstances of the country's public health and conditions in the pharmaceutical sector and are implemented through the signing of bilateral or multilateral agreements where one of the parties is the USA, as a rule.

In countries where the procedures of out-of-court dispute settlements under the patent linkage regime are used between patent owners and applicants for marketing authorisation, the negative impact of double consideration is indicated. Such a system allows pharmaceutical companies which lost the dispute to seek protection of their rights before a court during a review by the regulatory body (its chamber, special tribunal, etc.), which leads to the delay of the market entry of generic pharmaceuticals or suspension of sales until the case is resolved[50].

To reduce the prices for treatment of such serious illnesses as HIV/AIDS, competition on the market of pharmaceuticals is required. For example, according to the Doctors Without Borders[51], owing to competition and generic pharmaceuticals the annual cost of treatment with three originator drugs, lamivudine/stavudine/nevirapine (3TC/d4T/NVP), in the first year after the market entry of generic medicine decreased by 93% and in ten years the price of the originator was about 3% of its price at the time of the market entry of a generic medicine.

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[46]Francois Dabis, Marie-Louise Newell, Bernard Hirschel, 'HIV Drugs for Treatment, and for Prevention, The Lancet, Early Online Publication, 27 May 2010, www.natap.org/2010/HIV/052810_04.htm
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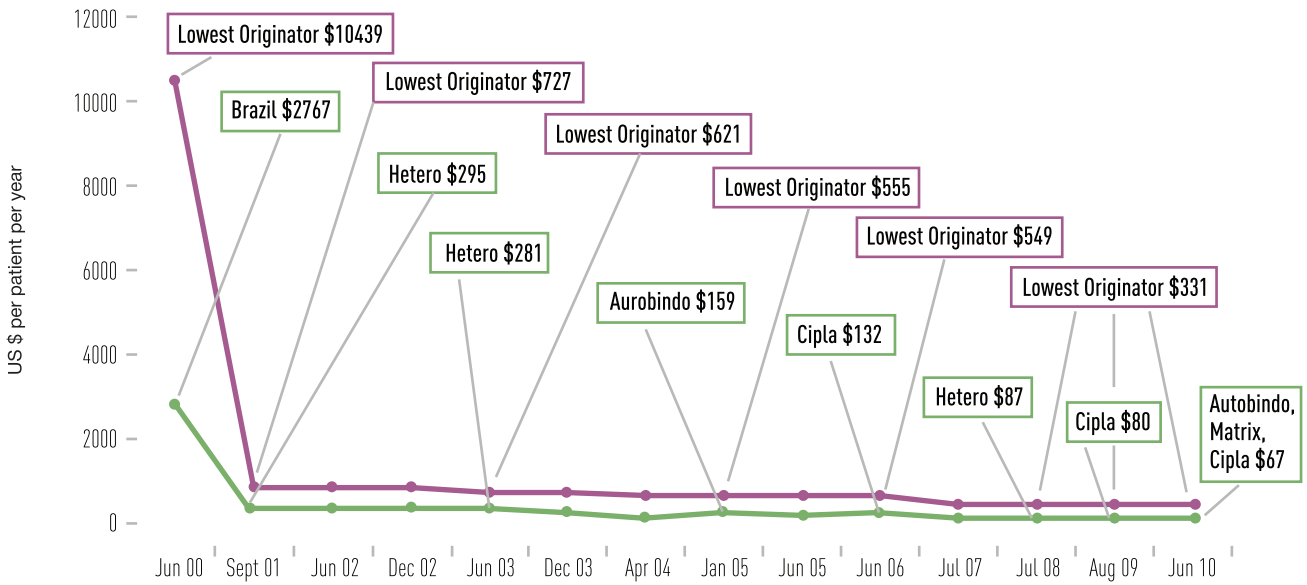
[48]Bouchard R, Empirical analysis of drug approval-drug patenting linkage for high value pharmaceuticals, Northwestern Journal of Technology & Intellectual Property, 8(2)(2010) 174-227.
[49]http://nopr.niscair.res.in/bitstream/123456789/20282/1/JIPR%2018(4)%20316-322.pdf
[50]Joel Lexchin and Marc-Andr Gagnon. CETA and Pharmaceuticals. Impact of trade agreement between Europe and Canada on the cost of patented drugs, 2013.
[51]Untangling The Web of Antiretroviral Price Reductions. Doctors Without Borders, 2010.



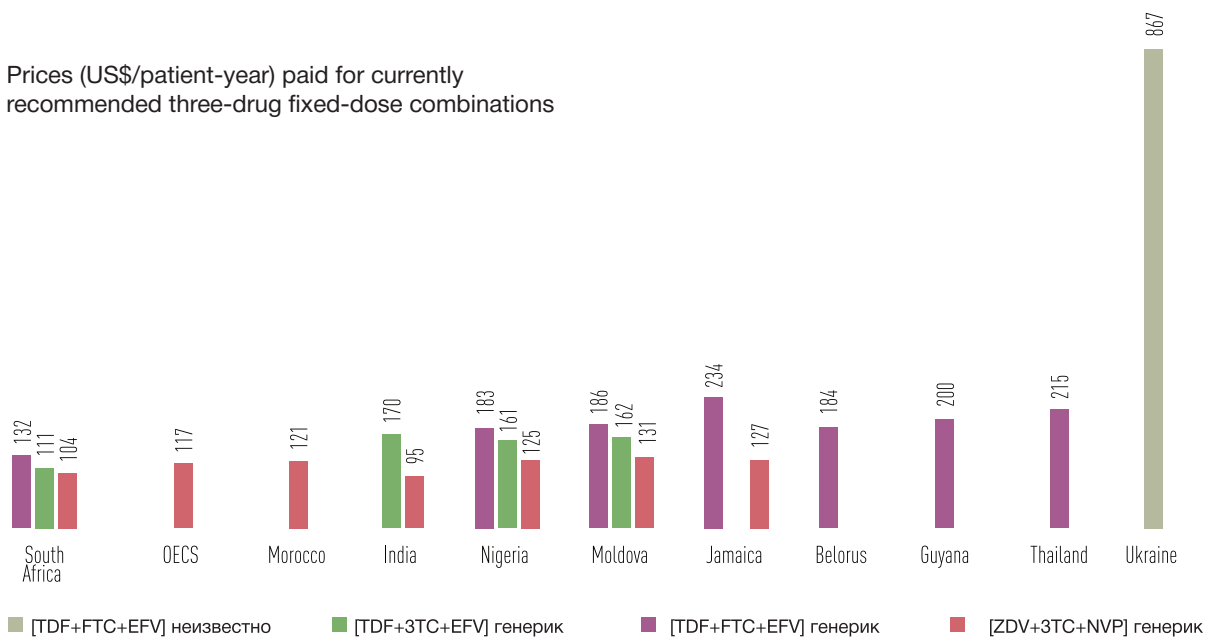
State budget savings

It has been repeatedly emphasised that the presence of generic pharmaceuticals on the market allows saving state budget expenditures on the procurement of certain pharmaceuticals. The difference in purchase prices is compared with the need to provide pharmaceuticals for all groups of population and is contrasted with the costs of pharmaceutical companies to the manufacture of new pharmaceuticals.

For instance, Canada spends more than USD 900 On Pharmaceuticals per person a year, which exceeds the expenses of many countries in this sphere. In order to estimate the amount of savings due to generic pharmaceuticals, in Ontario (Canada) expenses for Atorvastatin (Lipitor) amounted to USD 316 million. The following year after the expiration of the patent and the market entry of generic pharmaceuticals, these costs dropped to USD 133 million, which as a result saved USD 183 million for one medicine. At the same time, it should be noted that the patent linkage regime in Canada did not obstruct the market entry of generic pharmaceuticals. Originator companies complain that long-term protection of rights and royalties from pharmaceuticals sales are vital to financing highly costly research and pharmaceuticals trials. Simultaneously, the state budget funds are primarily invested in such socially important and highly costly studies as biology and medicine research.

It is very difficult to track the impact of the patent linkage regime via statistics, since price decrease do not automatically reduce the cost of purchasing pharmaceuticals, they can increase the volume of purchases instead. The adoption of such decisions depends on the government's policy on procurement in the public health sector and the state budget.

The funds allocated by the state for the purchase of expensive originator drugs may be aimed at financing the development of originator drugs. In this case manufacturers may not actually engage in innovative activities but only make minor improvements to the existing medicine. Under those circumstances, the amount of funds received as royalties and the amount of funds actually invested in new developments are unjustifiably different. The amounts that can be saved from the state budget when purchasing cheap generic pharmaceuticals can be allocated for the development of new pharmaceuticals and conducting the trials on a competitive basis, which will be a more equitable and effective way to develop pharmaceutical innovation.



In Ukraine such a principle can apply not to all types of pharmaceuticals because currently the demand for pharmaceuticals for patients with deadly diseases exceeds the state purchases of pharmaceuticals for them. The question of market entry of generic pharmaceuticals in Ukraine does not really concern savings of public funds that can be used for other needs, but the procurement of pharmaceuticals in the amount necessary for the survival of patients.

The statistics indicate a gap in the prices of pharmaceuticals in Ukraine and other countries, which demonstrates the need for active state policy aimed to promote access to pharmaceuticals. To exemplify, the World Health Organisation conducts data on the price of a combination of HIV pharmaceuticals in different countries (in US dollars per patient annually)[52]:

The patent linkage regime has a negative impact on the availability of pharmaceuticals, however, it is important to acknowledge that in order to provide pharmaceuticals to all groups of the population, the intellectual property and public health legislation shall be integrated to facilitate the access of generic pharmaceuticals to the market. To instantiate, there are several generic pharmaceuticals in South Africa which have already obtained marketing authorisation. Patients cannot get these pharmaceuticals because the current patent owner does not issue licenses to generic pharmaceuticals companies and, at the same time, there are difficulties in obtaining a compulsory license. According to Doctors Without Borders, due to market monopolisation by the patent owner there is a significant shortage of pharmaceuticals - about 65% of the citizens who sought for medical assistance did not receive the necessary drugs[53].

Access to the high-quality and effective drugs

It should be realised that the expiration of a patent validity for the active pharmaceutical ingredient and the generic pharmaceuticals enterance to the market does not mean complete substitution of originator drugs by generics. Generic pharmaceutical companies cannot cover the entire market due to the lack of industrial capacity or limited supply of resources. In addition, generic pharmaceuticals may not use the full composition or know-how of the originator, which is also reflected in the result of a medicine application and the possible benefits or the need to use specifically originator drugs (for example, the generic medicine is safe but has side effects and contains components that are not tolerated by some patients). By contrast, generic pharmaceuticals can also offer higher quality for patients.

Modern medicine tends to develop an individualised treatment that requires diversification of pharmaceuticals, which also entails diversification of the directions of development of pharmaceuticals (which involves additional expenses). Generic pharmaceuticals can fill the niche of individualised pharmaceuticals based on one original active ingredient with additional value. For example, generic pharmaceuticals with additional value include super generics (advanced versions of originator drugs), premium generics (improved by patient's assimilation or improved form that prevents erroneous or excessive medicine intake), specialised generics (made with the use of advanced technologies or improved elements), re-innovative generics having innovative, improved qualities, new therapeutic items (to satisfy the needs of certain categories of patients), etc[54].

[52] Increasing access to HIV treatment in middle-income countries. WHO, 2014. http://www.who.int/entity/phi/publications/WHO_Increasing_access_to_HIV_treatment.pdf?ua=1
[53]http://allafrica.com/stories/201510271243.html
[54]Value Added Pharmaceuticals: Rethink, Reinvent & Optimize Pharmaceuticals, Improving Patient Health & Access-May 2016

From a public health perspective, changing the prescription and application of pharmaceuticals has a positive effect but such activities are not considered economically attractive to pharmaceutical companies that are limited in time and resources, and such changing also encounters regulatory barriers of the pharmaceutical market. Among the benefits of generic pharmaceuticals with additional value are lowering the use of public health system, equality in access to pharmaceuticals, reduction of the procurement budget, prevention of increased application of pharmaceuticals and the rational use of pharmaceuticals as a result of an individualised approach, improvement of the quality of treatment.

However, such activities may be attractive to generic pharmaceuticals because due to the development and improvement of originator drugs or its reorientation for the new indication, they receive a significant competitive advantage.

Therefore, the complication of the entry of generic pharmaceuticals on the market due to patent linkage has negative consequences, consisting in the limited diversification and individualisation of pharmaceuticals created based on active pharmaceutical ingredients protected by the patent.

Analysis of Ukrainian case law regarding patent linkage

Number of cases (2011-2016)	Number of decisions in favour of the plaintiff	Number of refusals and the main reasons for the refusal	Taking measures to secure a claim	General tendencies
40 Including: 4 - administrative proceedings 36 - commercial proceedings Among them: 1 case in which the decision in the first instance has not yet been made, 2 – claims were left without consideration, 2 – proceedings in the case have been terminated due to the absence of the subject of dispute, 1 – proceedings were terminated due to the withdrawal of the claim	28 2 of them prior to the state authorisation of pharmaceuticals	6 1 of them prior to the state authorisation of pharmaceuticals Main reasons of refusal: - Ministry of Health of Ukraine acted on the basis, within the limits of authority and in the manner prescribed by the legislation of Ukraine; - There are no evidences of illegality of the state authorisation of pharmaceuticals, the fact of making decision on marketing authorisation does not constitute violation of patent rights; - No violation of intellectual property rights is detected.	Declared in 20 cases, in 2 cases the court has denied to take measures, in 18 cases measures were taken, 6 cases were cancelled by higher courts. Measures taken: - prohibition of amendments to the authorisation materials of medicinal products, - prohibition of issuance of a conclusion on the recommendation for the authorisation of a medicinal product (when the usage of a patent linkage regime is required before the authorisation); - prohibition of distribution on the territory of Ukraine; - prohibition to manufacture, use, offer for sale, including on the Internet or otherwise, to sell or otherwise engage in distribution; - prohibition to carry out customs clearance of medicinal products, marketing authorisation of which is contested. <u>Tendencies:</u> - measures were applied in most cases in which the corresponding trial motion was filed; - Measures to secure a claim were cancelled in 5 of 8 cases during 2011-2013. After that, the contesting of measures in most cases was not successful. However, the latest juridical practice denotes the return of the trend: measures to secure a claim are being cancelled by higher courts again.	Jurisdiction over cases of commercial courts Motivation: this category of disputes concerns the protection of intellectual property rights of right holders who are not in the relations of administrative subordination with the Ministry of Health; disputes have a civil nature and do not relate to the field of public-legal relations; Duration of case review: on average 2.5 years, some cases are heard repeatedly after the cancellation of decisions by the court of cassation; Court implements patent linkage in case of violation of intellectual property rights, even if the Ministry of Health and “the State Expert Centre of the Ministry of Health” prevented procedural violations; The conclusion of the court regarding the existence of violation of intellectual property rights (and satisfaction of the claim) directly depends on the conclusion of the forensic expert; The competence issue of the Ministry of Health and the “State expert centre of the Ministry of Health” concerning investigations of violation of intellectual property rights at the stage of marketing authorisation of pharmaceuticals is investigated by courts only in rare cases. Courts do not differentiate the intellectual property right and the procedure of authorisation based on different criteria of protection – the criterion of patentability (or the protection of a trademark) and the criterion of quality and safety of pharmaceuticals; Authorisation is cancelled not only in cases of violation of rights to inventions protected by Ukrainian patents, but also to patented utility models, as well as marks for good and services (trademarks).

Due to the application of the patent linkage regime in the period from 2011 to 2016, the authorisation of 28 pharmaceuticals was cancelled:

1. Oftamirin
2. Lopicip
3. Maxicin[55]
4. Emletra
5. Abacavir Sulfate
6. Corvalment
7. Virol
8. Alteika
9. Reditux
10. Moxifloxacin Zdorovye
11. Moxif
12. Moflox
13. Moxifloxacin
14. Ental-Zdorovye
15. Citin
16. Newkapibin
17. Erlonat-Zdorovye
18. Moxifloxacin-Norton
19. Miristamid-chpc
20. Abamune
21. Cormenthol
22. Ritocom
23. Ritopin
24. Ritopin-Zdorovye
25. Ental
26. Cormagnil 75, (and -150)
27. Erlonat
28. Viferon

Ritovir-L and Abavir were not authorised due to patent linkage since court decision prohibits the Ministry of Health from the issuance of authorisations of the disputable pharmaceuticals.

The amount of expenses for the authorisation of a medicine in Ukraine ranges USD 5 000 to USD 40 000, depending on specific circumstances.

Consequently, the cancellation of authorisation due to the use of patent linkage entails corresponding financial losses for holder of marketing authorization.

[55] The case is under consideration in court of cassation

Conclusions and recommendations

The application of patent linkage negatively affects the public availability of pharmaceuticals. In view of the high rates of HIV/AIDS in Ukraine and inaccessibility of pharmaceuticals for people in need, Ukraine should claim priority to public health protection interests and exclude the patent linkage provision from Art. 9 of the Law “On Pharmaceuticals”.

Ukraine needs to find consistency with the legislation reform and obligations under the Association Agreement with European Union. European law does not imply the use of patent linkage, hence the linkage of two regimes - the compliance control of intellectual property rights and the control of the quality and safety of pharmaceuticals - is defined as inadmissible in the EU. European patent linkage policy is reflected, in particular, in the Association Agreement which does not contain such a provision.

