THE CONCEPT OF IMPLEMENTING A COMPULSORY LICENSING

MECHANISM IN THE PUBLIC HEALTH SECTOR IN UKRAINE

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CONTENT

240 000
people are HIV-positive

42 666
people diagnosed with AIDS

139 394
HIV-positive patients diagnosed with AIDS were under medical surveillance of the HIV/AIDS Service healthcare facilities

INTRODUCTION

Article 12 of the International Covenant on Economic, Social and Cultural Rights enshrines the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, as well as access to essential pharmaceuticals. Not only does the lack of access to essential medicine directly concern human rights issues but also may cause a healthcare crisis.

In 2015, there were approximately 36.7 million people living with HIV worldwide[1]. In Ukraine, about 240,000 people are HIV-positive[2]. As of October 2017, about 139.394 HIV-positive patients and 42.666 people diagnosed with AIDS were under medical surveillance of the HIV/AIDS Service healthcare facilities[3].

[1] UNAIDS. Global AIDS Update 2016.
[2] UNAIDS Ukraine data (http://www.unaids.org/ru/regionscountries/countries/ukraine).
[3] According to the Ukrainian Centre for Disease Control of the Ministry of Health of Ukraine http://ucdc.gov.ua/pages/diseases/hiv_aids/statistics

The number of people living with HIV is still growing, largely because more and more people worldwide get access to antiretroviral therapy and, consequently, enjoy longer and healthier lives. As of June 2015, 15.8 million people received antiretroviral therapy[4].

Despite the fact that the number of new HIV infections has decreased, there is still an unacceptably high number of patients newly infected with HIV, as well as deaths caused by AIDS. In 2014, about 2 million people were infected with HIV, and 1.2 million died of AIDS-related medical conditions.

The availability of essential pharmaceuticals depends on multiple factors, especially the price. 50-90% of health expenditure in low-income economies is allocated specifically for procurement of pharmaceuticals[5].

In 1986, 49 of 98 Member States of the Paris Convention for the Protection of Industrial Property excluded pharmaceuticals from patent protection, 10 states did not allow patenting pharmaceutical processes, and 22 excluded chemical processes from patent protection. However, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), within the framework of the WTO, changed the state of affairs. In accordance with Article 33 of the TRIPS Agreement signed on 15 April 1994, the owner of the patent for pharmaceutical invention enjoys the monopoly right to manufacture such medicine during the 20 years, starting from the filing date. Consequently, less expensive generic pharmaceuticals are generally not allowed on the market throughout the above period.

One of the arguments most often used to support the strong global patent protection regime under the TRIPS Agreement is that strengthening of the intellectual property rights protection stimulates the development of new vital pharmaceuticals. Nevertheless, since the TRIPS Agreement was signed, there has been no significant increase in the number of new drugs, despite a relatively strong growth of the protection of intellectual property rights throughout the world. The number of patents on brand new pharmaceuticals is rather small and is constantly decreasing. At the same time, drug patents may number in the thousands although they are often issued on somewhat modified versions of existing pharmaceuticals[6].

The TRIPS Agreement contains a set of provisions that can be used by the Member States to improve public health and, in particular, increase access to pharmaceuticals. These rules, which are also referred to as TRIPS flexibilities, as well as the results of their implementation in Ukraine and the directions for their further implementation are analysed in the document under consideration.

[4] UNAIDS. AIDS in numbers 2015.
[5] WHO. WHO Pharmaceuticals Strategy: Countries at Core 2004-2007.
[6] Correa C. Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective. ICTSD, WHO, UNCTAD and UNDP, 2007.

INTERNATIONAL LEGAL REGULATION ON COMPULSORY LICENSING MECHANISMS FOR INVENTIONS IN THE PUBLIC HEALTH SECTOR

Compulsory licensing of inventions in the public health sector in international intellectual property law

In order to protect human rights to life and health and in connection with numerous cases of restrictions on such rights by a patent monopoly, the modern international legal doctrine of intellectual property rights provides for a mechanism of issuing a state compulsory license for inventions in the public health sector. Such a mechanism is a systemic link of international intellectual property law, which has been extracted into a separate institute due to a need to harmonize human rights and intellectual property rights addressed to the respective states. Such a social function of the state in balancing the patent monopoly and ensuring access to healthcare is stipulated in international legal instruments that are implemented in jurisdictions on a national or regional level.

Article 5 of the Paris Convention for the Protection of Industrial Property 1883 (Paris Convention) provides that each country of the Union shall have the right to take legislative measures providing for the granting of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent.

Article 31 of the TRIPS Agreement provides for the right to use a patent without the authorisation of the rights holder, including use by the government or third parties authorised by the government, in the case of a national emergency or other circumstance of extreme urgency.

In order to interpret and promote the use of the TRIPS flexibilities, including compulsory licensing in the public health sector, WTO Ministerial Conference of 2001 in Doha adopted the Doha Declaration on the TRIPS Agreement and Public Health on 14 November 2001.