At the same time, Ukraine must ensure a high level of protection of intellectual property rights by international agreements. For effective protection of rights, the right holder must be able to find out about a violation and apply effective legal protection mechanism.

Authorisation of a medicine does not constitute the use of a patented invention or utility model. Offering a medicine for sale, promotion, and distribution during the patent validity is deemed to be the use of such a medicine and thus violates the rights of a patent owner. Such actions can be carried out only after the patent expiration. However, preparation for the lawful distribution of a medicine that requires efforts and time cannot be unjustifiably delayed. Thus, during the patent validity the generic medicine company may file materials for authorisation and receive a marketing authorisation, which can come into force from the day following the date of patent expiration.

In order to ensure the opportunity for a patent owner to prevent violation of the rights arising from his/her patent, a person indicated as the patent owner to originator (reference) drug may be notified of the registration of generic medicine immediately when such decision is issued. Such notification allows the patent owner to monitor violations on the market before the patent expiration and seek protection of his/her rights in court. The introduction of such a system may be the subject to discussions, a way of reaching a compromise by the proponents and opponents of the current patent linkage regime in Ukraine.

LEGAL FRAMEWORK FOR DATA EXCLUSIVITY AND OPPORTUNITIES FOR LIMITING THE REGIME IN THE PUBLIC HEALTH SECTOR

The nature of the regime

The term "Data exclusivity" first appeared in the USA in 1984 in connection with enactment of the Drugs Price Competition and Patent Term Restoration Act (Hatch-Waxman Act). During the period from 1962 to 1984, patent term of many pharmaceuticals expired and, despite this, manufacturers continued to distribute them at inflated prices. With enactment of the Act, innovative companies were provided with the data exclusivity regime, and generic pharmaceuticals companies were given the opportunity to submit abridged applications for marketing approval, provided that they had proved the bioequivalence of their pharmaceuticals. At the same time, a generic company, which first submitted the application for marketing approval and obtained it, was provided with 180-days of marketing exclusivity regime, and during this period such company had no competitors among other generic pharmaceuticals companies. Thus, the introduction of this mechanism, on the one hand, was an additional measure to maintain monopoly of originators (delaying entry of generic equivalents to the market) and, on the other hand, provided a simplified procedure for generics to enter the market.

In 1988, the data exclusivity regime was introduced in Japan, and in 1993 - in the EU countries. The necessity of such mechanism is caused by specific nature of medicinal products, the processes of their development and regulatory approval. According to a report prepared by the analysts at the Tufts Centre for the study of drugs development, USA, the cost for development of a new medicine was USD 2.6 billion in 2014, and USD 1.04 billion in 2003. This amount includes the cost of failures, which are usually more common than success. The final stage of development is clinical studies. Its outcomes together with the results of preclinical studies make the basis for the registration dossier. Thus, taking into account the desire to cover investments put into the research as well as the market competition, the data exclusivity regime is an additional measure that allows to extend the monopoly of originators by postponing the market entry of generics.

Besides, the introduction of “the data exclusivity” is associated with the intention to compensate for the short period of effective protection. Patents provide the exclusive right to use an invention or utility model relating to a new active ingredient, a method of its manufacturing, etc. In addition, the availability of the patent itself does not provide any economic benefits to the holder, since it is not possible to start using the product until marketing approval is obtained. As the process of conducting clinical research and authorisation procedure may last for years, even though the patent was obtained at the initial stage of development, its term often expires when the drug enters the market. In this case, in order to obtain commercial benefits the data exclusivity regime may be applied. In other words, originator companies are offered a certain amount of rights on the market, which should guarantee non-competition over a specified period in exchange for investing in the latest developments. Other than that, the data exclusivity regime is more strict and unequivocal compared to the patent protection, so the originator company should have more incentive for innovation.

Below is a schematic illustration of two typical scenarios (based on the terms of patent protection and data exclusivity in the European Union).

Patent Protection Duration 20 years

The duration of patent protection exceeds the duration of data exclusivity

Patent Protection Duration 20 years

Thus, the data exclusivity is a specific measure of originator medicinal products protection. In addition to the pharmaceutical industry, such a regime operates in the agricultural chemistry.

The term of the data exclusivity is disclosed by Volska O.A., indicating that it is the exclusive right of originator company to use the research data from its registration dossier for a certain period in order to launch the medicinal product. This right of the originator is supported by the prohibition to accept authorisation requests from generic companies that contain references to the results of preclinical and clinical trials of the originator.

Carlos Correa, director of the Centre for Interdisciplinary Studies on Industrial Property and Economics at the Law Faculty, University of Buenos Aires, states that the main idea of the data exclusivity is to provide the originator with a unique right to the data provided to the regulatory authorities. During a specified period, the regulatory authority cannot rely on these data approving generic pharmaceuticals. All other companies willing to introduce equivalent products, should either perform the entire cycle of preclinical and clinical trials, or wait for the expiration of the data exclusivity. By this time, the originator company can use market exclusivity as a monopoly to produce and sell such medicinal products.

It should be mentioned that the data exclusivity differs from related concepts - patent protection and so-called Bolar provision.

In particular, patent protection and a data exclusivity regime are two parallel means to protect innovative developments in healthcare. However, unlike data exclusivity, patent protection protects certain components of pharmaceuticals - the novelty of the active ingredient, the method of manufacturing and packaging. Another difference is that the data exclusivity regime starts automatically from the moment of authorisation and, unlike patent protection, does not require passing any additional administrative procedures.

The following table compares the data exclusivity and patent protection regimes.

Characteristics	Data exclusivity	Patent protection
Description	Establishing a no entry period for generics in order to provide a temporary monopoly of originator to compensate the costs incurred during the research.	Providing exclusive intellectual property rights for a limited period in exchange for disclosing the nature of the patented product that will become available to the public after the expiration of the patent.
Subject matter	Registration data (clinical trials data, data on the quality and safety of pharmaceuticals, depending on the jurisdiction) of originators, or new therapeutic indications of already registered pharmaceuticals.	A product (device, pharmaceutical ingredient, etc.); A process (method); A new application of existing product or process.
Authority that provides protection	A regulatory body authorized to decide on the marketing authorisation of pharmaceuticals.	The central executive body that implements state policy in the field of intellectual property.
Legal nature	The obligation of the authorized body (decision on the marketing authorisation) on the pharmaceuticals permission. Does not require additional administrative procedures.	The right of the inventor that may be implemented through certain administrative procedures.

The mechanism of protection	Prohibition of authorisation of generic pharmaceuticals that refer to the data of the originator product; rejection of applications for marketing authorisation that refer to the data of the original product.	Prohibition of the use of an invention (utility model), namely: - prohibition of the product manufacturing, the usage of such product, offering for sale, distribution, import, storage for the specified purposes; - application of the process protected by the patent.
Validity	Since granting marketing authorisation (internal or external, depending on the jurisdiction) until the expiration of the term specified in the national legislation and/or international agreements.	20 years from the date of filing a patent application with the possibility of extension for up to 5 years.
Use exemptions	Permission/consent of the data owner. Public health needs. Other cases stipulated by the national law and/or international agreements.	In compliance with the statutory requirements: - In extraordinary circumstances (natural disaster, catastrophe, epidemic, etc.); - within compulsory licensing procedure; - for scientific research or an experiment; - in other cases, determined by law.

Bolar provision authorizes a generic pharmaceuticals company to manufacture some batches of such pharmaceuticals for the purpose of conducting trials before the expiration of the patent term. As a result, sales of generics become possible immediately after the expiration of the patent term. For example, in the United States, this provision applies to the last 8 out of 12 years of data exclusivity. In the EU, this provision extends to the last 2 out of 10 years of the data exclusivity.

Statutory regulation under Ukrainian legislation

Accession to the WTO and the EU integration provides the obligation to implement international agreements including the TRIPS Agreement, which was ratified by Ukraine in 1994. TRIPS Agreement establishes minimum standards for the recognition and protection of intellectual property rights, and gives the parties a certain range of methods for implementing its provisions. In particular, the TRIPS Agreement does not impose a mandatory period of the data exclusivity that currently lasts for 5 years in Ukraine.

The data exclusivity was detailed and became mandatory for Ukraine due to the establishment of such regime in paragraph 433 of the Report of the Working Party on the Accession of Ukraine to the WTO. Thus, a representative of Ukraine confirmed that before the accession to the WTO, the government will approve amendments to the Law of Ukraine «On Pharmaceuticals» according to Article 39.3 of the TRIPS Agreement. Such Article provides that members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use and disclosure. During the data exclusivity period, no person or institution (public or private) besides the person or institution submitting the relevant information, is entitled to rely on this information to support the application or to obtain an authorisation without the direct consent of the owner. Moreover, further applications on marketing authorisation shall not be accepted, unless the applicant submits their information that meets the same requirements as the information provided by the originator. In addition, Ukraine will guarantee the protection of such information from disclosure during this period, except cases where it is necessary to ensure public interests or when measures are taken to ensure data protection against unfair commercial use. The representative of Ukraine confirmed that regulatory acts aimed at the implementation of the Law of Ukraine «On Pharmaceuticals» would determine that the term «use of information submitted during authorisation» should contain “reference or use of other information”. The working group took into consideration such obligations.

Thus, the obligations under this agreement have been reflected in both the general legislation - the Civil Code of Ukraine, and in the special legislation - the Law of Ukraine «On Pharmaceuticals» and other by-laws.

In Ukraine, the so-called TRIPS-plus provisions on the protection of clinical research data are reflected in the Law of Ukraine «On Pharmaceuticals». Thus, the «data exclusivity» provision appeared in Ukraine in 2006 after introducing relevant provisions in the Law «On Pharmaceuticals». At the same time, this term has not received the established definition yet.

Although the term of «data exclusivity» is not defined in Ukrainian legislation, the subject matter of the regime is stipulated by Article 9 of the Law «On Pharmaceuticals», which has been improved compared to 2006 edition.

Thus, according to the paragraph 11 of Article 9, information contained in the application for authorisation and its annexes (authorisation information) is a subject of state protection against disclosure and unfair commercial use. The Ministry of Health is required to protect such information from disclosure and to prevent unfair commercial use of such information.

Pursuant to the law, if the medicinal product obtained the authorisation on the basis of the full application (originators), the authorisation of other pharmaceuticals containing the same active ingredient may be conducted not earlier than five years from the date of the first authorisation granted to the originator medicinal product.

This requirement does not apply to cases when in accordance with the law the applicant has the right to refer and/or use the data of the originator or has submitted their own complete information that meets the requirements for the originators.

The five-year term can be extended to 6 years if during the first three years after the marketing authorisation the product was approved to be used for one or more indications that are considered to be of particular importance over existing ones. Rules and criteria for determination of indications that have particular importance are established by the Ministry of Health. A 5-years term of exclusivity is established if the application for the marketing authorisation of the originators in Ukraine is submitted during two years from the day of the first marketing authorisation in any other country.

According to paragraph 3-1 of the Regulation No.376 of 26 May 2005 approved by the Cabinet of Ministers of Ukraine, the information contained in the application and its annexes (authorisation information), in accordance with the Law "On Pharmaceuticals" and other regulations, is a subject of state protection from disclosure and unfair commercial use. The Ministry of Health and the State Expert Centre of the Ministry of Health are obliged to protect such information from disclosure and unfair commercial use.

According to paragraph 3-2 of the Regulation, it is prohibited to use the authorisation information regarding the safety and efficacy of the medicinal product during 5 years from the date of the marketing authorisation, unless the right to refer to such information is received in the lawful way or the information is prepared by the applicant. The similar provision is set by the Order of the Ministry of Health No. 426 of 26.08.2005 (§ 36 clause 1 section II).

These requirements do not prohibit to carry out relevant developments and to conduct the research regarding equivalence of the generic and originator medicinal product, and submit registration dossier to the regulatory authority for marketing authorisation before the expiration of a five-years term as defined in the preceding paragraph.

Pursuant to the paragraph 6 clause IV of the abovementioned legislative act, a medicinal product cannot be recommended for marketing authorisation if according to a special examination its efficacy, safety and quality were not confirmed. Namely, such conclusion can be made if during an examination of the registration dossier it was found that the usage and reference to information on the effectiveness and safety of the originator, registered in Ukraine for the first time on the basis of the full authorisation information, occurred before the expiration of the 5-year period.

To sum up, it should be pointed that:

1. The Law provides a wider range of information covered by the data exclusivity regime. In particular, the Law provides the protection of the entire authorisation information of the originator, while the Regulations protect only information on the efficacy and safety of the originator.

2. The authorisation information regarding the originator medicinal product is a subject of protection during 5 years from the day of its authorisation in Ukraine. For the society, it would be more beneficial to start countdown from the first marketing authorisation in any country of the world, but unfortunately, it would constitute a violation of the Ukrainian commitments before the WTO, which clearly indicate that this term should be counted from the moment of marketing authorisation in Ukraine.

3. Peculiarities of orphan drugs are not taken into account. A term of clinical data protection is equal for all categories of medicinal products and accounts for 5 years. Thus, Ukraine has more moderate terms of the data exclusivity than in some other countries that provide for longer data exclusivity terms for orphan drugs.

4. The Ministry of Health and the State Expert Centre of the Ministry of Health are responsible for protection of data submitted for authorisation. On the other hand, there are no specific tools for protection of such data and clear differentiation between responsibilities of regulatory authorities. Moreover, there is no statutory liability for violation of the data exclusivity term. Therefore, the originator companies are concerned about the risks of rights violation. The judicial system inefficiency, namely lengthy and non-transparent arbitration, makes things even worse.

5. Lack of procedure on obtaining permission from the originator.

The main points of the data exclusivity regime in Ukraine are as follows:

- data exclusivity regime applies only to originator medicine, that obtained the marketing authorisation on the basis of full application;

- to enjoy the data exclusivity regime the originator should apply for marketing authorisation in Ukraine within 2 years from the day of the first marketing authorisation in any country;

- marketing authorisation of other pharmaceuticals that contain the same active ingredient as the originator medicinal product is prohibited, but the submission of the application for authorisation is allowed;

- the applicant may refer and/or use the authorisation information of the reference medicinal product if applicant has the right to refer to it in accordance with the law;

- the applicant may obtain marketing authorisation for generic medicine during the data exclusivity period in case of submission of its own full application.

Legal regulation in foreign jurisdictions and balancing the regime with public health

Research and development of innovative pharmaceuticals are characterized by the high level of scientific, regulatory and economic risk. According to a rating of the International Federation of Pharmaceutical Manufacturers and Associations, the development process takes about 10-15 years, and for every 5000-10000 tested compounds only one receives marketing approval and entries the market. Thus, the cost of developing of new pharmaceuticals usually exceeds USD 1 billion.

The data exclusivity regime encourages pharmaceutical companies to invest in research and development of innovative pharmaceuticals, as it guarantees the return of such investments during a temporary monopoly.

The data exclusivity in the TRIPS Agreement

WTO members and TRIPS countries use different approaches to the interpretation of the TRIPS provisions. Overall, different approaches to interpretation of the TRIPS provisions (not only regarding data exclusivity) as well as different priority growth areas of pharmaceutical market caused the formation of two opposite strategies for balancing the interests of originator companies, generic companies and consumers. Ambiguousness of the TRIPS Agreement as to data exclusivity led to the conclusion of free trade agreements (FTAs) that require establishment of the data exclusivity in accordance with the US standards. It has become a major tool of the US policy, and sometimes of the EU, in relation to developing countries, since the absence of the data exclusivity regime in the national legislation resulted in serious commercial conflicts between transnational pharmaceutical companies (innovators) and powerful local generic producers.

	USA, other high income countries	WHO, developing countries
Interpretation of Article 39.3 TRIPS	The “data exclusivity” is a justified interference in order to prevent “unfair commercial use”. It prohibits not only to use the data directly, but also to refer to the data during specified period for the purpose of generic pharmaceuticals approval.	TRIPS provision does not require the introduction of data exclusivity regime, but only refers to the interference of “unfair commercial use” or acts of “unfair competition”. Generic pharmaceuticals companies cannot be considered as those using the data of the originators, because they do not have access to it. Similarly, regulation authorities do not use this data for commercial purposes, but they take it into account for the implementation of authorisation procedures.
Requirements for the parties	Implementation of the “data exclusivity” provision into national legislation is required, as well as the establishment of its duration.	Since TRIPS does not provide a definition of “unfair commercial use”, every country implementing this provision has the right to determine which actions will be considered as unfair use.
Consequences	The national legislation was amended based on abovestated interpretation of the TRIPS Agreement.	The national legislation does not contain more restrictive provisions than those established by TRIPS. As a result, there is no notion of “data exclusivity” in many least developed countries at all.

A strategy of TRIPS-plus provisions implementation

The initiators of such strategy, in particular the EU and the USA, due to the “unsatisfactory” response to the TRIPS provisions from some countries, began to strengthen international intellectual property protection standards through bilateral and multilateral TRIPS-plus agreements.

Among main TRIPS-plus provisions, the data exclusivity is introduced as a temporary monopoly for originators.

The free trade agreements also specify that:

- the data exclusivity period may exceed the patent term (the USA-Singapore (2003), the USA-Australia (2004), The USA-Peru (2006);
- the data exclusivity applies not only to new chemical compounds, but also to new therapeutic indications (the USA-Australia (2004), the USA-Morocco (2004), the USA-South Korea (2007);
- the data exclusivity may apply not only to new chemical compounds, but also to new therapeutic indications of previously registered pharmaceuticals.

Other provisions are related to patents protection: the possibility of the patent term extension for more than 20 years (supplementary protection certificate), the introduction of a patent linkage (the obligation of state authorities responsible for registration of pharmaceuticals to check whether patent rights are being violated before authorisation of the new medicine), and toughen liability for patent rights infringement.

In general, international agreements aimed at consolidation of the TRIPS-plus strategy include the EU Association Agreements, agreements with the European Free Trade Association, free trade agreements initiated by the United States, the EU and some other developed countries.

2. Denial of the data exclusivity regime as not provided for in the TRIPS Agreement. Non-existence of the data exclusivity requirement in the TRIPS Agreement is a comparatively weak motive, since such position still has not found a unified formal expression in international documents. However, a policy of the countries that refuse to implement the data exclusivity into national legislation, including beyond the patent term, can be qualified as a separate strategy - the TRIPS-plus opposition strategy. The countries that support such position are India, Indonesia, Thailand, Brazil, Argentina, and UAE. International organisations such as WHO, UNDP, UNAIDS are also calling for developing countries to take on such a position.

Supporters of such a strategy state that in the least developed countries patent protection is enough to ensure the rights of innovators, while the data exclusivity initiative is nothing but the lobbying of their commercial interests, which unjustifiably limits the competitiveness access to treatment for the low-income population. Prof. Brook K. Baker states that if India opposes the United States regarding the establishment of the «data exclusivity», it will have the support of other developing countries, including those involved in the FTA negotiation process[56].

Below is the data on the national laws of some countries regarding data exclusivity as well as the introduction of this regime through bilateral and multilateral agreements. The order of the countries is based on the longer to shorter terms of data exclusivity.

[56] «A critical analysis of India's probable data exclusivity/data compensation provisions», http://www.healthgap.org

№	Jurisdiction GDP per capita[57], 2015 (USD)	Data exclusivity regime (hereinafter – DE): general information	Peculiarities: exemptions and obligation according to international agreements	Regulation (national legislation, international agreements*) *year of the announcement, signature or entry into force
1.	EU countries	10 years (8+2) 8 years It is prohibited to apply for authorisation of a generic medicinal product until 8 years have elapsed from the initial authorisation of the reference product. +2 years It is prohibited to grant marketing authorisation to a generic medicinal product and place it on the market. +1 year If, during the first eight years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies. + 6 months For paediatric medicinal products. 10 years for orphan pharmaceuticals From the moment of marketing authorisation in the EU. +2 years for paediatric pharmaceuticals	Exemptions Disclosure and use of data is allowed: - subject to the prior consent of the originator company; or - if the company is not able to satisfy the demand for such pharmaceuticals; or - if the generic medicinal product has significant advantages over the originator. Data exclusivity 8+2 is applied if the member-state granting marketing authorisation to the reference medicinal product is different from the member-state granting it on the generic product. The applicant should indicate the name of the member-state where the originator was granted a marketing authorisation. The EU is one of the regions with the longest terms of data exclusivity. The foreign policy of the EU is intended to encourage other countries to introduce or extend the data exclusivity. This is evidenced by a number of bilateral and multilateral agreements that will be mentioned below. Nevertheless, the EU policy seems less rigid compared with the policy of the USA in this respect.	<u>The EU legislation:</u> Directive 2001/83/EC of 6 November 2001 (art. 10,10a,10b) Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 Regulation (EC) No. 141/2000 of 16 December 1999 on orphan medicinal products Regulation (EC) No. 1901/2006 of 12 December 2006 on medicinal products for paediatric use Regulation (EEC) No 1768/92, Directive 2001/20/EC.
2.	Switzerland, 82 178	10 years The generic company has the right to use the results of pharmacological and toxicological tests and clinical studies only: - If they obtain a permission from the originator (data holder); - in 10 years since the marketing authorisation of the originator medicinal product. +3 years - For new indication, new dosage form or a new mode of administration obtained as the result of additional clinical studies, or + 5 years If this “novelty” provides better clinical benefit in comparison with existing therapies.	Switzerland advocates the rigid data exclusivity regime. In foreign policy, including within the EFTA, Switzerland stands for the strengthening of such a regime in other countries, as evidenced by the conclusion of EFTA States - Mexico (2001), China-Swiss FTA (2013).	<u>National legislation:</u> Federal Law on Medicinal Products and Medical Devices (Law on Therapeutic Products) of 15 December 2000 (ch. 2, sec.1, art.12) <u>International agreements:</u> EFTA – Mexico FTA (July 1, 2001) China-Swiss FTA (2013)

[57] https://en.wikipedia.org/wiki/List_of_countries_by_GDP_(nominal)_per_capita

№	Jurisdiction GDP per capita[1], 2015 (USD)	Data exclusivity regime (hereinafter – DE): general information	Peculiarities: exemptions and obligation according to international agreements	Regulation (national legislation, international agreements*) *year of the announcement, signature or entry into force
3.	Canada, 43 935	8 years (6+2) 6 years since marketing authorisation of the reference medicinal product (including biologic pharmaceuticals) it is prohibited to submit applications for authorisation of generics. +2 years It is prohibited to grant marketing authorisation and place generics on the market. + 6 months for paediatric pharmaceuticals that have proven its therapeutic effects during the first five years of an 8-year period.	Exclusions The term of protection does not apply to pharmaceuticals containing an active ingredient already authorized in Canada, even if these pharmaceuticals have new indications, dosage forms or other changes already known in existing products. Based on the Biotechnology Innovation Organization (hereinafter - BIO) Report[58] 2016, the provisions of the C-17 Bill on amendments to the Food and Drug Act allow the Health Minister to disclose confidential business information to members of the public, foreign governments and competitors, without obligation to respect confidentiality or other protection measures in some cases. Charter 11, article 10 CETA Chapter 22, Article 10 of CETA obliges parties to adhere to the 8-year term of data exclusivity.	National legislation: Food and Drug Regulations, Section C.08.004.1 Bill C-17, An Act to Amend the Food and Drug Act (2015) International agreements: EU-Canada agreement (CETA, 2014) Trans-Pacific Partnership agreement 2015 (not ratified)
4.	The USA, 55 904	5 or 12 years 5 years since authorisation of reference medicinal products it is prohibited to submit applications for authorisation of generics. + 3 years For new dosage forms, new therapeutic indications, or prescription to over-the-counter reclassification, obtained as the result of additional clinical studies having high significance (other than bioavailability studies) +6 months For pharmaceuticals for which the manufacturer has conducted clinical studies to determine the possibility of their paediatric use. 7 years for orphan pharmaceuticals From the moment of marketing authorisation, it is prohibited to apply for authorisation of the generic product containing the same active ingredient and used for the same indications. 12 years – the data exclusivity period for biological medicinal product. During 4 years – from the moment of biologic medicinal product authorisation biosimilar filings cannot be accepted.	Exemptions Generic medicine can be authorised if it is significantly safer, more efficient and convenient to use, compared with the originator. The data exclusivity term established for biologic pharmaceuticals does not apply to: - a supplement for the biological product that is the reference product; or - a subsequent application filed by the same sponsor or manufacturer for: - a change (not including a modification of the structure) that results in new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or - a modification to the structure that does not result in a change in safety, purity, or potency. Apparently, the USA is a leader in a number of bilateral and multilateral TRIPS-plus agreements including concerning data exclusivity, i.e.: - NAFTA (Mexico, 1994) - U.S – Jordan FTA (2000); - U.S.-Singapore FTA (2003); - U.S.-Chile FTA (2004) - U.S.-Morocco FTA (2004); - Australia-US Free Trade Agreement (AUSFTA) (2004); - U.S.-Peru FTA (2006); - U.S.-Colombia FTA (2006); - South Korea-US Free Trade Agreement (KORUS) (2007); - Trans-Pacific Partnership (TPP) Agreement (2015). In these agreements, the United States managed to pave legal way for data exclusivity regime for a term of 5 years, in some cases additional 3 years for new therapeutic indications, as well as up to 8 years for biologic pharmaceuticals.	National legislation: Federal Food, Drug, and Cosmetic Act) Public Health Service Act There are no international obligations that would extend the term of data exclusivity, which is provided by the USA legislation. Trans-Pacific Partnership agreement 2015 (not ratified)

[58] BIOTECHNOLOGY INNOVATION ORGANIZATION, SPECIAL 301 SUBMISSION,2016

№	Юрисдикция/ ВВП на душу населения[1] за 2015 год (долл. США)	Общий режим эксклюзивности данных (далее – ЭД)	Peculiarities: exemptions and obligation according to international agreements	Regulation (national legislation, international agreements*) *year of the announcement, signature or entry into force
5.	Japan, 32 481	Data exclusivity is successfully implemented throught so-called re-examination period, which lasts during 3 months after each sale period determined in accordance with the category of medicinal product: - Orphan or paediatric pharmaceuticals – 10 years; - Pharmaceuticals containing new active ingredient (except orphan pharmaceuticals) - 8 years; - Improved pharmaceuticals with new therapeutic indications– 4-6 years.	Possibility of extension The Minister may extend the data exclusivity for re-examination. However, any extension of such period cannot last more than 10 years from marketing approval. Japan is one of those countries supporting the strategy of imposing the TRIPS-plus provisions to other jurisdictions. Since 2009 the country holds negotiations with India concerning the conclusion of FTA (the provision of data exclusivity is contained in the document), but specific arrangements have not been reached.	National legislation: Pharmaceutical Affairs Law, (article 14-4) There are no international obligations regarding enforcement of data exclusivity regime in comparison with already established ones in Pharmaceutical Affairs Law. Trans-Pacific Partnership agreement 2015 (not ratified)
6.	China, 8 280	6 years During first 6 years from the marketing authorisation of the originator, its generics cannot be authorised unless the data is based on the applicant's own trials. The filing of application for marketing authorisation of a generic drug is permitted not earlier than 2 years before the expiration of the patent.	Exemptions Data exclusivity regime is not applied if: - the data disclosure is necessary for the protection of the population; - measures will be taken to ensure the protection of such data from unfair commercial use. According to Article 11.11 China-Swiss FTA, a 6-year exclusivity period for pharmaceuticals will be established.	National legislation: Regulations for Implementation of the Drug Administration Law of the People's Republic of China (Decree of the State Council No. 360) Provisions of Drug Registrations (art.19,20) International agreements: China-Swiss FTA (2013)

№	Jurisdiction GDP per capita[1], 2015 (USD)	Data exclusivity regime (hereinafter – DE): general information	Peculiarities: exemptions and obligation according to international agreements	Regulation (national legislation, international agreements*) *year of the announcement, signature or entry into force
7.	South Korea, 27 513	4 or 6 years Data exclusivity regime is applied during re-examination and lasts for 3 months after termination of the following marketing periods, depending on the category of the medicinal product 6 years for new pharmaceuticals and prescription pharmaceuticals changed compared to the earlier authorised pharmaceuticals in terms of active ingredients, composition or route of administration. 4 years for prescription pharmaceuticals with known active ingredient and route of administration but with different indications. For other medicinal products, the period of re-examination is established by the authority.	Exemptions The disclosure and use of data if possible: - on the basis of permission of the data holder; or - after the termination of re-examination period. South Korea-US Free Trade Agreement Pursuant to Article 18.9.1, 18.9.2 KORUS, the term of data exclusivity accounts for 5 years. +3 years is provided also for new clinical data (new therapeutic indications), 18.9.02 KORUS. The EU-Korea Free Trade Agreement (Art. 10.36) – Obliges the parties to adhere to a 5-year data exclusivity term.	National legislation: Pharmaceutical Affairs Law Ministerial Decree to Pharmaceutical Affairs Law KFDA Regulations regarding the Licensing, Report and Examination of Drug Products International agreement: South Korea-US Free Trade Agreement (KORUS) 2007, will take effect on 15 March 2012 The EU-Korea Free Trade Agreement (2010)
8.	Turkey, 9 290	*6 years Data protection term is established for originators from the moment of marketing authorisation on the market of any country of the Customs Union (the EU+ some other countries). At the end of this period the abridged authorisation procedure is available for generic product (art.9). *this period cannot exceed the patent term, established in Turkey.	Exemptions Data exclusivity does not apply to: - combinations of known chemical compounds; - biological pharmaceuticals. Data exclusivity begins from the first day of marketing authorisation in any country of the Customs Union, but due to a long-running procedure in Turkey (2-3 years[58]), in practice, originators have no more than one/two years of data exclusivity.	National legislation: Regulations on Licensing the Human Medicinal products

[59] PhRMA, SPECIAL 301 SUBMISSION, 2016

№	Jurisdiction GDP per capita[1], 2015 (USD)	Data exclusivity regime (hereinafter – DE): general information	Peculiarities: exemptions and obligation according to international agreements	Regulation (national legislation, international agreements*) *year of the announcement, signature or entry into force
9.	Russian Federation, 8 447	*6 years (4+2) Within 6 years from the authorisation of the reference medicinal products it is prohibited to use data about the results of preclinical and clinical studies for commercial purposes. During the first 4 years out of the 6-year period it is prohibited to apply for marketing authorisation of generics. 3 years - for biologic pharmaceuticals. An application for biosimilar may be lodged within 3 years from the reference medicinal product authorisation.	Earlier Article 18 of the law (2012) used to prohibit the use of the data on pre-clinical and clinical studies for commercial purposes and for authorisation of the product during 6 years from the reference medicinal product authorisation. However, there was no case law that would enforce this provision to protect the rights of originators. As of 01.01.16 a new version of Article 18 came into force. Now the data protection relates to "use in commercial purposes". Such change in the understanding of "data exclusivity" contributed to the formation of the case law not in favour of the originators. Case law[60] *The decision of Supreme court of the Russian Federation of 03.06.2016 (case of Novartis Pharma AG BioIntegrator): "The provision of paragraph 6(18) Article 18 61 does not provide for the data exclusivity in terms of marketing approval prohibition during 6 years from the marketing authorisation of the originator, but protection of data from its disclosure. The court has also admitted that publications in special editions and other open sources are not prohibited."	National legislation: Federal Act "On the circulation of pharmaceuticals" (paragraphs 18-21 of Article 18).
10.	Israel, 35 702	5 (5,5) or 6 (6,5) years Authority can provide marketing authorisation for generic medicine in case one of the following conditions is met, namely: - the applicant has obtained the permission from the data owner; - minimum 5 years has elapsed from originator's authorisation in Israel, or 5.5 years from the authorisation in the USA, Europe, Canada, Australia, New Zealand, Switzerland, Norway, Island or Japan granted before 07.07.2011, or - minimum 5 years has elapsed from the originator's authorisation in Israel, or 6.5 years - from the authorisation in the USA, Europe, Canada, Australia, New Zealand, Switzerland, Norway, Island or Japan granted after 07.07.2011.	Exemptions Data exclusivity regime is not applied if: - the applicant has provided all the data, which is considered satisfactory to prove safety, efficacy and quality of a new medicinal product; - the necessity of a new medicinal product (generic medicine) exists due to one of circumstances indicated in Article 20 (1) of People's Health Ordinance. - there is a risk of serious danger to the public health, which is stated in official publications by the Minister; - it does not apply to biological pharmaceuticals. Amendments to the legislation regarding extension of the term of data exclusivity were adopted due to agreements reached between governments of Israel and the USA[61] in 2010.	National legislation: Health Amendment of the Pharmacists Ordinance Agreements are reached between governments of Israel and the USA[62] in 2010.