Paragraph 4 of the Doha Declaration states that TRIPS does not and should not prevent members from taking measures to protect public health, and that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members right to protect public health and, in particular, to promote access to medicines for all. With reference to paragraph 5 (b) of the Doha Declaration, each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

On 6 December 2005, the WTO General Council adopted the Protocol Amending the TRIPS Agreement (Protocol) in order to implement the Doha Declaration for the purpose of export to countries with limited or no pharmaceutical production capacity under compulsory licenses.

Article 219 of the Association Agreement between the European Union and its Member States, of the one part, and Ukraine, of the other part (Association Agreement) states that the Parties recognise the importance of the Doha Declaration. In interpreting and implementing the rights and obligations under the Chapter 9 "Intellectual Property", the Parties shall ensure compliance with the Doha Declaration.

The EU legislation is a guideline for Ukraine for the introduction of a compulsory licensing mechanism in the public health sector on a national level, taking into account the foreign policy course aimed at EU accession. The Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medical products for human use and Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, establish as follows:

- the main purpose of any rules governing the manufacture, distribution and use of medical products is to treat or prevent disease in human beings (Article 1 (2) of Directive 2001/83/EC);
- compulsory licensing for the manufacture and export of medical products to countries with relevant economic indicators and issues in the field of public health (paragraph 5 of the Preamble of the Regulation (EC) No. 816/2006).

A Brief overview of the TRIPS Agreement compulsory licensing flexibilities

The TRIPS Agreement establishes an approach that sets minimum standards of protection to be met by the WTO Members.

Thus, the Members of the TRIPS Agreement have large discretionary powers to fulfil their obligations. A number of provisions include the term "flexibility", in particular, paragraph 6 of the Preamble to the TRIPS Agreement, where the terms and motives for concluding the Agreement are established:

"…Recognizing also the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base".

The rationale behind the inclusion of the flexibilities in TRIPS is that they identify mechanisms that assist countries to achieve the necessary balance between protecting intellectual property rights and public health needs. The above is enshrined in Article 7 "Objectives" of TRIPS:

"The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."

Mechanisms that are provided to the WTO Members by the TRIPS flexibilities include, inter alia, compulsory licensing. A brief analysis of some key aspects of the compulsory licensing, such as the grounds, initiation and format, is provided below.

Legal grounds for compulsory licensing

The legal grounds for the use of compulsory licensing mechanisms by the countries, in accordance with paragraph 5 (b) of the Doha Declaration, are determined by each country at their own discretion:

"Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which licences are granted."

Some grounds specified in Article 31 of the TRIPS Agreement are as follows:

- public non-commercial use;
- use in the case of a national emergency or other circumstances of extreme urgency;
- use to correct anti-competitive practices;
- interdependence of patents.

Additionally, Paris Convention allows compulsory licensing in the event of failure to work or insufficient working of the invention. It should be noted that the above may be applied to the public health sector.

An overview of the best practices in enforcing compulsory licensing mechanisms in the public health sector shows that the first two grounds are widely used in developing and least developed countries.

In contrast, in the EU, the most common ground for compulsory licensing is preventing anti-competitive practices.

Preventing and/or correcting anti-competitive practices that impede access to pharmaceuticals is one of the most crucial TRIPS flexibilities. Thus, clarification of the provision is contained in Article 8 (2), Article 31 (1) (k), and Article 40 of the TRIPS Agreement. However, TRIPS Agreement does not define anti-competitive conduct, and provides the WTO Members with some freedom to identify the anti-competitive actions and develop their own policies on them.

When issuing compulsory licenses provided for in Article 31 (1) (k) of the TRIPS Agreement as an anti-competitive practice remedy, unlike compulsory licenses under Article 31 (1) (b) of TRIPS, prior negotiations with the patent owner are not required. Patent owner's notice is also not provided, as in the case of using a patent in the interests of the state.

According to Article 31 (1) (k) of TRIPS, the need to correct anti-competitive practices may be taken into account when determining the amount of compensation to the patent owner. In other words, in particularly serious anti-competitive cases, compensation may be not paid at all. In practice, antitrust bodies resort to imposing fines on offenders, which is another deterrent of anti-competitive behaviour.

Consequently, the TRIPS Agreement does not limit the possibility of determining the grounds for compulsory licensing on a national level, but requires their proper establishment in the national legislation.

Obviously, for Ukraine, the need to provide healthcare for internally displaced persons, uncontrolled migration and the objective increase in the spread of life-threatening diseases (HIV, tuberculosis, hepatitis, cancer diseases, etc.) may serve as additional grounds for compulsory licensing.

Initiation of the compulsory licensing procedure

According to Article 31 of the TRIPS Agreement, several scenarios for the use of patented inventions are possible without authorisation from the rights holder, depending on the initiator of compulsory licensing:

- use by a **third party** authorised by the government;
- use by the **government** or by the contractor authorised and initiated by the government, in the case of public non-commercial use.

Who is entitled to grant compulsory licenses

Legal approaches regarding the entity entitled to grant compulsory licenses differ from country to country, depending on the state system and administration:

- in countries where executive authorities are vested with such power, such entity is an executive authority represented by the government or relevant ministry/ministries, minister/ministers (the USA, France);
- in some countries, other competent authorities are identified (the Department of Patent Rights under the Council of People's Republic of China in China, the Egyptian Patent office in Egypt);
- in monarchies, the authority to issue the compulsory licenses of inventions in the interests of the state is mainly given to the monarch (Australia);
- in some countries such authority historically is given to the judiciary (Germany, the United Arab Emirates, Croatia, Madagascar, Kyrgyzstan).

Thus, the entity that decides to use a patented invention without authorisation from the patent owner is the relevant body (bodies) or official (officials) of the state authority (executive, judicial, etc.) established by the national legislation of the relevant jurisdiction.

Compulsory licensing procedure

According to Article 31 of the TRIPS Agreement, a compulsory license may be issued:

- within a general procedure: mandatory prior measures to be authorised by the patent owner are required;
- within a simplified procedure: no prior measures are required, but the patent owner must be notified that a compulsory license has been issued ex post facto (only when a compulsory license has been issued on grounds of public non-commercial use, in case of national emergency, and other circum stances of extreme urgency);
- within a simplified procedure: no prior measures are required, no notice to the patent owner on the issuance of a compulsory licence is required (only when a compulsory license is issued to prevent anti-competitive practices).

According to Article 2 of the EU Regulation, both the rights specified in the patent and those extended under the supplementary protection certificate are subject to compulsory licensing. The Ministry of Economic Development and Trade of Ukraine is currently developing legislative proposals regarding the implementation of supplementary protection certificates in Ukraine on implementing the Association Agreement.

Thus, the TRIPS flexibilities provide extended opportunities for WTO member states to improve pharmaceuticals supply of the population by providing details, grounds, terms and mechanisms for issuing compulsory licenses on a national level.

Implementing some of the TRIPS flexibilities in different countries indicates that an effective compulsory licensing mechanism enshrined in the legislation of a WTO Member, as well as explicit legislative provisions on freedom of competition, largely contribute to the achievement of the main objective – access to pharmaceuticals – sometimes without coercive measures, through voluntary licensing on reasonable terms.

Implementation of the mechanism for using inventions in the public health sector without the patent owner's authorisation: analysis of the experience in different jurisdictions

The laws of most countries contain provisions that allow a state and/or third parties to use patents without authorisation from the patent owner under certain circumstances and conditions.

The history of the compulsory licensing mechanism, intended to protect the interests of society and public health, goes back to over 80 years old. Thus, 107 compulsory licenses were issued in the United States from 1941 to 1959[7]. Between 1950 and 1972, 76 compulsory licenses were applied for and 21 were issued in the UK[8].

The modern world practice, likewise, has similar examples. The governments of the USA, the EU, Asian, African and Latin American countries in the recent decades granted many compulsory licenses.

A number of experts state that compulsory license provisions in the national law of a Member State are an important tool for ensuring the fair exercise of patent rights, for example, in the form of encouraging the issue of voluntary licenses on reasonable terms or creation of competition[9].

Both examples of compulsory licensing mechanisms application initiated in the EU such as issuance of compulsory license by the government or just initiation of compulsory license which already stimulated a patent owner to significantly reduce the price may be relevant to Ukraine. However, in the EU countries, the wording "in order to ensure public health and to fight anti-competitive practices" was used.

Thus, in 2000, Roche applied for a compulsory license for a HIV/AIDS screening test in Germany, initially patented by Chiron. The initiatives of Roche and the government's explicit political will to issue a compulsory license were enough to allow Roche and Chiron to conclude a licensing agreement in May 2001 and come to the mutual agreement regarding the price. The very facts of the availability of legal instruments for issuing compulsory licenses and the demonstration of relevant political will of the state are sufficient mechanisms for balancing the interests of society and intellectual property rights.

At the beginning of the 2000s, a pro-active stance of the French patient's society regarding the exorbitant price of breast cancer tests, the patent for which was owned by Myriad, led to appropriate legislative initiatives and amendments to the Intellectual Property Code in 2004. According to Article L 613-17, in case of healthcare needs and in the absence of voluntary consent, a compulsory license for a medicine, a medical device for in vitro and in vivo diagnostics and related therapeutic products may be issued upon a plea of the Minister of Industry and the Minister of Health.

In 2005, the compulsory licensing mechanism to safeguard the interests of the society that were violated by anti-competitive activities was effectively used in Italy. Italian Competition Authority (AGCM) issued a compulsory license for the imipenem/cilastatin of the Glaxo Company. In 2007, AGCM obtained a voluntary license from Merck for finasteride two years before the expiration of the supplementary protection certificate.

[7] Finnegan, Marcus (1977) The folly of compulsory licensing. Licensing Executive Society (LES), June, 128-147.
[8] Goldstein, Sol (1977) A study of compulsory licensing. Licensing Executive Society (LES), 122-125.
[9] Jayashree Watal, Intellectual Property Rights in the WTO and Developing Countries (2001).