[60] http://www.chemrar.ru/press/press_detail.php?ID=21166
[61] http://djf.typepad.com/files/1664-ustr-letter-agreement.pdf
[62] http://djf.typepad.com/files/1664-ustr-letter-agreement.pdf

№	Jurisdiction GDP per capita[1], 2015 (USD)	Data exclusivity regime (hereinafter – DE): general information	Peculiarities: exemptions and obligation according to international agreements	Regulation (national legislation, international agreements*) *year of the announcement, signature or entry into force
11.	New Zealand, 36 963	5 years If the Minister obtains confidential information about innovative pharmaceuticals, within 5 years the Minister: - takes reasonable measures to ensure the confidentiality of information; - should not use this confidential information to grant any other authorisations. The similar term of protection is established for biological pharmaceuticals.	Exemptions Disclosure and usage of information is possible: - with the consent of the owner, or if it is necessary to protect the health of society; - The Minister can disclose information for: Advisory Committee or Technical Committee; Classification Committee; Committee of examination of medicinal products; Any consultant for medical advisement; Government department or any other body, body if, in the opinion of the Minister, the relevant committee, the adviser of the government, department, official body or person will take reasonable measures to ensure confidentiality of information. - for the World Health Organization, the Food and Agriculture Organizations of the United Nations, any other regulatory body of one of the WTO countries, any person or organisation established by the regulations in accordance with the law. - with the consent of another person, if the holder of the information informs that this person can provide such permission, or if the holder does not inform the Minister about the revocation of such permission; - rights to such information were provided to other person, and the minister was informed in written. Trans-Pacific Partnership Agreement, 2015 Ratification of Trans-Pacific Partnership Agreement may lead to the enforcement of the data exclusivity regime, in particular, concerning biologic pharmaceuticals for up to 8 years; +3 years for significant changes in the authorised pharmaceuticals, and +5 years for new combinations of known chemical compounds.	National legislation: Pharmaceuticals Act 1981 No. 118 (Sec. 23 B, C), reprint as at 1 March 2016 Trans-Pacific Partnership agreement 2015 (not ratified)
12.	Australia, 50 961	5 years The Registrar should not use the information on protected pharmaceuticals assessing therapeutic products for their authorisation. The analogical term of protection is established for biologic pharmaceuticals.	AUSFTA Provisions 17.10.02 AUSFTA define the period of +3 years for new therapeutic indications, but it was not established in accordance with a note 17.19 of the Agreement. Trans-Pacific Partnership agreement, 2015 Ratification of Trans-Pacific Partnership Agreement may lead to the enforcement of the data exclusivity regime, in particular, concerning biologic pharmaceuticals for up to 8 years; +3 years for significant changes in the registered pharmaceuticals, and +5 years for new combinations of known chemical compounds.	National legislation: Data Exclusivity Provision of the Therapeutic Goods Act, Republication No 15 (Effective: 27 April 2016) International agreements: Australia-US Free Trade Agreement (AUSFTA) Art. 17.10.01 Trans-Pacific Partnership Agreement 2015 (not ratified)

№	Jurisdiction GDP per capita[1], 2015 (USD)	Data exclusivity regime (hereinafter – DE): general information	Peculiarities: exemptions and obligation according to international agreements	Regulation (national legislation, international agreements*) *year of the announcement, signature or entry into force
13.	Singapore, 53 224	5 years The authorisation for medicinal product cannot be provided based on the data on safety and efficacy of the originator medicinal product if the data owner has not permitted such use. This follows from the obligations of the regulatory authority to: - take reasonable measures to ensure the privacy regime; - not to use the confidential data granting other authorisations (ch.176, 19A). The similar terms of protection are established for biologic pharmaceuticals. According to Article 19A, confidential information means the information that has commercial value, and contained in the application for innovative medicinal product. Innovative medicinal product is an ingredient (active ingredient) for the drug for which the marketing authorisation has not been granted before.	Exemptions: Disclosure and use of information are possible (Ch. 176, 19B): - with the consent of the applicant who made a statement containing such confidential information; - if disclosure or use, in the opinion of the licensing authority, is necessary to protect the public health and safety; - is necessary for the government or other authorities; - to an official of the authority related to the authorisation procedure and other related procedures, provided that the above authorities and officials will take reasonable measures to ensure confidentiality; - to any of the following regulatory organisations: World Health Organization; Food and Agriculture Organizations of the United Nations; any other regulatory body of one or another country of the WTO; Advisory Committee, established in accordance with legislation. U.S.-Singapore FTA (2003), article 16.8 EU-Singapore Free Trade Agreement (2007, 2014) art.11.33. Trans-Pacific Partnership Agreement, 2015 Ratification of Trans-Pacific Partnership Agreement may lead to the enforcement of the data exclusivity regime, in particular, concerning biologic pharmaceuticals for up to 8 years; +3 years for significant changes in the authorised pharmaceuticals, and +5 years for new combinations of known chemical compounds.	National legislation: Pharmaceuticals Act International agreements: EU-Singapore Free Trade Agreement (2007, 2014) U.S.-Singapore FTA (2003) Trans-Pacific Partnership Agreement 2015 (not ratified)

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14.	Taiwan, 22 083	5 years (3+2) 3 years It is prohibited to submit applications for generic pharmaceuticals that are based on the examination data of reference medicinal products without the permission of such data holder from the moment of reference medicinal products authorisation. +2 years It is prohibited to issue decision on marketing authorisation of generic pharmaceuticals and, accordingly, their admission to the market (art. 40-2). The protection extends to a new chemical compound.	Exemptions Disclosure and use of data are permitted to protect public interests. It does not extend to the pharmaceuticals that are not protected by a patent; in such case, data on such pharmaceutical's studies may be used for education or clinical research. Protection of the data about originators placed on the foreign market is implemented if the application was filed to the competent authorities of Taiwan during 3 years since the authorisation at the foreign market. The government announced its readiness to amend the Law "On Pharmaceutical Activity" in December 2015 and provide 3 years of additional protection for new therapeutic indications and 2 years of additional protection for clinical studies conducted in Taiwan. Such obligations were taken by Taiwan within the framework of arrangements of TIFA[63].	National legislation: Pharmaceutical Affairs Law International agreements: U.S.-Taiwan Trade and Investment Framework Agreement (TIFA) (negotiation stage)
15.	Vietnam, 2 171	5 years If the legislation requires providing results of the studies and any other data containing commercial secrets, and if the applicant requests to keep confidentiality of such information, the authority shall respond appropriately. Until the end of a 5-year period from the marketing authorisation, the authority should not provide such authorisation to any subsequent applicant, who used confidential information without permission of the owner (art. 128, 126).	Exemptions Data exclusivity regime is not applied: - if it is necessary for public interests; - for non-commercial purposes. Data exclusivity is applied to new chemical compounds. The U.S.- Vietnam Free Trade Agreement (art.9) Every party shall ensure that on the basis of data provided for the marketing authorisation of originators, any other applicant will not be given such authorisation without the owner's permission during a reasonable period of time. As a rule, for this purpose the reasonable period makes no less than 5 years from the date of marketing authorisation. At the same time, the nature of the data, the human effort, and the cost for obtaining such permission are taken into account. Obviously, the establishment of data exclusivity regime was a result of the US assistance[64]. Data exclusivity does not expand to biologic pharmaceuticals. Trans-Pacific Partnership Agreement, 2015 Ratification of Trans-Pacific Partnership Agreement may lead to the enforcement of the data exclusivity regime, in particular, concerning biologic pharmaceuticals for up to 8 years; +3 years for significant changes in the registered pharmaceuticals, and +5 years for new combinations of known chemical compounds.	National legislation: Intellectual Property Law №50/2005/QH 11 25\11\2005 International agreements: The U.S.- Vietnam Free Trade Agreement (2001) Trans-Pacific Partnership agreement, 2015 (not ratified)

[63] http://www.trpma.org.tw/index.php/en/news/item/3021-taiwan-government-proposes-giving-new-indications-3-year-data-exclusivity
[64] http://keionline.org/node/1265

№	Jurisdiction GDP per capita[1], 2015 (USD)	Data exclusivity regime (hereinafter – DE): general information	Peculiarities: exemptions and obligation according to international agreements	Regulation (national legislation, international agreements*) *year of the announcement, signature or entry into force
16.	Iraq, 4 694	5 years If the Minister requests the submission of data relating to confidential studies or any data obtained as a result of significant efforts to authorise the sale of pharmaceuticals containing a new chemical compound, the Minister should protect such data from commercial use by prohibiting any other person who has not obtained the consent of the holder, to refer to such data, within 5 years from the marketing authorisation of the originator (ch.3 art.2).	Exemptions: Data exclusivity may be disregarded in cases necessary for public protection.	National legislation: Patent, Industrial Design, Undisclosed Information, Integrated Circuits and Plant Variety Law
17.	Morocco, 3 077	5 years The Party that requires the data on safety and efficacy of a new pharmaceutical product, or evidence on its preliminary approval on other territories, should not allow third parties that are not authorised by the data holder to enter the market based on such information with a generic product.	The U.S. - Morocco Free Trade Agreement obliged to protect researches data and trade secrets from unfair commercial use during 5 years for pharmaceuticals and 10 years for agricultural chemicals.	The national legislation: Regulations on Measures Related To Certain Regulated Products (art.15.10) International agreements: The U.S. - Morocco Free Trade Agreement (2004)
18.	Mexico, 9 592	*5 years (no less) from the moment of marketing authorisation obtained on innovative product any other party cannot refer to research data. According to Article 86 of Intellectual Property Law, the information necessary for determination of safety and efficacy of a pharmaceutical ingredient and agricultural chemicals which contain new chemical substances is protected under relevant international agreements. According to provisions of the Guidance on data protection exclusivity, data exclusivity does not extend to biologic pharmaceuticals and new indications.	Mexico has taken obligations under NAFTA to implement a 5-year data exclusivity period. However, foreign manufacturers claim that such protection is inefficient and is not finally implemented at the national level. Based on the interpretation of international agreements (namely, NAFTA and TRIPS) and Mexican law, innovative companies can enjoy the data protection for 5 years in court. Case law[65] In 2012, referring to international agreements, international comparative law and Mexican rules for the biologic approval of a medicinal product, the pharmaceutical company Janssen Cilag filed an application to the Mexican authorised body in order to obtain more than 5 years of exclusivity for its biologic pharmaceuticals. The application was denied. However, in a lawsuit initiated by Janssen Cilag, the Federal District Court ordered the Mexican authority to determine the possibility of applying for a longer than 5 years protection period (2015). Thus, the court found that a 5-year protection period was not final and could be extended. Trans-Pacific Partnership Agreement, 2015 Ratification of Trans-Pacific Partnership Agreement may lead to the enforcement of the data exclusivity regime, in particular, concerning biologic pharmaceuticals for up to 8 years; +3 years for significant changes in the registered pharmaceuticals, and +5 years for new combinations of known chemical compounds.	National legislation: Intellectual Property Law (as amended up to April 9, 2012) art.86 Guidance on data protection exclusivity of Federal Commission for Protection against Sanitary Risks (2012) International agreements: NAFTA, art. 1711, ch. 6 Free Trade Agreement between the EFTA States and Mexico (July 1, 2001) Treaty of Group of Three (Colombia, Mexico and Venezuela) art.18-22 Trans-Pacific Partnership agreement 2015 (not ratified)

[65] https://bricwallblog.com/tag/data-protection-exclusivity/

№	Jurisdiction GDP per capita[1], 2015 (USD)	Data exclusivity regime (hereinafter – DE): general information	Peculiarities: exemptions and obligation according to international agreements	Regulation (national legislation, international agreements*) *year of the announcement, signature or entry into force
19.	Chile, 13 331	5 years from the originators authorisation the competent authority cannot disclose or use any data on preclinical and clinical studies without the consent of data holder (art.89-91).	The competent authority may reasonably reduce the mentioned term for the purpose of public health, national security, non-commercial public use, or other circumstances of extreme urgency. Exemptions: The protection is not applied to: - a new chemical compound that is a subject to compulsory licensing; - a medical product that was not placed on the national market for 12 months from the moment of its marketing authorisation in Chile; - a medicinal product, that was authorised in another country more than 12 months ago. Despite the commitments made under the U.S.-Chile FTA Article 17.10.1, the data exclusivity for biologic pharmaceuticals is not provided. Trans-Pacific Partnership Agreement, 2015 Ratification of Trans-Pacific Partnership Agreement may lead to the enforcement of the data exclusivity regime, in particular, concerning biologic pharmaceuticals for up to 8 years; +3 years for significant changes in the registered pharmaceuticals, and +5 years for new combinations of known chemical compounds. The U.S.-Chile Free Trade Agreement (2004) (art.17.10, ch.17) The parties shall provide at least five years exclusivity term for an originator medicinal product (with a new chemical compound), unless it is necessary for public protection.	National legislation: Law 19.039 on Intellectual Property (2006) International agreements: The U.S.-Chile Free Trade Agreement (2004) Trans-Pacific Partnership agreement 2015 (not ratified)

№	Jurisdiction GDP per capita[1], 2015 (USD)	Data exclusivity regime (hereinafter – DE): general information	Peculiarities: exemptions and obligation according to international agreements	Regulation (national legislation, international agreements*) *year of the announcement, signature or entry into force
20.	Peru, 5 638	5 years (mostly) It is prohibited to use research data on innovative pharmaceuticals for registration of generics without the data holder permission (a new pharmaceutical ingredient is protected). The protection is not applied to: - new therapeutic indications of known substances; - dosage change and modifications; - changes in the pharmaceutical forms; - salts, esters, ethers, isomers, metabolites, etc.; - combinations of already known chemical compounds. The protection period is counted from: - the date of authorisation on the national territory; - the date of authorisation based on the fact of marketing approval of this medicinal product in other country with high level of sanitary monitoring. In order to clearly define the data protection period in each case, the authorised body takes into account the nature of the data, as well as the efforts and costs incurred in the course of research.	Exemptions: Disclosure of research data is allowed: • for the purposes and in cases specified by the WTO and in TRIPS; • in order to protect public health; • in other cases specified by the legislation of Peru. Data exclusivity is not applied to biologic pharmaceuticals. Trans-Pacific Partnership Agreement, 2015 In case of TPP ratification, data exclusivity regime will be strengthened, in particular, with regard to biologic pharmaceuticals. Free Trade Agreement between Peru and United States of America (p. 16.10) defines: If a party requires, as a condition for marketing of a product that utilizes a new chemical entity, the submission of undisclosed tests or other data necessary to determine whether the use of the product is safe and effective, such party should protect against disclosure of such data, except when the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use. A reasonable period of protection should normally mean 5 years from originators marketing approval, but the nature of exclusive data, human effort, the expenditures should be taken into account. The parties are also obliged to provide administrative and judicial procedures to protect the data exclusivity right and seek available remedies for infringements. Andean Community Decision No. 486 (2000) art. 266 Andean Community Decision No. 632 (2006) – clarification of art. 266 Decision No.486. Member States that require approval for the marketing of pharmaceuticals containing new chemical entity obtained with considerable effort, data on their safety and efficacy, should protect this data from any unfair commercial use, unless such use is necessary for public interests. If Member States consider it appropriate, they may establish the terms of the data exclusivity in their national legislations and provide for the exemptions when the violation of these terms is allowed. European Trade Agreement with Colombia and Peru (art.2.4) 5 years of data exclusivity on studies data obtained with considerable effort. Data exclusivity does not apply to biologic pharmaceuticals in accordance with national legislation. Trans-Pacific Partnership Agreement, 2015 Ratification of Trans-Pacific Partnership Agreement may lead to the enforcement of the data exclusivity regime, in particular, concerning biologic pharmaceuticals for up to 8 years; +3 years for significant changes in the registered pharmaceuticals, and +5 years for new combinations of known chemical compounds.	National legislation: Legislative Decree 1072 Protection of Undisclosed Test Data or Other Undisclosed Data Related to Pharmaceutical Products International agreements: Free Trade Agreement between Peru and United States of America (2006) Andean Community Decision №486 (2000), Andean Community Decision №632 (2006) (Bolivia, Colombia, Ecuador, Peru) European Trade Agreement with Colombia and Peru 2012 Trans-Pacific Partnership agreement 2015 (not ratified)

№	Jurisdiction GDP per capita[1], 2015 (USD)	Data exclusivity regime (hereinafter – DE): general information	Peculiarities: exemptions and obligation according to international agreements	Regulation (national legislation, international agreements*) *year of the announcement, signature or entry into force
21.	Colombia, 5 687	5 years for innovative pharmaceuticals, that were filed for authorisation during the third and the following years from the moment the decree was enacted. New pharmaceutical forms, indications or other new characteristics, new combinations of known chemical compounds, pharmaceutical forms, and other modifications do not fall under data protection.	Exemptions The data exclusivity is not applied: - if the permission for data usage is provided by the holder; - if the pharmaceutical ingredient is similar to another substance that is already authorised in Colombia; - for public health protection in cases specified by the Ministry; - when pharmaceutical product was not placed on the national market within 12 months from the date of its authorisation. Andean Community Decision No. 486 (2000) art. 266 Andean Community Decision No. 632 (2006) – clarification of art. 266 Decision No.486. Member States that require approval for the marketing of pharmaceuticals containing new chemical entity obtained with considerable effort, data on their safety and efficacy, should protect this data from any unfair commercial use, unless such use is necessary for public interests. If Member States consider it appropriate, they may establish the terms of the data exclusivity in their national legislations and provide for the exemptions when the violation of these terms is allowed. European Trade Agreement with Colombia and Peru (art.2.4) 5 years of studies data obtained with considerable effort. Data exclusivity does not apply to biologic pharmaceuticals in accordance with national legislation. U.S.-Colombia FTA (2006, 2012) 5 years of data exclusivity for studies data related to the development of pharmaceuticals. However, if Colombia, for authorisation procedure of generics relies on the approval to appropriate reference medicinal products issued by the US FDA, the data exclusivity protection of such reference medicinal product is terminated in Colombia with the termination of this protection in the United States. Thus, it can accelerate launch of generics to the Colombian market.	National legislation: Data Protection Decree No. 2085 International agreements: Andean Community Decision №486 (2000), Andean Community Decision №632 (2006) (Bolivia, Colombia, Ecuador, Peru) European “Trade Agreement” with Colombia and Peru 2012 U.S.-Colombia FTA (2006, 2012)

№	Jurisdiction GDP per capita[1], 2015 (USD)	Data exclusivity regime (hereinafter – DE): general information	Peculiarities: exemptions and obligation according to international agreements	Regulation (national legislation, international agreements*) *year of the announcement, signature or entry into force
22.	Moldova, 1804	Not provided Article 3 of the Law states that generic pharmaceuticals have the same quality and quantity of the active ingredient and the same dosage as the originator, bioequivalence of which was proven by the relevant studies. Paragraph 12 of the "Regulation on the authorisation of pharmaceuticals", approved by the Order of the Ministry of Health No. 739 of 23 June 2012, states that the application for authorisation of generic pharmaceuticals does not require its own toxicological, pharmacological and clinical studies.	The EU Association Agreement (art. 315) 5 years since the date of authorisation of a reference medicinal product it is prohibited to apply for authorisation of its generic medicine. +2 years it is prohibited to grant marketing authorisations of generic pharmaceuticals and place them on the market. +1 year the protection is provided if the manufacturer proves that new therapeutic indications have a significant advantage over the already existing ones. Due to the EU Association Agreement introduction, the amendments of the national legislation are expected to be made in order to implement the data exclusivity regime.	National legislation: the Law of the Republic of Moldova «On drugs»17.12.1997 No. 1409-XIII) the introduction of the data exclusivity regime is not provided. International agreement: the EU Association Agreement, signed in June 2014, ratified in May 2016 and came into force on 1 of July 2016.
23.	Georgia, 3788	Not provided Article 4.2 (b) prohibits the use of the scientific and technical information on authorised pharmaceuticals for granting a decision on authorisation of generics.	The EU Association Agreement (article 187) 6 years From the moment of granting authorisation in the EU or Georgia, it is prohibited to submit applications or grant authorisations to generics. +1 year if the manufacturer proves new therapeutic indications that have a significant advantage over already existing ones. Due to the EU Association Agreement introduction, the amendments of the national legislation are expected to be made in order to implement the data exclusivity regime.	National legislation: The Law of Georgia "On Pharmaceuticals and pharmaceutical activity" (17.04.1997 No. 659). International activities: the EU Association Agreement signed in June 2014, came into force on 1 of July 2016.
24.	Thailand, 5742	Not provided During Safety Monitoring Program, generic pharmaceuticals are admitted to the market. Data on the studies is protected under the Law on commercial secrets. Paragraph 3 of Article 15 provides for that in cases when the legislation requires the submission of data relating to confidential studies or any data obtained as a result of significant efforts, the authorised body that obtained such information shall maintain the commercial secret and prevent unfair competition at the request of the applicant. The regulator (the Ministry) should determine the procedure for implementing this paragraph, in particular, the conditions for submission of the application to secure commercial secrets, criteria for defining information that may be classified as commercial secret, the period and way of protection, and the liability of officials for violations.	In a previous edition of the law the period of exclusivity was provided between 2 to 4 years within Safety Monitoring Program. Originators companies had the exclusive right to sell their products in public and private hospitals. Generic pharmaceuticals were not allowed on the market during this period. However, as a result of the government's social policy to increase the availability of pharmaceuticals in public sector, the data exclusivity regime was cancelled. Due to The Public Health Ministerial Regulation Regarding Trade Secrets (2007) it was established that as soon as information is recognised as commercial secret, the authorized body shall keep the confidentiality regime during 5 years. However, the authority interprets this provison as an obligation to protect from disclosure confidential information of the originators, and does not exclude granting marketing authorisation of generic pharmaceuticals based on the research data of originators.	National legislation: Trade Secrets Act, 2002 (art.15, ch.3). The Public Health Ministerial Regulation Regarding Trade Secrets 2007 (Data Protection). International agreements: There is no international obligation regarding implementation of TRIPS-plus provisions on data exclusivity.

№	Jurisdiction GDP per capita[1], 2015 (USD)	Data exclusivity regime (hereinafter – DE): general information	Peculiarities: exemptions and obligation according to international agreements	Regulation (national legislation, international agreements*) *year of the announcement, signature or entry into force
25.	Belarus, 5749	Not provided Legislation of Belarus does not establish any special exclusivity period for clinical research data. At the same time, data can be protected within a general procedure, provisions on commercial secrecy and confidentiality, which oblige experts who examine the registration dossier to protect the information. Decree No. 156 does not provide the submission of reports about preclinical and clinical studies for authorisation of generics.	Belarus participates in regional integration associations that impose an obligation to unify the legal approach of member states regarding a number of issues. It is possible that as the result of the WTO accession, the country will have to assume obligations on 6 years of data exclusivity, similar to the obligations of the Russian Federation.	National legislation: The Act "On medicinal products" of 20.07.2006 No. 161-3 Resolution of the Government of Ministers No. 156 of 17.02.2012 «On approval of the unified list of administrative procedures performed by state bodies and other organisations concerning legal entities and individual entrepreneurs, addition to the Resolution of the Government of Ministers of the Republic of Belarus No. 193 of 14 February, 2009, and the invalidation of certain resolutions of the Ministers of the Republic of Belarus" (par. 10.3) International agreements: There is no international obligation regarding implementation of TRIPS-plus provisions on data exclusivity.
26.	Brazil, 8 802	Not provided for any type of pharmaceuticals, including paediatric and orphan drugs. Article 195 of the Law 9.279 on Intellectual Property states that "The disclosure or use of tests results or other undisclosed data without permission, the development of which requires significant effort and which were provided to state authorities to obtain authorisation is a criminal offence of unfair competition."	The decision on terms and scope of information that falls under the national protection is made by court. Thus, data exclusivity protection is not guaranteed. In August 2011, Deputy Chairman of the Supreme Court resumed the authority of the National Agency for Sanitary and Hygienic Supervision on the registration of generic[66] pharmaceuticals based on escitalopram (antidepressant) (active ingredient) and suspended the decision of the Federal Court. According to Minister Fischer, such decision is important "to avoid the risk of weakening the government policy regarding generic pharmaceuticals in the country, which are undoubtedly valuable to the population, especially given the low purchasing power."	National legislation: Law 9.279 on Intellectual Property; Title V, Crimes Against Intellectual Property; Chapter VI, Protection Against Unfair Competition; Biodiversity Law No. 13123/2015 (2015) International agreements: There is no international obligation regarding implementation of TRIPS-plus provisions on data exclusivity.

[66] https://donttradeourlivesaway.wordpress.com/2011/08/24/brazilian-court-rejects-data-exclusivity/

№	Jurisdiction GDP per capita[1], 2015 (USD)	Data exclusivity regime (hereinafter – DE): general information	Peculiarities: exemptions and obligation according to international agreements	Regulation (national legislation, international agreements*) *year of the announcement, signature or entry into force
27.	Argentina, 13 428	Not provided Article 4 of the Trade Secret Law: "Since information about the efficacy and safety of a product containing a new chemical substance is a result of significant technical and economic efforts, it will be protected from unfair commercial use as defined by this law, and its disclosure will be prohibited". However, such protection from unfair commercial use does not provide for the establishment of data exclusivity regime.	Terms and procedure of protection are not specified. Thus, Argentina does not provide for data exclusivity regime, as the law No. 24.766 allows appropriate officials to rely on data from reference medicinal products research in the authorisation procedure. Some data may be protected under the Trade Secret Law through court as part of the requirement to oblige an authorized body to refrain from granting marketing authorisations to generic pharmaceuticals. However, courts usually take the side of generic pharmaceuticals. Thus, on 1 February 2011, in the decision[67] "Novartis Pharma AG vs. Monte Verde SA", the Federal Court of Appeal for Civil and Criminal Cases upheld the decision of the first instance, which denied the protection of research data (data exclusivity). The plaintiff requested the establishment of the data exclusivity regime for the active pharmaceutical ingredient imatinib mesilate in Argentina in accordance with Article 39.3 of the TRIPS. The court noted that TRIPS Article 39.3 may be implemented by TRIPS members in two ways: - through the establishment of rules for unfair competition, and in this case, the provision of a marketing authorisation for generic pharmaceuticals with reference to the originator's research data does not imply that Argentina's obligations to protect data from unfair commercial use are not fulfilled; or -through a system of exclusive rights to undisclosed data for a certain period, but such a system is not implemented in Argentina.	National legislation: Law on the Confidentiality of Information and Products (Trade Secret Law), No. 24.766, Articles 4, 5, 11 International agreements: There is no international obligation regarding implementation of TRIPS-plus provisions on data exclusivity.
28.	India, 1617	Not provided There is no marketing exclusivity in India. Biosimilars can be authorised to enter the market only if reference medicinal products are registered in India. Otherwise, reference medicinal products should have marketing authorisation and be placed in the strictly regulated market for at least 4 years to be eligible to enter Indian market. According to Drugs and Cosmetics Act, biologic pharmaceuticals are considered new if at least one new characteristic compared to the analogue is established.	Moreover, the generic medicinal product may be admitted on the market during the patent term on the reference product if the patent rights are disputed. Thus, it is enough for generic companies to dispute patent rights of originator in order to obtain marketing authorisation. India has not yet signed any international agreement containing the TRIPS-plus provisions. More information about India's policy can be found in conclusions.	National legislation: Drugs and Cosmetics Act 1945 (as corrected up to November 30, 2004) International agreements: There is no international obligation regarding implementation of TRIPS-plus provisions on data exclusivity.
29.	Indonesia, 3 412	Not provided There is no marketing exclusivity.	Trade Secrets Law protects data from disclosure. Moreover, in course of regulatory review the National Agency of Pharmaceuticals and Food Products may rely on data that was earlier used to obtain marketing authorisation for reference medicinal products. This applies to cases where generic pharmaceuticals have the same active ingredient, the same composition, dosage form and indications, as authorised pharmaceuticals.	National legislation: Trade Secrets Law, No. 30 of December 20, 2000 International agreements: There is no international obligation regarding implementation of TRIPS-plus provisions on data exclusivity.

[67] http://www.internationallawoffice.com/Newsletters/Intellectual-Property/Argentina/Obligado-Cia/Courts-decision-confirms-lack-of-protection-of-test-data

№	Jurisdiction GDP per capita[1], 2015 (USD)	Data exclusivity regime (hereinafter – DE): general information	Peculiarities: exemptions and obligation according to international agreements	Regulation (national legislation, international agreements*) *year of the announcement, signature or entry into force
30.	Egypt	Not provided Authority that received information obtained with significant efforts in order to grant marketing authorisation, should protect such information from disclosure and prevent its use for 5 years or until it loses its confidential status (art.55-62). However, such protection does not mean the observance by the authorities of the data exclusivity regime.	Exemptions Disclosure of the data by relevant authorities for public purposes is not considered as a violation. Information is protected by the law if it meets the following criteria: - it is not publicly available; - it has a commercial value; - it requires measures to protect its confidentiality; - it is obtained with considerable effort; - it is provided to the authority to obtain a marketing approval	National legislation: Intellectual Property Law No. 82 International agreements: There is no international obligation regarding implementation of TRIPS-plus provisions on data exclusivity.
31.	The Republic of South Africa, 6 477	Not provided Currently, the legal system of RSA does not provide for a marketing exclusivity.	Reform in the field of intellectual property is socially oriented and identifies health care and the availability of pharmaceuticals as its priority. - Provisions established during reform[68]: - more stringent standards for patenting and reviewing patent applications; - the procedure for opposing patent applications; - limitation of the patent term to 20 years without the possibility of extension; - simplification of the parallel import procedure and the compulsory licensing mechanism; - absence of data exclusivity regime. Such policy was supported by UNDP, UNAIDS, WHO as conforming to the Doha Declaration.	International agreements: There is no international obligation regarding implementation of TRIPS-plus provisions on data exclusivity.

[68] http://infojustice.org/archives/31986

Conclusions of the comparative table

Balancing and restricting the data exclusivity regime

Analysing foreign legislation and some international agreements on the application of the data exclusivity regime, it has to be stated that a number of countries actively use legal mechanisms to restrict/reduce this regime. These mechanisms include:

1. Establishing a list of circumstances under which the authorised body of the country has the right not to apply the data exclusivity, for example:

- for the protection of public health (such cases are usually defined by the same authority that provides significant opportunities for restricting the data exclusivity, as is the case in laws of many countries: Vietnam, Egypt, Iraq, Peru, Israel and others);
- if the manufacturer of reference medicinal products is not able to meet the demand for such a medicine (EU);
- if generic pharmaceuticals have significant advantages over the originators (EU, USA);
- if reference medicinal products were not placed on the market for a certain period after authorisation (12 months in Colombia).

2. Authorising the relevant regulatory body to reduce the term of the data exclusivity in cases determined by law or by its own decision (Chile).

3. The data exclusivity period depends on the date of authorisation of pharmaceuticals in other countries (for example, in Turkey this period starts from the moment of granting marketing authorisation on the territory of any country of the Customs Union).

4. Restriction on the data exclusivity of the originator drugs, authorised a long time ago in other countries (in Taiwan, the data exclusivity regime does not apply to pharmaceuticals if the application has been submitted to the competent authority of Taiwan three years after the date of authorisation of pharmaceuticals on the market of foreign countries; in Chile this period amounts to 12 months).

5. The mechanism of administrative and court appeal.

6. Establishing at the level of bilateral and multilateral agreements the mechanism of mutual enrolment of data exclusivity period (U.S.-Colombia FTA (see table). The introduction of such a mechanism at the level of bilateral agreements is an effective mean of limiting the data exclusivity regime that can be exercised by Ukraine in its foreign affairs. At the same time, reaching multilateral agreements regarding the use of such a mechanism may take more time and may not fulfill its intended purposes.

7. The data exclusivity regime may depend on the patent life span (for example, in Turkey the period of data exclusivity protection cannot exceed the patent validity term, in Taiwan the data exclusivity regime does not apply to the data On Pharmaceuticals not covered by a patent).

8. Avoiding the establishment of the data exclusivity regime for any other “novelty” criterion of a drug than a new chemical compound (active ingredient). Thus, the innovators will not be able to prolong the data exclusivity due to the discovery of new therapeutic indications, new dosage forms or other properties of previously authorised reference medicinal products, whose data exclusivity period expires. Elimination of opportunity to obtain the data exclusivity to the composition of previously known chemical compounds. In addition, establishing clear and strict criteria for the “novelty” of a chemical compound for the purposes of restriction of DE

regime applicability for modifications of previously authorised chemical compounds will hinder manufacturers in submission of groundless claims on data exclusivity application.

9. Establishing restrictions on the data exclusivity regime in cases of application of the compulsory licensing procedure (the experience of Chile).

Undoubtedly, such mechanisms contribute to a significant mitigation of the negative impact of the data exclusivity regime on the availability of pharmaceuticals for patients in other jurisdictions. The introduction of similar legislative tools at the national level in Ukraine would create a comfortable climate for the admission of generic pharmaceuticals to the market, especially of the acute needs. In addition, there is a legal conflict regarding the use of the compulsory licensing mechanism during the data exclusivity regime in some countries. Therefore, along with the implementation of the above tools to influence the data exclusivity in the national laws, it is also advisable to establish the relationship between this regime and the compulsory licensing procedure. This relationship can be conveyed by including the decision of a competent authority on the issuance of a compulsory license to the list of the grounds for termination of the data exclusivity regime.

Detailed recommendations on the implementation of these legal mechanisms into Ukrainian legislation are set in the follow-up sections of this report.

The data exclusivity in transnational agreements

Apart from listed in the comparative table international agreements with the TRIPS-plus provisions, already implemented by the Members in their national laws, some other agreements on world's pharmaceutical industry-driven agendas may substantially influence the availability of pharmaceuticals and their cost.

1. The Trans-Pacific Partnership Agreement

The Trans-Pacific Partnership Agreement (hereinafter – TPP) has the most global nature. The TPP was signed by 12 countries in New Zealand in February 2016[69]. This agreement was grounded by the conclusion of AUSFTA and KORUS and it has become one of the most significant trade covenants in history. The partnership includes the United States, Japan, Malaysia, Vietnam, Singapore, Brunei, Australia, New Zealand, Canada, Mexico, Chile and Peru, 40% of the world economy in total. The TPP provides complete cancellation of customs duties on goods and services in the Asia-Pacific region. It is expected that the Agreement will come into force several years after its ratification by all member states.

It should be noted that the definition of the exclusivity period for biologic pharmaceuticals was one of the main issues discussed during the TPP negotiations. The United States and Japan favoured longer periods of exclusivity (up to 12 years), while Australia and New Zealand insisted on five years. Biologic pharmaceuticals are used to treat various types of cancer, multiple sclerosis, diabetes (insulin is biologic) and represents the most fast-growing segment of pharmaceutical market[70] in the world. Many countries opposed the introduction or extension of data exclusivity period for

[69] http://www.bbc.com/news/business-35480600
[70] http://theconversation.com/why-biologics-were-such-a-big-deal-in-the-trans-pacific-partnership-48595

biologic pharmaceuticals due to the fact that a lot of them keep such pharmaceuticals in the reimbursement system. The USA failed to impose a twelve-year protection period on other countries, which may be one of the reasons of the refusal of the US to ratify the agreement[71] and the reason for its review[72]. The final version of the TPP Agreement provides for 8 years of data protection for biologic pharmaceuticals but allows Parties (countries that will ratify the Agreement) to declare only 5 years of protection if other forms of patent protection can guarantee the same 8-year period of market exclusivity minimum. Obviously, these provisions slow down the access of patients to such pharmaceuticals, especially in countries where biologic pharmaceuticals were not protected at all. For new chemical compounds, a 5-year period of protection is provided.