The table below contains examples of implementing the compulsory licencing provisions in national legislation of various states:

Country	Use by the government in the interests of society	Emergency and extreme urgency	Provisions
Austria	+	+	Para.36 of the Patent Law (as amended on 2010)
Bulgaria	+	+	Art.32 of the Patent Law
Georgia	+	+	Art.61 of the Patent Law
Denmark	+		Para.47 of the Consolidated Patent Act (access to all necessary information – see Art. 48 (1)
Estonia	+	+	Para.4 of the Patent Act
Canada	+	+	Para.21 of the Patent Act
China	+	+	Art.50 – in the healthcare sector; Art.49 – the Patent Law state of emergency
Cyprus	+		Art.55 of the Patent Law
Latvia	+ (court decision)	+ (government order)	Para.54 of the Patent Law
France	and preventing anti-competitive actions		Arts.L 613-18, R613-10 of the Code of Intellectual Property
Czech Republic	+	+	Art.20 of the Law on Inventions, Industrial designs and Rationalization proposals

A survey conducted at the request of the World Bank and the African Regional Intellectual Property Organization (ARIPO) on the analysis of compulsory licensing as a tool for improving access to medical products in Africa revealed that of the three countries that were attempting to establish a local production, compulsory licenses were actually issued only in one of them, Zimbabwe. In two other countries, Kenya and South Africa, an agreement on voluntary licensing was reached. A similar practice allowed Brazil to achieve significant price reduction when procuring essential patent protected pharmaceuticals.

Consequently, successful exercise of the compulsory licensing mechanism as an instrument for expanding access to healthcare is efficient and depends on a clear definition within national law and the political will of the state.

It is worth considering the experience of different jurisdictions in terms of the grounds for using inventions in the interests of the state without authorisation of the patent owner; entities that initiate authorisation of such use of inventions in the interests of the state; entities that may be authorised to use such inventions in the interests of the state; mechanisms for granting permission for such use of the invention by the government or by third parties authorised by the government.

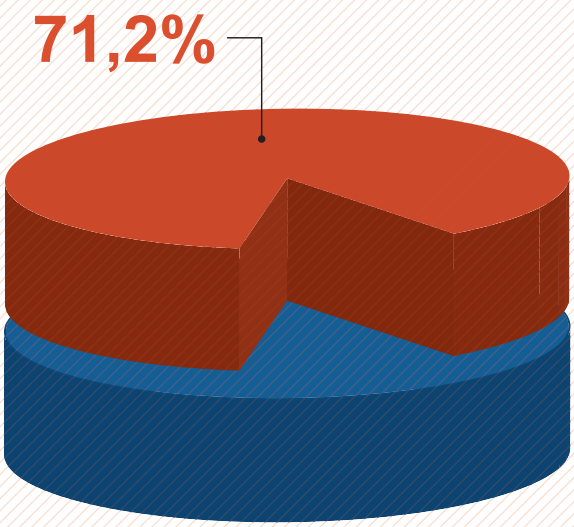
Grounds for the use of patented inventions in the interests of the state without permission from the patent owner

In many developing countries, most of the population relies on public healthcare[10]. Procurement of less expensive pharmaceuticals can ensure significant budget savings.

In accordance with the TRIPS Agreement, WTO Members may introduce simple mechanisms that empower public authorities to grant authorisation to use patented inventions for the benefit of the state, subject to subsequent compensation to the patent owner.

For instance, in accordance with paragraph 1498 of the United States Code, the US Government has wide powers to use or grant authorisation to any third party to use any patented invention. Thus, (1) the said powers are limited only by the compensation requirement, and (2) patent owners have no right to challenge such use of a patent by the state in court.

[10] WHO. Statistical Information System: Core Health Indicators, 2008.



62 countries provide for the use of patented inventions without obtaining an authorisation from the patent owner in the interests of the state

87 Countries that enforced compulsory licensin

In 2014, by the decision of the Standing Committee on the Law of Patents of the World Intellectual Property Organization (WIPO), the Secretariat sent a letter to member states with a request to complete a questionnaire on patent restrictions and exceptions. The WIPO questionnaire included a separate section on compulsory licensing and the use of patented inventions in the interest of the state (“Government Use”).

According to the questionnaire results (http://www.wipo.int/scp/en/exceptions), among 87 countries that enforced compulsory licensing, the laws of 62 countries provide for the use of patented inventions without obtaining an authorisation from the patent owner in the interests of the state.

Among the overwhelming majority of 62 countries whose patent laws provide for the government use of patented inventions, there are several grounds for using the invention in the interests of the state:

- national security (in the legislation of 46 countries);
- public health (in the legislation of 38 countries);
- national emergency and/or extreme urgency (in the legislation of 35 countries);
- anti-competitive practices and/or unfair competition (in the legislation of 16 countries);
- refusal to issue licenses on reasonable terms (in the legislation of 14 countries);
- non-working or insufficient working of the patented invention (in the legislation of 11 countries).

Among other grounds for using patented inventions in the interests of the state, the following should be noted:

- national economy needs (Morocco);
- national defence (France);
- vitally important state interests (Poland).

The grounds for the government use of inventions without authorisation from the patent owner are either unlimited or defined broadly and inexhaustibly in the laws of some states as follows:

- there are no terms and restrictions on the use of inventions in the state interests under the law (India);
- any public needs (Thailand, Vietnam);
- national security or national urgency, as well as other grounds (New Zealand);
- the use of any patented invention in the public interest, if reasonable compensation is granted to the patent owner (US).

Thus, each state, at the level of its national legislation, includes different areas to the concept of “state interests”: national security, emergency response, public health, development of other crucial sectors of national economy, etc.

The table below shows data on the application of the compulsory licensing mechanism in various jurisdictions based on government use in the public interest, emergency use, and preventing anti-competitive practices:

Country	Medical product	Legal ground	Results
Italy	2005 – antibiotic: imipenem + cilastatin; 2006 – medication for migraines: sumatriptan succinate; 2007 – finasteride for treatment of prostatic hypertrophy, prostate cancer and male hair loss	Termination of anti-competitive practices	Reducing the cost of medical products
Zimbabwe	HIV/AIDS pharmaceuticals	Emergency state, extreme urgency	The average price of ARVs has fallen from USD 30 – USD 50 a month to just over USD 15 a month, with a price drop of at least 50%.
Malaysia	HIV/AIDS pharmaceuticals (combivir)	Government use in the interests of society	The average cost reduction is 81% per patient monthly; the number of patients treated for public funds has increased from 1500 to 4000.
China	HIV/AIDS pharmaceuticals	Emergency state, extreme urgency Government use in the interests of society	The cost of pharmaceuticals reduced by 50%
Thailand	HIV pharmaceuticals: efavirenz, lopinavir/ritonavir (LPV/r); clopidogrel	Government use in the interests of society	LPV/r reduced by 75%; clopidogrel – by 91%; docetaxel – by 24 times; letrozole – by 70 times. After a compulsory license, Abbott Company has lowered its lopinavir/ritonavir price by more than 55% for more than 40 low and middle-income countries. By 2010, the number of patients receiving efavirenz increased from 4539 to 29360 people.
Brazil	efavirenz	Government use in the interests of society	Compulsory licensing saved USD 31 million.
India	sorafenib	Provisions of the national law	The cost of pharmaceuticals is estimated to be reduced by 97%, from USD 5,500 to USD 175 per patient monthly.

The following are examples of defining the purposes and grounds for using patented inventions without authorisation of the patent owner in the state interests, which are enshrined in laws of some countries:

Canada	Facilitating access to pharmaceuticals to address public health issues, in particular those related to HIV/AIDS, tuberculosis, malaria and other epidemics.	(article 21.03(1) Patent Act R.S.C., 1985)
Brazil	A state of emergency or in the interests of citizens.	(Decree n. 3.201, 1999 and articles 68 to 74 of Law n. 9.279, 1996)
Argentina	Ensuring national security, including in the state of emergency.	(article 42–50 of Law No. 24.481, 1996)
Burkina Faso	Strategic interests related to public health, national defence or national economy.	(annex I, article 56 of Bangui Agreement)
Australia	National defence.	(section 133 of Patents Act, 1990)
Bhutan	Enabling the country to use the invention where necessary.	(section15, Industrial Property Act of the Kingdom of Bhutan, 2001)
USA	Providing the state with the opportunity to procure the means and services necessary for the purposes of a state.	(title 35 – Patent, United States Code, 1926)
Great Britain	The provision on the use of patents in the state interests means that availability of patents should not prevent public authorities from performing their functions.	(sections 48–59 of the Patents Act, 1977)
Hong Kong (China)	Ensuring the immediate use of inventions to meet the urgent needs of the population in the state of emergency.	(sections 64–67 of Patents Ordinance (chapter 514, Laws of Hong Kong)
Kyrgyzstan	Emergency complicated by the epidemiological situation.	(article 12 of the Patent Law)
China	Ensuring national public interests.	(article 48 of the Patent Law)
Uganda	Providing solutions to issues of paramount importance to the country.	(section 30 of the Patents Act)

Entities that may be authorised to use inventions in the interests of the state

In accordance with the provisions of Article 31 (1) of the TRIPS Agreement, the permission to use inventions in the state interest without authorisation of the patent owner may be used:

- directly by the government, or
- by third parties authorised by the government.

Moreover, Article 31 of the TRIPS Agreement does not specify which entities may be the "third parties authorised by the government". Article 31 (f) of the TRIPS Agreement merely states that such use is permitted mainly to supply the domestic market of the member state that authorised such use.