However, some experts do not predict pivotal changes[73] in case of ratification of the TPP in the agreed edition. They refer to the fact that the main parties to the Agreement would not amend their laws in part of the exclusivity of biologic pharmaceuticals. For example, the United States would not reduce its 12-year exclusivity period, while Japan and Canada would probably stick to eight years of exclusivity for biologic pharmaceuticals already enshrined in their laws. Australia and New Zealand insist that their five-year exclusivity periods meet the TPP requirements. These countries do not intend to amend national legislation. Meanwhile, Mexico has not yet adopted any particular period for biologic pharmaceuticals, but as noted above, Mexican courts consider extending the five-year protection under NAFTA.

Regarding the duration of the data exclusivity protection for small molecules of pharmaceuticals, it shall be at least 5 years + at least 3 years of additional exclusivity for modifications of existing pharmaceuticals, or + 5 years for combinations. Such periods of exclusivity extend the monopoly of the originators by blocking the authorisation and sale of generic pharmaceuticals. It should be emphasised that from all the countries that have signed the TPP Agreement only Brunei currently provides less than five years of exclusivity.

2. ASEAN – EU

Since 2006, when the ASEAN (South East Asian Nations) was identified by the EU as a priority region for the globalisation of economic relations, South East Asian Nations began active negotiations in this direction. During such negotiations parties discussed signing of the ASEAN-EU Free Trade Agreement. Among the provision of the Agreement there are TRIPS-plus requirements, including the establishment of the data exclusivity regime. However, such multilateral negotiations proved to be futile and collapsed. Therefore, the EU decided to change the way of establishing economic preferences and turn to bilateral negotiations.

Nevertheless, taking into account public interests some ASEAN member states took a strong stance regarding the introduction of the data exclusivity regime, claiming that not only would it adversely affect the price of pharmaceuticals but also would limit the availability of medicine to citizens. Meanwhile, the EU persists in reporting of its openness to continuation of negotiations[74] with Thailand and other partners in the region. The EU representatives expect to close such negotiations by signing the Free Trade Agreement, as it was the case for Singapore. Having concluded such an

[71] http://asia.nikkei.com/Politics-Economy/International-Relations/Japan-says-no-to-renegotiating-TPP
[72] http://cogitasia.com/how-to-revive-u-s-trans-pacific-partnership-ratification-in-2017-five-recommendations-for-the-next-president/
[73] https://bricwallblog.com/tag/data-exclusivity/
[74] http://www.euractiv.com/section/trade-society/news/eu-and-asean-to-jumpstart-trade-agreement-talks/

agreement with the EU and the US, Singapore committed itself to complying with the 5-year data exclusivity period. The other side of the coin is the implementation of the generalised scheme of preferences[75] (reduction of rate duty levied on exports of goods from the Asian developing countries to the EU). Therefore, it should be expected that Thailand may give up some positions and adopt certain TRIPS-plus provisions.

3. India and TRIPS-plus

Particular attention should be drawn to the Indian policy in the pharmaceutical industry which provides a long-standing defence of the rights of generic companies and prevention of the establishment of monopolies of originators. During the last 10 years, the United States, the EU, and some Asian countries have been pushing India to conclude multilateral free trade agreements and to introduce, among other things, the data exclusivity regime at the national level. The associations of pharmaceutical manufacturers, in particular, in the recent reports Pharmaceutical Research and Manufacturers of America (PhRMA)[76] and Biotechnology Innovation Organization[77] (BIO) also express their concerns. Innovators state that the reference to research data from originator drugs in order to get admission to the market for generics constitutes the violation of the commitments undertaken within the framework of the TRIPS Agreement. That said, India still shows a firm stand on the issue within international affairs, refusing to undertake any obligations that may complicate the admission of generic pharmaceuticals to the market.

4. India - EU

Thus, FTA negotiations between India and the EU have lasted since 2007 but a compromise on the TRIPS-plus provisions has not been achieved yet. The United Nations expresses particular support for such a policy, agreeing that the introduction of the data exclusivity regime in developing low-income countries threatens the public health. The UN special reporter Anand Grover, as well as many other organisations dealing with health issues, directly appealed to the EU with a request to abandon such a requirement[78], especially since it goes beyond the existing rules of the WTO in the field of intellectual property. UNAIDS also supports India's refusal, stating that India produces about 85% of antiretroviral pharmaceuticals and that the cost of this therapy has fallen from USD 15,000 to USD 86 per person annually. The next round of negotiations is scheduled for 15 July 2016.

5. India - EFTA

The pressure on the establishment of the data exclusivity regime also comes from the EFTA. In the negotiation with India on the conclusion of the FTA, which also lasts from 2007, Switzerland was flatly lobbying the interests of pharmaceutical giants such as Sandoz, Roche, Novartis. However, India turned out to be a tougher partner than Colombia and Peru and did not agree on the establishment of the data exclusivity. It was one of the reasons for termination of negotiations. It should be mentioned that requirements of the EU and EFTA are analogical from the point of imposing the TRIPS-plus provisions. Now the resumption of negotiations is discussed and India expresses its readiness[79].

[75] https://donttradeourlivesaway.wordpress.com/2015/01/08/thailand-hopes-to-resume-talks-with-eu-on-fta/
[76] PhRMA, SPECIAL 301 SUBMISSION, 2016.
[77] BIOTECHNOLOGY INNOVATION ORGANIZATION, SPECIAL 301 SUBMISSION, 2016.
[78] http://www.alliancesud.ch/en/policy/trade/fta-india-fights-back-over-its-generics
[79] http://articles.economictimes.indiatimes.com/2016-04-05/news/72070594_1_india-eu-fta-efta-india-eu-summit

6. India - ASEAN

The establishment of data exclusivity is discussed in the framework of the Regional Comprehensive Economic Partnership Agreement (RCEP). It is also worthwhile noting that RCEP includes 16 countries[80]: 10 members of the Association of Southeast Asian Nations: Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, Vietnam, as well as six countries with which free trade agreements are concluded: Australia, China, India, Japan, South Korea, New Zealand (more than 3 billion people and total GDP of about USD 17 trillion). Negotiations between participants began in early 2013 and should be completed by the end of 2016.

During negotiations, Japan and South Korea made some "alarming" offers[81] regarding the inclusion of the TRIPS-plus provisions in the RCEP Agreement, in particular, the establishment of the data exclusivity regime and the patent term extension. Let us emphasise that the obligation in the field of intellectual property, which is stipulated in Art. 39 of TRIPS Agreement (to which developed countries refer requiring to establish the data exclusivity regime), is not mandatory for implementation by least developed countries by 2033 in accordance with the WHO decision as of 06.11.2015. Doctors Without Borders warns India[82] that if India signs the RCEP it will not remain a "pharmacy of the developing world". The reason is that in case of signing this agreement, India will be obliged to introduce a 5-year term for data exclusivity and to make respective amendments to the Drugs & Cosmetics Act.

Therefore, some transfigurations in the abovementioned negotiation processes can be expected in the near future, probably relating to the positions of the Parties regarding the TRIPS-plus provisions.

[80] http://www.livemint.com/Politics/37pnX4pjCINPeglF6d53HL/RCEP-negotiations-India-likely-to-take-a-more-aggressive-st.html
[81] http://www.thehindu.com/sci-tech/health/mdecins-sans-frontires-on-indias-role-in-the-rcep-meet/article8728609.ece
[82] http://www.thehindu.com/sci-tech/health/mdecins-sans-frontires-on-indias-role-in-the-rcep-meet/article8728609.ece

Pros and cons of the regime according to the findings of international governmental and non-governmental organisations. The impact of the regime on the access to pharmaceuticals

Clearly, each phenomenon has both proponents and opponents. Likewise, with the data exclusivity regime. It is clear that the regime is supported primarily by producers-innovators since the data exclusivity regime protects their economic interest. Antagonists are mostly patients organisations whose main argument is that the data exclusivity regime affects the cost of pharmaceuticals and their availability for the average consumer. Generic producers are also among the opponents.

The proponents of the data exclusivity regime substantiate their position in the following way. The argumentation regarding the implementation and in some cases strengthening of the the data exclusivity regime can be provisionally divided into three parts.

Firstly, the data exclusivity regime is claimed to be an important policy tool for stimulating innovations.

Secondly, the data exclusivity regime is a legitimate measure to protect property rights for clinical research data.

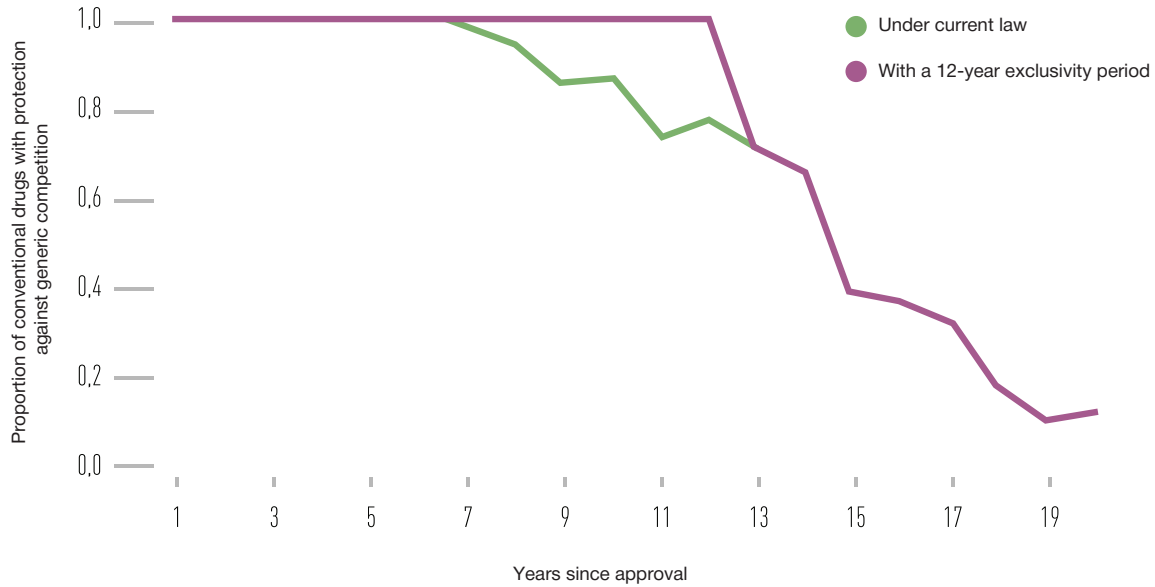
The final argument is the argument for "fairness".

Regarding the first argument, the data exclusivity is required to allow pharmaceutical companies to reimburse the cost of clinical trials. Clinical research requires significant investment, whereas patent protection may be insufficient or absent at all, and therefore, additional years of data exclusivity provide significant financial benefits. Thus, according to supporters, this regime assists to provide a limited period during which it is possible to ensure an adequate return of the investments[83].

Hence, according to research sponsored by INTERPAT[84] it has been determined that the extension of the data exclusivity for up to twelve years will result in an increase of incomes during the life cycle of pharmaceuticals by 5.0 percent on average.

[83] International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), Data Exclusivity: Encouraging Development of New Pharmaceuticals, 2011.
[84] Health Affairs, The Benefits From Giving Makers Of Conventional `Small Molecule' Drugs Longer Exclusivity Over Clinical Trial Data, 2011.

Effect of a Twelve-Year Data Exclusivity Period On Introduction of Competition From Generic Drugs



In addition, supporters argue that catalysing clinical trials will trigger the development of innovative pharmaceuticals[85].

If the country provides this incentive, R&D investments and innovation are expected to increase. According to IFPMA, it would be unwise for countries not to use the data exclusivity regime, especially in the global pharmaceutical market, since the data exclusivity regime gives incentives for business to move products, investments, and industrial capacity to the market of such counties earlier than to the others. If other companies could immediately use exclusive data to obtain their own marketing authorisation, the innovators would have less motivation to invest.

PhRMA also strives for the introduction of the data exclusivity regime regulation, arguing that not all countries provide patent protection for new biologic pharmaceuticals that are more complex and costly in manufacture than traditional ones. In these countries the data exclusivity can provide one of the few incentives for innovators and can become an impulse for launching new innovative products in the country[86].

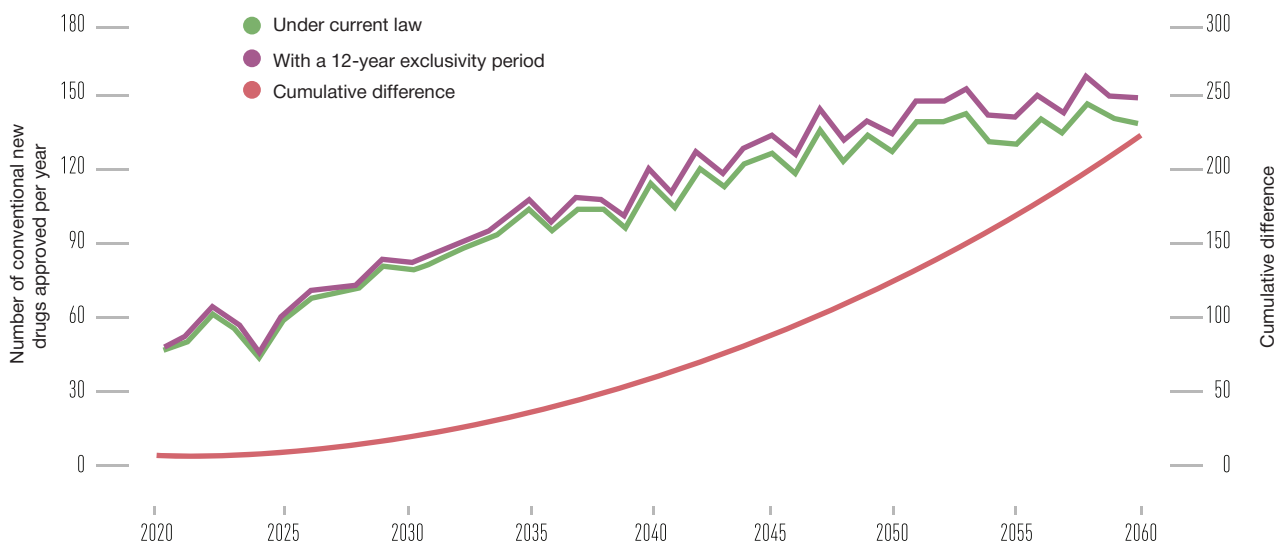
For example, BIO – the Biotechnology Innovation Organisation – advocated the adoption of a twelve-year period of data exclusivity for biologic products under the Trans-Pacific Partnership (TEC).

[85] Journal of Intellectual Property Law and Practice, Unfair Competition and the Financing of Public-Knowledge Goods: the Problem of Test Data Protection, 2008.
[86] Pharmaceutical Research and Manufacturers of America (PhRMA). Pharmaceutical Research and Manufacturers of America Special 301 Submission, 2014.

Turning to the results of the research sponsored by INTERPAT, it indicated that the extension of data exclusivity up to twelve years would result in 228 additional approvals of drugs between years 2020 and 2060 in relation to the number of approvals that were planned in accordance with the current provisions on data exclusivity.

The second argument unfolds that the exclusive rights for clinical data is a legitimate mean of property rights protection in the pharmaceutical industry. In fact, since subjects of the pharmaceutical industry funded and generated clinical data, it is them who own these data. Obtained results are the property of the company that uses such results to manufacture pharmaceuticals.

Effect of a Twelve-Year Period of Data Exclusivity On Number of Conventional Drug Approvals In The United States



Concerning the third argument, the data exclusivity is often described by the representatives of the pharmaceutical industry as a necessary step, in addition to patent protection, for the prevention of the "free circulation" of the goods of the generic industry[87].

In addition, PhRMA notes that data protection is crucial for sustained medical progress, R & D investment, and economic growth. Reducing data protection for innovators can decline R & D investments and redirect it to other countries with more favourable intellectual property policy, and also can eliminate well-paid work places[88].

Finally, another reason for the pharmaceutical industry to strive for the introduction of data exclusivity is to increase the trend towards the transparency of clinical research data after lobbying the new EU legislation on clinical research by community groups, which came into force in May 2016 and requires the registration of all clinical trials in the EU database to ensure open access to clinical research[89].

IFPMA also notes that if a developer does not benefit from the data of clinical and preclinical trials, he falls under commercially disadvantageous position. This situation undermines the investment potential, even in countries with a strong and effective patent protection regime, as the results of the originator's trials become available to competitors immediately and free of charge after the registration of reference medicinal products, while the patent protection could have been already expired.

In view of the imbalance between the cost of pharmaceuticals and the costs involved in their creation and research, the applicant's incentive to invest in this field is substantially reduced which, in its turn, causes harm to patients as there will be no new and innovative pharmaceuticals.

Data exclusivity is particularly important when a new medicinal product is not patentable. For example, TAXOL® (paclitaxel), Bristol-Myers Squibb for treatment of cancer which does not have patent protection for its active ingredient could obviously be authorised immediately, but Bristol-Myers Squibb would not have had any incentive to incur significant costs (estimated at more than USD 500 million) for its development, trials, and market entrance.