Legal provisions of different states regarding third parties (contractors, agents, etc.) authorised or designated by the government or other public authority indicate that:

United Arab Emirates	Any interested party may obtain the right to compulsory licensing by filing an application to a competent court if that person fulfils a number of requirements specified in the applicable law.	(articles 23, 29 - Federal Law No. 44 of 1992)
Arab Republic of Egypt	The Egyptian Patent Office may grant a decision on compulsory license to a third party if that person fulfils a number of terms established by the applicable law.	(articles 23, 52 Egyptian IP Law No. 82 of 2002
Republic of Zimbabwe	Any person authorised in writing by the Minister of Health has the right to manufacture and use the patented invention, which the Minister of Health considers necessary or appropriate, by submitting an application to the Patent Office in accordance with the law.	(section 34,35 - Zimbabwe Patents Act)
Great Britain	• Any person may file an application to the UK Intellectual Property Office to obtain a compulsory license. • If the applicant is a government, a license to exploit a patented invention may be granted to any person indicated in the annex to the relevant government request.	(sections 48 to 55 of the Patents Act 1977)
Germany	The enforcement of a compulsory license is carried out by the Federal Patent Court on an individual basis, on the application of any person who complies with a number of terms, in accordance with applicable law.	section 24 of the German Patent Act (German Patent Act (GPA)

People's Republic of China	The Patent Rights Department at the Council of the People's Republic of China may, by appropriate application, grant the compulsory licensing right to all persons who are qualified and experienced in the matter of the use of a specific invention or utility model that is protected by a patent, and subject to compliance with the number of terms and in accordance with the law.	(article 48 of the Patent Law of the People's Republic of China)
Austria	If there is a public interest in a license to exploit a patented invention, any person is entitled to apply for a compulsory license in relation to this invention.	(section 36(3) - Patent Law)
France	Any public or private person may obtain the right to compulsory patent licensing if one complies with a number of terms in accordance with applicable law.	(article. L. 613-11. Law on the Intellectual Property Code)
Kingdom of Denmark	If there is an overriding public interest, any applicants who wish to use a patented invention are entitled to obtain a compulsory license from other patent owners.	(section 47 of the The Consolidated Patents Act)
Spain	Any public or private person may obtain the right to compulsory patent licensing if they comply with a number of terms in accordance with the applicable law.	(article 87(1) of the Law on Patents)

Authorising the use of an invention by the government in the interests of the public.

The mechanism for authorising the use of an invention by the government in the best interest of the public is stipulated by laws of certain jurisdictions.

In general, such a mechanism involves two key aspects: (1) a person authorised to initiate the consideration of the use of invention in the interests of the public; and (2) a person authorised to grant permission to use the invention in the interests of the public.

Given the above criteria, the mechanism for granting permission to use a patented invention in the interests of the public without authorisation from the patent owner consists mainly of the following key stages:

1. An authorised state body or a third party initiates the consideration of the use of invention by the government or an authorised body or a third party in the interests of the public;

2. An authorised state body considers the use of the invention by the government or an authorised body or a third party in the interests of the public, evaluates whether there are sufficient grounds for such use, checks compliance with other terms;

3. An authorised state body makes a reasonable decision to grant or refuse permission to use the invention by the government or an authorised body or a third party in the interests of the public;

4. The patent owner is being informed about the decision;

5. Direct use of such permission by the person specified therein or duly determined (so-called “open license”, where the range of potential users of the license is unlimited at the time of the decision, the contractor is determined later, for example, through selection of the most economically advantageous tender offer in an open bidding, or as a result of a tender held by a specialised organisation);

6. Royalty payments to the patent owner.

Experience of the jurisdictions that have introduced a mechanism for using public health inventions in the interests of the public without permission from the patent owner indicates that the TRIPS flexibilities allow the WTO Members to independently determine (1) the reasons, (2) the content (3) and the mechanism for granting permission to use a patented invention in the interests of the public without authorisation of the patent owner, taking into account national legislation, the structure of state authorities, economic level and social development.

This allows the TRIPS Members to use measures and means to improve public access to treatment once a patent is granted.

CURRENT UKRAINIAN LEGISLATION ON COMPULSORY PATENT LICENSING OF INVENTIONS IN THE PUBLIC HEALTH SECTOR

Current Ukrainian legislation on the procedure of compulsory patent licensing of inventions in the public health sector

The use of inventions in order to ensure public health without the patent owner's consent in Ukraine is regulated by national and international laws.

The Decree of the President of Ukraine No. 526/2012 of 30 August 2012 introduced the Decision of the National Security and Defence Council of Ukraine of 25 May 2012 "On Providing the Population with Quality Accessible Medical Products".

In accordance with paragraph 3 of the Decision, the National Security and Defence Council of Ukraine has instructed the Ministry of Health and the Ministry of Justice to consider issues related to implementation of the TRIPS provisions into the national legislation on the protection of public health, and promote universal accessibility of pharmaceuticals by introducing the compulsory licensing system.

In this regard, the Resolution of the Cabinet of Ministers No. 877 of 4 December 2013 approved the Procedure for granting a permission to use a patented invention (utility model) related to a medicine (Procedure No. 877) by the Cabinet of Ministers. Procedure No. 877 was developed in accordance with Article 30 (3) of the Law "On the Protection of Rights to Inventions and Utility Models" and Article 9 (11) of the Law "On Medical Products", which govern the compulsory alienation of rights to an invention (utility model) in order to ensure public health, national security, environmental safety, etc.

Procedure No. 877 was developed in accordance with Article 30 (3) of the Law "On the Protection of Rights to Inventions and Utility Models" and Article 9 (11) of the Law "On Medical Products", which govern the compulsory alienation of rights to an invention (utility model) in order to ensure public health, national security, environmental safety, etc.

Development of the Procedure No. 877 was entrusted to a joint Working Group on Intellectual Property and Access to Pharmaceuticals, approved by the Joint Order No. 178/130 of the Ministry of Health and the National Academy of Law.

In 2013, the Working Group submitted to the Ministry of Health a draft Resolution of the Cabinet of Ministers "On Approval of the Procedure for Granting the Permission for the Use of a Patented Invention (Utility Model) for a Medical Product" by the Cabinet of Ministers, but the version of the current Procedure No. 877 significantly differed from the draft elaborated by the Working Group. In particular, the essential difference is that the Draft Procedure No. 877, in addition to the above norms, also covered the grounds of Article 31 (second part, paragraph 5) of the Law "On Protection of Rights to Inventions and Utility Models".

Instead, the Procedure No. 877 does not apply to legal relations governed by the provisions of Article 31 of the above Law. In order to apply the procedure for granting a compulsory license to use a patented invention in accordance with the current Procedure No. 877, emergency in the public health is unnecessary, while reference to one of the constituent purposes is sufficient: public health, national security, environmental safety and other interests of society in accordance with Article 30 of the Law "On Protection of Rights to Inventions and Utility Models".

The main aspects of the current compulsory licensing procedure in terms of grounds, mandatory terms, subject, and objects are indicated below.

GROUNDS

According to national legislation, the circumstances under which a compulsory license may be issued are contained in Articles 30 and 31 of the Law of Ukraine "On Protection of Rights to Inventions and Utility Models":

Article 30 of the Law of Ukraine "On Protection of Rights to Inventions and Utility Models" provision of public health, national security, environmental safety and other interests of society

Article 31 of the Law of Ukraine "On Protection of Rights to Inventions and Utility Models" force-majeure circumstances (natural disaster, catastrophe, epidemic, etc.)

The freedom to interpret the rules above on a national level is provided by the Doha Declaration, which states that "each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency".

MANDATORY TERMS

The mandatory terms for issuing a compulsory license should include failure to obtain permission from the patent owner.

In the case of issue of a compulsory license on the grounds of Article 30 of the Law "On Protection of Rights to Inventions and Utility Models", such use may only be permitted if, prior to such use, the user has made efforts to obtain permission from the rightsholder on acceptable commercial terms, and that such efforts were not successful within a reasonable time frame.

In the case of the issue of a compulsory license on the grounds of Article 31 of the Law "On Protection of Rights to Inventions and Utility Models", the above requirement to make efforts to negotiate with the rightsholder may be temporary neglected. However, the rightsholder should be informed of the use of the invention as soon as it is practically possible.

SUBJECT

In accordance with the current Procedure No. 877, the subject of a compulsory license is an invention (utility model), the object of which is a medical product.

Ukraine's ratification of the Protocol amending the TRIPS Agreement requires extension of the subject of compulsory licensing in the field of public health, since according to the Protocol, the compulsory license object in the public health sector is a "pharmaceutical product" – any patented product or product manufactured using a patented process in the pharmaceutical sector necessary to address health problems as defined in paragraph 1 of the WTO Doha Declaration on the TRIPS Agreement and Public Health. Thus, active ingredients necessary for their manufacture and the diagnostic kits required for their utilization are also included. Hence, a pharmaceutical product includes the following objects:

1) Medical product

In accordance with the Law of Ukraine "On Pharmaceuticals", a "medical product" is any substance or a combination of substances (one or more APIs and excipients) possessing properties intended for the treatment or prophylaxis of diseases in humans, or any substance or combination of substances (one or more APIs and excipients), which may be intended to prevent pregnancy, to restore, correct or modify physiological functions in humans by pharmacological, immunological or metabolic action or for the establishment of a medical diagnosis.

2) Diagnostic kit

The legislation of Ukraine does not contain the notion of a diagnostic kit; its content varies depending on the scope of diagnostics and may consist of both substances and medical products, as well as auxiliary means. In accordance with the Technical Regulations on pharmaceuticals approved by the Resolution of the Cabinet of Ministers No. 753 of 02/10/2013.