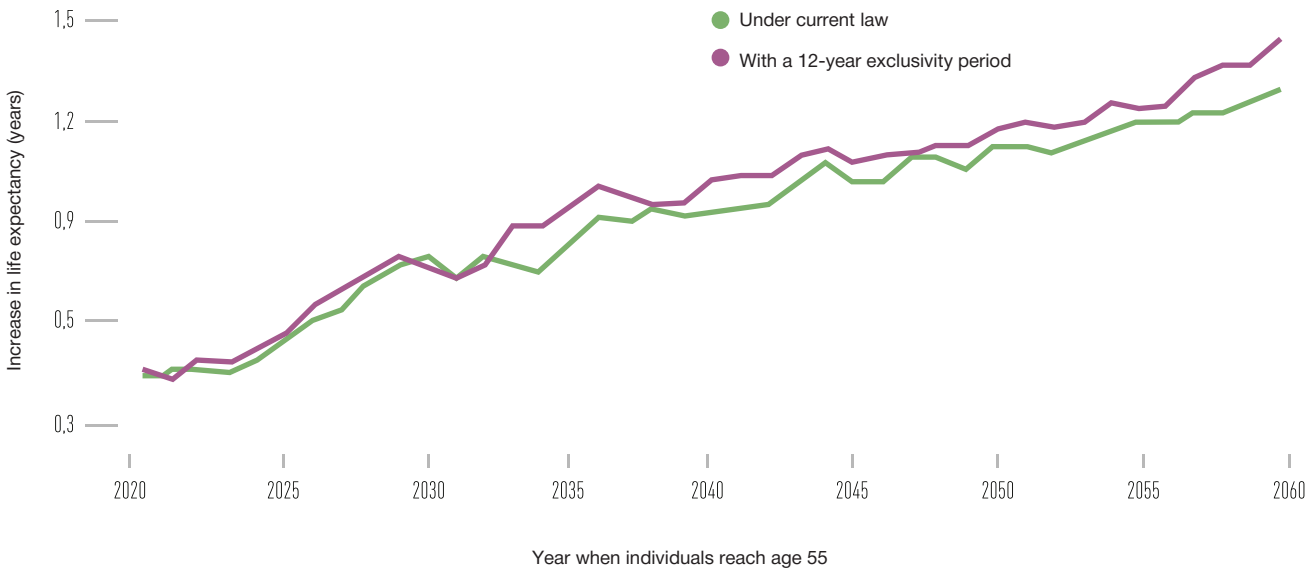
The dual nature of drug development determines the need for both patent protection and the availability of the data exclusivity regime:

- without a period of market exclusivity provided by the patent, the research sector will not have any incentive to initiate trials that may lead to the development of an innovative pharmaceutical form;
- without the data exclusivity, manufacturers of innovative pharmaceuticals will be put at a disadvantageous position compared to generic pharmaceuticals companies, since the latter will receive similar profits at lower cost[90].

[87] Pharmaceutical Research and Manufacturers of America (PhRMA). GSK Public policy positions: Regulatory Data Protection GlaxoSmithKline Communications and Government Affairs, 2015.
[88] Pharmaceutical Research and Manufactureres of America (PhRMA), REDUCING DATA PROTECTION FOR BIOLOGICS WOULD SLOW MEDICAL PROGRESS AND CHILL R&D INVESTMENT IN THE U.S., 2015
[89] Regulation (EU) No 536/2014 of the European Parliament and the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.
[90] International Federation of Pharmaceutical Manufacturers Associations (IFPMA), ENCOURAGEMENT OF NEW CLINICAL DRUG DEVELOPMENT: THE ROLE OF DATA EXCLUSIVITY, 2000.

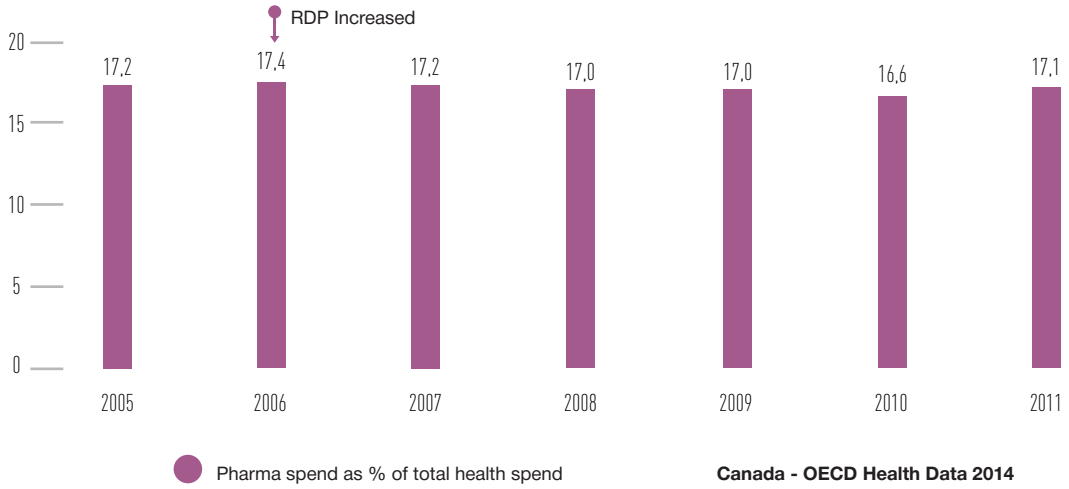
The attention should also be drawn to the arguments in support of the introduction of the data exclusivity regime, and even the extension of the exclusivity period, obtained as a result of researches sponsored by INTERPAT. Thus, the research illuminated that the 12-year period of data exclusivity has a negligible beneficial effect on the life expectancy of people under the age of 55. Taking into consideration that Americans will bear expenses on innovative pharmaceuticals in the early 2020s (by this time their number will increase), they will receive more health benefits using them, and the life expectancy is expected to increase by 1.44 years contrary to 1.30 years, as it is now. That is, new pharmaceuticals that have already been introduced on the market because of extended data exclusivity, will make no contribution to the life expectancy in the future in case of increase in the duration of data exclusivity.

Moreover, the researches of Geneva Network are worth attention[91]. According to the example of Canada and Japan, an increase in the period of data exclusivity does not lead to a significant growth in health care or pharmaceuticals expenditures if compared with the total health care expenditures.



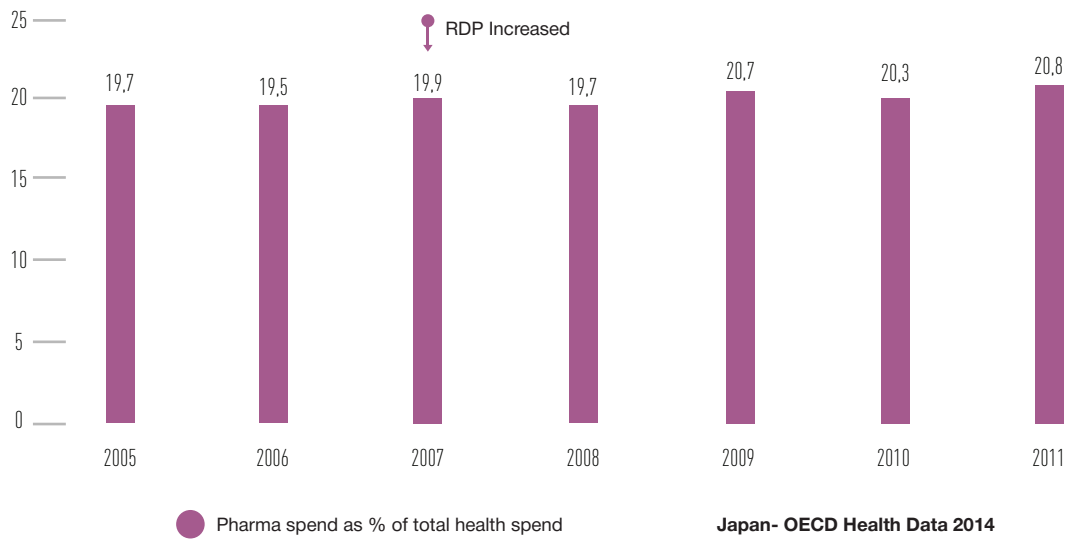
[91] Geneva Network, Will increasing the term of data exclusivity for biologic drugs in the TPP reduce access to pharmaceuticals?, 2015.

Pharmaceutical healthcare expenses in Canada in percentage (2005-2011)



Canada - OECD Health Data 2014

In 2006, Canada changed its data exclusivity rules in such a way that data exclusivity period is extended from 0 to 8 years. The graph above demonstrates no increase in pharmaceutical costs compared to total health care expenditures in percentage terms. Similarly, Japan enlarged the data protection period from 6 to 8 years in 2007.



Japan- OECD Health Data 2014

As the diagram below shows, the further expenditure fluctuations corresponded to an increase in the healthcare expenses in GDP percentage. In fact, pharmaceutical industry expenditure declined in 2010, while the healthcare expenses increased.

The fact that the health insurance system was established in Canada and Japan explains such phenomena. The majority of patient's expenses on pharmaceuticals are covered by insurance, and thus, the increase of the data exclusivity regime period had no effect on the cost of pharmaceuticals for citizens.

Contrary to the above, a great number of examples and findings of international organisations and experts can be named, indicating the negative effect of the exclusivity regime on the availability of pharmaceuticals and their cost.

For instance, the US Trade Representative Office and the EU are of the opinion that paragraph 3 of Article 39 of the TRIPS Agreement imposes obligations regarding exclusivity. According to the EU stance, WTO Members should only set the duration of the data exclusivity period.[92] However, some of the WTO Members stick to another position, which is based on the assumption that the TRIPS Agreement does not require the introduction of the "data exclusivity regime" but only refers to the interference to "unfair commercial use" or acts of "unfair competition". Indeed, the TRIPS Agreement does not define the notion of "unfair commercial use", which means that each country has to decide what actions are to be considered unfair.

Concerning the use of inventions, the TRIPS Agreement stipulates that a compulsory license may be issued, in particular, to ensure public health by public authorities. However, a compulsory licensing mechanism is not foreseen. As a result, provisions concerning a fixed period of "data exclusivity" or "marketing exclusivity" contained in the legislation of a WTO Member may be an obstacle to the registration of pharmaceuticals manufactured under a compulsory license. In this regard, national laws should not contain requirements that are more restrictive than those established within the scope of the TRIPS Agreement.

Thus, Oxfam International notes that the data exclusivity creates a new system of monopoly, separately from patents, by blocking the registration of generic pharmaceuticals for five or more years, even if there is no patent for such pharmaceuticals. Regulatory authorities are not able to use the clinical research data, developed by the company of reference medicinal products to confirm the safety and efficacy of generic pharmaceuticals. It inhibits competition from generic pharmaceuticals turn. At the same time, the TRIPS Agreement only protects "undisclosed data" to prevent "unfair commercial use"; it does not grant exclusive rights or a period of marketing monopoly. In support of this statement, WHO also provided a report by the WHO Commission on intellectual property rights, innovation and public health in 2006. It is stated in the report, "the text of the Article [39.3] does not make any reference whatsoever to exclusivity or exclusive rights [unlike with patents]. Article 39.3 requires countries to protect undisclosed registration data about new chemical entities (i) against disclosure and (ii) against unfair commercial use." It does not create property rights, does not prevent the rights of others to use data for obtaining marketing authorisation for the same product by a third party, or use of the data, except in cases of unfair commercial practices. In addition, WHO notes that pharmaceuticals fall under two separate legal and regulatory systems: the intellectual property system and the drug regulatory system. "These systems have different objectives, are administered separately and function independently"[93].

[92] Alfred Adebare «Data Exclusivity: The Indian Position», 2005

[93] World Health Organization, Briefing Note Access to Pharmaceuticals World Health Organization: DATA EXCLUSIVITY AND OTHER "TRIPS-PLUS" MEASURES, 2006.

Studies show that data exclusivity leads to a significant increase in pharmaceuticals prices. For example, in Jordan, only during the first five years after the implementation of the TRIPS-plus provisions medicine prices increased by more than 20% and a quarter of the budget of the Ministry of Health was spent on the procurement of pharmaceuticals. The data exclusivity regime delayed the market entry of generic pharmaceuticals. As a result, in the period from 2002 to 2006 79% of pharmaceuticals prices increased by 800% above the prices of the neighbouring Egypt (where price reductions were possible due to the presence of generic products that are not restricted by data exclusivity)[94,95].

The New England Journal published a thematic study about an effect of data exclusivity on the pricing, even in regard to those medicines which are not covered by the patent protection. In the United States, the cost of colchicine (used primarily for the treatment of gout) increased by more than 5,000% after the data exclusivity rights have been put into effect. Colchicine has been used for thousands of years (conventional medicine) and cannot be patented. Thus, pills have been widely available since the 19th century. However, the colchicine monopoly has been introduced in 2009 when the FDA accepted clinical data from a one-week medicine trial and established the data exclusivity for URL Pharma. URL Pharma subsequently brought a case to the court in order to force other manufacturers in the market to raise prices from USD 0.09 to USD 4.85[96].

In turn, IFARMA suggests that the introduction of data exclusivity simultaneously with patent protection in Peru will lead to an increase in the total pharmaceutical expenditure by USD 459 million in order to ensure the current level of consumption of pharmaceuticals by 2025, or to reduce consumption by 20%. In 2025, due to the strengthening of intellectual property protection, the prices for pharmaceuticals on the private market would increase by 27%. According to the organisation's estimations, the prices will increase by 25% in the public sector by 2025, when expenditures for provision of the population with medicines will raise by USD 48 million[97].

According to the Pan-American Health Organisation, by 2020, the Colombian healthcare system will pay additional USD 940 million annually to cover medicinal expenses; about 6 million patients will not have access to pharmaceuticals in the result of conclusion of the Free Trade Agreement with the USA[98]. Signing of the Free Trade Agreement between the United States and developing countries will have serious consequences for the health and well-being of people in these countries. FTA provides for strict TRIPS-plus provisions, including patent term extension, data exclusivity, and patent linkage. Research confirms that consequentially to signing FTA with developing countries, the prices for new pharmaceuticals would increase and it would catastrophically influence poorer people. According to the research conducted by the Bangkok University, the conclusion of the US-Thailand FTA would result in a 32% increase of pharmaceuticals prices and a reduction in Thailand's pharmaceuticals market by USD 3.3 million by 2027[99].

In this situation, the experience of Chile is representative. Guided by the national law, the government of Chile attempted to limit effects of the data exclusivity provisions contained in the Free Trade Agreement with the United States through direct exclusion of a number of intellectual property objects from the data exclusivity regime[100].

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[94] Journal of Generic Pharmaceuticals, Malpani, R., All costs, no benefits: how the US-Jordan free trade agreement affects access to pharmaceuticals, 2009.
[95] Oxfam. All Costs, no Benefits: How TRIPS-plus Intellectual Property Rules in the US–Jordan FTA Affect Access to Pharmaceuticals, 2007.
[96] The new England journal of medicine, Kesselheim, A.S, Solomon, D.H, Incentives for Drug Development —The Curious Case of Colchicine, 2010.
[97] International Federation of Pharmaceutical Manufacturers Associations (IFPMA). Impact of the EU-Andean Trade Agreement on Access to Pharmaceuticals in Peru, 2009.
[98] Pan American Health Organization, Impacto de fortalecer las medidas de Propiedad Intelectual como consecuencia de la negociación de un Tratado de Libre Comercio con Estados Unidos: Aplicación del modelo a Colombia, 2005.
[99] The Southeast Asian Journal of Tropical Medicine and Public Healt, «Impact on Access to Pharmaceuticals from TRIPS-plus: A case study of Thai-US FTA», 2010.
[100] WTO, Argentina—Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals, 2002.

According to the Doctors Without Borders, introduction of data exclusivity regime in Guatemala led to increase in prices up to 846%[101].

Oxfam International claims that higher pharmaceuticals prices also threaten the financial viability of healthcare programmes in the public sector. A study of the World Bank predicts that the US-Thailand FTA could seriously harm the national programme of the Thai government for HIV and AIDS treatment (including provision of antiretroviral pharmaceuticals)[102].

Subsequently, Doctors Without Borders expressed growing concern that the approval of the data exclusivity provisions could prevent the use of generics of the latest antiretroviral pharmaceuticals such as atazanavir. If taking Guatemala, it will make second-line treatment unaffordable in this country[103].

On 29 March 2011, the Minister of Commerce and Industry of India, Sri Anand Sharma, made an official statement that data exclusivity is far beyond international commitments and that provision of the data exclusivity will have a significant impact by delaying the market entry of cheaper generic pharmaceuticals. Later, the head of Doctors Without Borders supported India in strong determination under the constant pressure from the EU[104]. It was noted that India was recognised as the "pharmacy of the developing world" as it produces a large number of available high-quality pharmaceuticals at the price of generics. The cost of Indian first-line antiretroviral generic pharmaceuticals decreased from approximately USD 10,000 per person annually in 2000 to about USD 150 in 2012 per person annually. This significant decline in prices was advantageous for the expansion of HIV treatment worldwide. More than 80% of HIV pharmaceuticals that are used to treat 6.6 million people in developing countries originated from Indian manufacturers and 90% of paediatric pharmaceuticals for HIV treatment are manufactured in India. Nevertheless, the Free Trade Agreement, that is currently under negotiation between the EU and India, can substantially limit the capacity of Indian manufacturers of unpatented pharmaceuticals to continue their production[105]. By postponing the authorisation of generic pharmaceuticals to ten years, the data exclusivity actually gives a company a status of an illegal monopoly, even in respect to the pharmaceuticals that do not qualify for a patent in accordance with the Indian law. Such provisions have been criticised by the global health organisations, including the Global Fund, WHO, UNAIDS, and UNITAID, supporting the view that the data exclusivity regime threatens further competition and reductions of generic pharmaceuticals prices in India, whereas in the presence of such factors the price for HIV pharmaceuticals decreased by 99% compared with the last ten years[106,107]. Professor B.K. Baker expressed the view that India should not establish any fixed period of data protection. From where he stands, India should set an example in confronting the TRIPS-plus provisions. If India opposes the United States regarding the establishment of the "data exclusivity" regime, it will serve as an example for other developing countries, including those involved in the negotiation on free-trade agreements with the US[108].

101. Health Affairs, Shaffer E, Brenner J. A trade agreement's impact on access to generic drugs, 2009.
102. Oxfam, Public health at risk: A US Free Trade Agreement could threaten access to pharmaceuticals in Thailand, 2006.
103. Médecins Sans Frontières (MSF)/ Doctors Without Borders, Data exclusivity and access to pharmaceuticals in Guatemala, 2005.
104. Médecins Sans Frontières (MSF)/Doctors Without Borders , EUROPE! HANDS OFF OUR MEDICINE, 2011.
105. Médecins Sans Frontières (MSF)/Doctors Without Borders, How a Free Trade Agreement between the European Union and India could threaten access to affordable pharmaceuticals for millions of people worldwide, 2012.
106. Médecins Sans Frontières (MSF)/Doctors Without Borders, India Says 'No' to Policy that Would Block Access to Affordable Pharmaceuticals, 2011.
107. Michel Sidibe, It's time to provide universal access to science achievements, Conference on pathogenesis, treatment and prevention of HIV infections, 2011.
108. Professor Brook K. Baker. A critical analysis of India's probable data exclusivity/data compensation provisions, 2006.

Generic competition has been the best way to decrease prices for pharmaceuticals and improve access to treatment. Doctors Without Borders began providing antiretroviral treatment for HIV/AIDS in 2000, when the cost of treatment was more than USD 10,000 per patient annually. Today Doctors Without Borders provides treatment to 285,000 participants within the scope of HIV/AIDS projects in 21 countries, mainly by unpatented pharmaceuticals produced in Asia. These generic pharmaceuticals reduced the cost of treatment by almost 99%, to less than USD 140 per patient a year[109].

By refusing data exclusivity, the patent legislation of Brazil can ensure that the monopoly of originator companies will not be undeservedly prolonged through regulatory procedures[110].

Doctors Without Borders argue that developing countries should remain vigilant about attempts to introduce data exclusivity rules or to extend existing rules during bilateral negotiations on free trade agreements or under the pressure of the pharmaceutical industry[111]. In particular, they expressed their concerns regarding the signing of the TPP Agreement and noted that it will go down in history as the worst trade agreement that will affect access to pharmaceuticals in developing countries. Although it may lead to lower costs for pharmaceuticals in many countries, its controversial approach of blocking fully legitimate competing pharmaceuticals developments will eventually create chaos with access to pharmaceuticals in developing countries[112].

As an example of what constraints are imposed on healthcare by the data exclusivity regime, Judit Rius Sanjuan, the author of the study "The protection of the pharmaceutical test data: a policy proposal", provides the official letter from the head of the European Commission's Pharmaceutical Division to the European Generic Pharmaceuticals Association. According to the authors of the study, the European Commission has confirmed the worst fears expressed by critics of data exclusivity, that this regime would postpone or impede the use of compulsory license aimed at bringing generic pharmaceuticals as a replacement for Tamiflu (oseltamivir) to the market in the event of an avian influenza pandemic. The worst thing in this story is that the lack of pharmaceuticals in many countries will not be caused by a high price of the originator drugs, but by its physical inaccessibility. Such a precedent, when countries faced the lack of this drug for ensuring strategic national stockpile due to limited manufacturing capacity of the originator, Roche company, already exists.

As it is stipulated in the specified letter, EU pharmaceutical legislation does not provide for exceptions to the eight- or ten-years data and market exclusivity even in cases of national emergency or other situation of urgency, or in case that compulsory license is granted by the Member State. These means that the applicant, applying for marketing authorisation in the EU, will have to provide the necessary documentation for preclinical and clinical trials in accordance with Art. 8 (3) (i) of Directive 2001/83/EU, or to apply for informed consent under Art. 10c of Directive 2001/83/EU. In conclusion, national emergency rules of EU Member States may allow the provision of compulsory patent licenses that will allow generic pharmaceuticals or other companies to use a patented product in a given country. However, the

[109] Médecins Sans Frontières (MSF)/Doctors Without Borders Open letter to TPP countries: Don't trade away heats Geneva, 2013.
[110] Médecins Sans Frontières (MSF)/Doctors Without Borders, WHY BRAZIL SHOULD REFORM ITS PATENT LAW AND BOOST MEDICAL INNOVATION TO PROMOTE ACCESS TO PHARMACEUTICALS, 2015.
[111] Médecins Sans Frontières (MSF)/Doctors Without Borders, Provisions in U.S. Domestic Health Care Legislation Could Limit Access to Vaccines and New Class of Drugs, 2010.
[112] Inter Press Service, PP is "Worst Trade Agreement" for Medicine Access, Says Doctors Without Borders, 2015.

pharmaceutical legislation of the EU currently does not contain any provisions allowing waiver of the above data exclusivity regimes and the period of market protection in the event of a national or Pan-European emergency.

There are no compelling reasons to state that countries are obliged to include data protection provisions in national law. There are no explicit requirements foreseen in the TRIPS Agreement to address data exclusivity, and even the developer of this regime, congressional representative Henry A. Waxman, criticised its application in the countries with different levels of income and healthcare systems. Interestingly, H.A. Waxman himself drew attention to the fact that data protection provisions in the US legislation (Hatch-Waxman Act, 1984) were developed, in particular, in order to stimulate the entry of generic pharmaceuticals on the market. Naturally, the copying of this law in other countries with other conditions will lead (and already does) to completely different consequences – foreign pharmaceutical giants are in a privileged position but cannot exercise it because of the low demand for their expensive pharmaceuticals. As a result, a country economy suffers (pharmaceutical field) along with the citizens whose access to modern pharmaceuticals is limited[113].

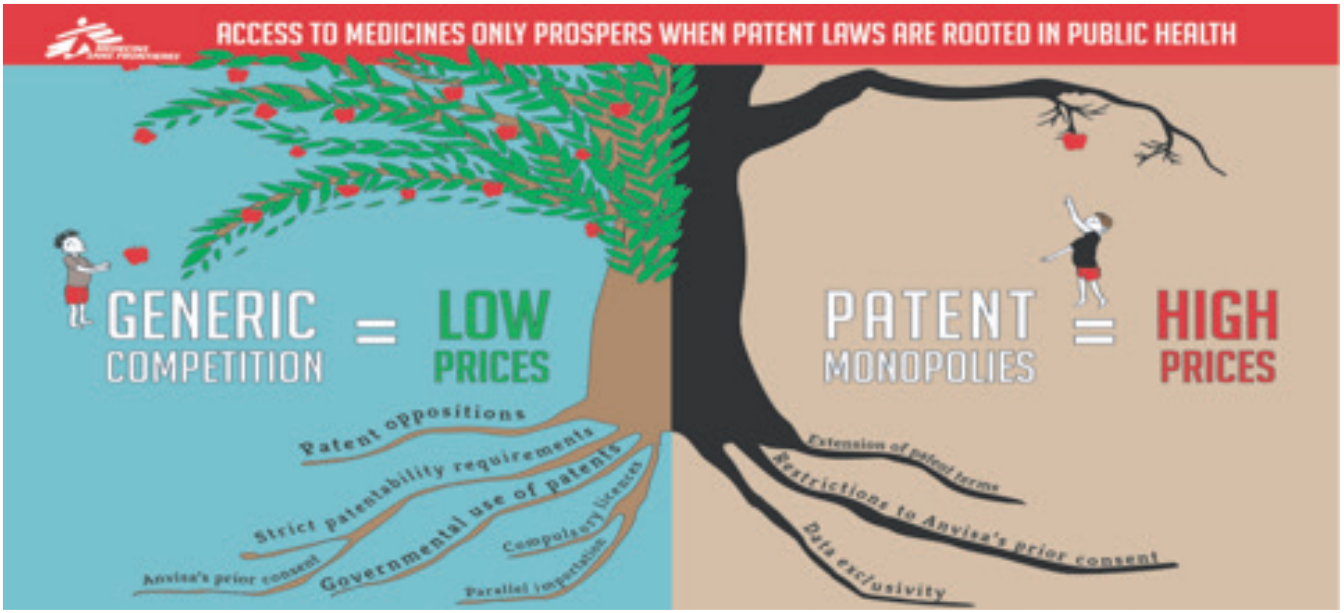
In another research on the predicted impact of the data exclusivity according to FTA between the United States and Thailand it was found that while comparing negative effects of patent term extension with the help of data exclusivity, results were different at the same temporal interval. During the next 5 years (in 2013) the impact of the five-year data exclusivity period will make 81356 million baht, which is more than the impact of the five-year patent term extension totalling 27883 million baht. However, over the next 15 years (in 2023) the economic impact of the five-year data exclusivity period of 125288 million baht will reckon less than the effect of the five-year patent term extension, 136922 million baht[114].
The aforementioned influence is obvious in the case of Ukraine, too. There is sufficient evidence to claim that the data exclusivity is already used by manufacturers of branded pharmaceutical products to prevent the access of generic antiretroviral equivalents to the Ukrainian market[115]. Olga Baula reports that in April 2001, the courts reviewed five cases related to the exclusivity of data of pharmaceutical products[116].

Another argument against the data exclusivity regime is the violation of medical ethics. Thus, Oxfam International emphasises that the data exclusivity prohibits generic competition during certain period. The repetition of clinical trials of pharmaceuticals to prove their safety and efficacy could serve as an alternative for generic pharmaceuticals manufacturers. Yet, the repeated conduct of clinical trials contradicts ethical principles accepted by the World Health Organization, which must be respected in human-based research, since, according to the clinical research

[113] Statement of Congress Representative Henry A. Waxman at the House Committee on Ways and Means, 2008.
[114] Jiraporn Limpananont, Vithaya Kulsomboon, Nusraporn Ketsomboon, Usawadee Maleewong, Achara Eksangsri, Thai-US FTA: Access to Pharmaceuticals, Social Pharmacy Research Unit, Chulalongkorn University, Thailand, 2009.
[115] Lezhentsev K., WTO Accession and Restriction of Access to Basic Pharmaceuticals, Speech at the Regional Meeting "Access to Basic Pharmaceuticals, HIV and Intellectual Property Rights", 2009.
[116] Baula O., Speech at the seminar "Intellectual Property and Access to Pharmaceuticals in Ukraine", 2010.

methodology, it is necessary that some patients receive placebo[117]. The usage of placebo at a time when the clinical validity and safety of a medicinal product have already been tested and proved is unethical[118]. Health Action International seems to be on the same page.

Doctors Without Borders illustrated their approach to the data exclusivity regime, patent term extension, and other TRIPS-plus provisions in the image below.



[117] World Medical Association. Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, 2008.
[118] Journal of Generic Pharmaceuticals, Malpani, R., All costs, no benefits: how the US-Jordan free trade agreement affects access to pharmaceuticals, 2009.

The table below summarises all pros and cons of data exclusivity regime from the viewpoint of world public and private organisations in the field of healthcare:

Pros	Cons
IFPMA, INTERPAT, PhRMA, BIO	Oxfam, IFARMA (IPHARMA), Pan American Health Organization, Doctors Without Borders, WHO, UNDP, UNAIDS
An important tool to catalyse innovation, i.e. the invention of new pharmaceuticals.	A system of monopoly is created by blocking marketing authorisation of generic pharmaceuticals.
Legitimate way to protect the property rights for clinical research data.	The financial viability of healthcare programs is destructed.
Cost-recovery tool for pre-clinical and clinical research.	The cost of pharmaceuticals for the private sector is increasing and, accordingly, access to pharmaceuticals for low-income segments of society is decreasing.
Investing in the state economy through the creation of additional workplaces, manufacture, etc.	The costs of financing the state pharmaceutical sector are increasing.
Patent protection is not enough to balance the cost of pre-clinical and clinical trials and possible revenues from the implementation of innovative pharmaceuticals.	The rules of medical ethics during the preclinical and clinical trials are violated.

It is worth mentioning that UNDP also opposes the existence of a data exclusivity regime. To exemplify, in its report “Good practice guide: improving access to treatment by means of public health of the WHO TRIPS flexibilities” among recommendations UNDP names the need to “avoid/limit data exclusivity obligations”.

Analysis of Ukrainian case law regarding data exclusivity

Exclusivity as the basis for cancellation of marketing authorisation of medicinal products (2012-2016)

Number of cases (2014-2016)	Number of decisions in favour of the plaintiff	Number of refusals and the main reasons for refusal	Measures taken to secure a claim	General tendencies
7 Including: 5 - administrative proceedings, including: 1 dispute is pending; 2 – commercial proceedings	5	1 Main reasons for the refusal (administrative dispute): the decision of the Ministry of Health on the authorisation of generic drug is legal, as it is based on the positive conclusion of the State Expert Centre of the Ministry of Health. There were no reasons for rejection of the authorisation of such medicinal product. none of the participants appealed for the legality of the conclusion of the State Expert Centre of the Ministry of Health, with the recommendation to grant authorisation to generic drug, based on which the Ministry of Health issued a disputed order.	3 cases Economic proceedings: two applications for an injunction were filed in two cases; two applications were satisfied; Measures taken: - ban on placing a controversial generic drug on the market of Ukraine. Administrative proceedings: One application for an injunction was filed and denied by court. Measures claimed by the plaintiff: - suspension of the Order of the Ministry of Health on authorisation of the controversial generic drug.	Courts tend to protect the data exclusivity of the originator's registration dossier; Resolving disputes regarding the data exclusivity is a complicated and time-consuming process (2-6 years); making a decision in favour of the originator does not make sense without a preliminary injunction as dispute resolution can continue throughout the data exclusivity period; The circumstances that courts determine to settle the dispute are as follows: - the same active ingredient (reference/generic); - presence/absence of the results of own preclinical trials and clinical trials in the generic's registration dossier; - presence/absence of the data owner consent to use the data by the applicant of generic product; - the time that has passed from the date of granting authorisation to the reference medicine until the date of recommendations for state authorisation or state authorisation of the generic; - Granting injunctive relief to suspend the Ministry of Health order on generic authorisation is considered unacceptable as taking this measure would mean to satisfy the lawsuits. A reference to the damage caused to the plaintiff is not enough for injunctive relief according to the Art. 117 Code of Administrative Procedure of Ukraine, as entrepreneurship is a business activity held at one's own risk (the decision of the first instance court was not appealed).

Conclusions and recommendations

The world's experience in the field of administering the data exclusivity regime explicated above, as well as practical methods of its mitigation may serve an example for Ukraine in its current realities. Obviously, while implementing healthcare policy it is worth keeping a firm stand against additional international obligations regarding the data exclusivity regime, and to prevent amendments to Ukrainian legislation aimed at extension of the data exclusivity period compared to existing one. Considering the amount of GDP per capita and low solvency, Ukraine cannot afford imposing a stricter data exclusivity regime, since such changes will have a direct impact on the cost of pharmaceuticals, as proved by a large number of studies. It is worthwhile to mention that the data exclusivity regime valid for about 5 years is available in the developed countries with a high GDP per capita, while less developed countries attempt to establish the validity period not exceeding 5 years, or not to establish it at all.

It is necessary to define the following recommendations for further state policy in the field of public health and/or amendments to the current Ukrainian regulations on the matter:

1. To establish a wide range of circumstances in the presence of which the authorised body of the state has the right not to apply the data exclusivity regime.

2. To eliminate the legal conflict that blocks the use of the compulsory licensing mechanism during the validity of the data exclusivity regime, for example, to include the issuance of compulsory license by the Cabinet of Ministers in accordance with Article 30 of the Law "On the Protection of the Rights to Inventions and Utility Models" to the list of circumstances provided for in the preceding paragraph.

3. To limit the implementation of the data exclusivity regime for the originator drugs, regarding which from the moment of registration in other countries and to the moment of filing an application in Ukraine, a period exceeding one year has passed.

4. To create an effective mechanism for administrative and judicial appeal against the data exclusivity regime.

5. To establish the mechanism of mutual enrolment of data exclusivity terms at the level of bilateral and multilateral agreements. Thus, the data exclusivity period begins not from the date of registration of originator drugs in Ukraine but from the registration of these pharmaceuticals in any of the countries that are party to such agreements, depending on where such registration has taken place earlier.

6. To cancel the establishment of the data exclusivity regime on any other new characteristics of medicinal products (in particular, new therapeutic indications), except for new

chemical compounds/active ingredients; to establish the criteria for the «novelty» of the chemical compound at the legislative level.

These measures will assist to mitigate the climate on the Ukrainian market for the promotion of generics, to make them more accessible to the citizens, and to minimise the negative impact of an economic crisis on the health of the population.

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