Medical product means any product that is used alone or in conjunction with such products, including software provided by the manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for the proper functioning of a medical device, and is intended by the manufacturer to provide diagnostics, prophylaxis, monitoring, treatment or relief of a patient's health condition in case of illness; diagnostics, monitoring, treatment, relief or compensation of a patient's health condition in case of injury or disability; research, replacement or modification of the human anatomy or physiological process; fertilization control, the main predictable action of which in or on the human body is not achieved by pharmacological, immunological or metabolic means, but whose functioning may be promoted by such means;

Auxiliary means denotes products, other than pharmaceuticals, that are used form in vitro diagnostics and are intended by the manufacturer to be used in conjunction with a medical product. At present, the notion of a pharmaceutical product is an integral part of national legislation in accordance with Article 19 of the Law "On International Treaties of Ukraine" and thus it may be subject to compulsory licensing. However, absence of a pharmaceutical product as a legal category in national legislation complicates the definition of its components.

ENTITIES

In accordance with the current Procedure No. 877, the permission may be initiated only upon request of the business entity concerned.

As the draft Procedure covered a wider range of grounds, it provided for two initiating entities. The procedure for granting permission could start with an application submitted by an entity concerned to the Ministry of Health with a request for granting a governmental permission to use the patented invention to promote public health or in other interests of society, or upon an address of the Ministry of Health to the government in the event of a public health emergency.

In accordance with the current Procedure No. 877, an entity concerned addresses the Ministry of Health regarding obtaining a permission. The applicant justifies the need for a patented invention (utility model) and provides for specific circumstances of the case and the required validity term of the license. In our opinion, preparation of the calculation of an adequate remuneration to the patent owner should be assigned to the appropriate state institution, which is authorised to carry out scientific and practical research in the field of intellectual property in accordance with the law.

In accordance with the Procedure No. 877, the entity concerned must meet certain technical requirements. In support of one's ability to reach the purpose of a compulsory license, the feasibility study of the capacities, terms and conditions of using the patented invention should be attached to the license request. It would seem appropriate to maintain the provisions of the draft Procedure containing requirement of the mandatory availability of a GMP certificate or WHO prequalification for such an entity.

In case there are several applicants, the competent ministry drafts proposals for the selection of the person to whom the permission may be granted, taking into account the aforementioned justification.

Unfortunately, the Procedure No. 877 has proven to be ineffective due to the absence of a compulsory licensing practice and its mere initiation from the date of adoption of the above Procedure. It is due to the lack of political will, burdensome terms for issuing permits, failure to initiate the issue of permits by state bodies without third party appeals, the lack of clearly defined grounds, subjects of initiation and state guarantees.

To analyse the current compulsory licensing regime in Ukraine, it is worth considering the existing compulsory licensing procedure in the form of an algorithm.

The algorithm is based on the current Ukrainian legislation and is set out chronologically with a detailed description and analysis of each circumstance and/or action that should consistently exist or must be fulfilled.

The algorithm also includes analysis of risks and disadvantages that prevent or compromise compulsory licensing.

Subsequently, the algorithm contains recommendations for eliminating the identified risks and disadvantages in order to ensure transparency of the compulsory licensing procedure, observance of the rights and interests of all parties to the procedure, as well as minimising the risks of challenging the compulsory licensing in court.

COMPULSORY LICENSING ALGORITHM APPLICABLE IN UKRAINE

TERMS OF COMPULSORY LICENSING	LEGISLATION	COMMENTARIES	RISKS AND CAUTIONS
1. Preparatory stage: the circumstances and actions that precede the application for a compulsory license			
1.1. The purpose of compulsory licensing			
Ensuring public health	The use of a patented invention (utility model) may be authorised ***for public health purposes***, national security, environmental safety and other interests of society. (Article 30 (part 3, para.1) of the Law "On the Protection of Rights to Inventions and Utility Models") The license may be granted ***to ensure public health***, as well as to fight: - HIV/AIDS; - other life-threatening diseases. (clause 2 of the Procedure No. 877)	Compulsory licensing must be driven by the need to ensure public health. These circumstances do not depend on the will of an applicant.	
1.2. The circumstances for compulsory licensing			
1.2.1. Failure of the patent owner to satisfy the demand for a medicine			
Failure of the patent owner to satisfy the demand for a medicine	A license may be granted if: ***- the patent owner cannot satisfy the demand for a medicine*** with the means and capacities commonly used for the manufacture of such a medicine. (clause 2 of the Procedure No. 877)	Failure of the patent owner to satisfy the demand for a medicine must be confirmed.	The legislation does not contain a list of grounds and does not specify the patent owner's failure to satisfy the demand for a medicine (insufficient amount of a medicine, excessively high cost, etc.).

TERMS OF COMPULSORY LICENSING	LEGISLATION	COMMENTARIES	RISKS AND CAUTIONS
Documentary evidence of the patent owner's failure to satisfy the demand for a medicine	A license may be granted in the event there is ***documented evidence*** of such circumstances. (clause 2 of the Procedure No. 877)	The circumstances must be documented.	The procedure for documenting the patent owner's failure to satisfy the demand for a medicine (order, form, documents content, etc.) has not been established. This may constitute a risk of challenging a compulsory license (or refusal to issue a compulsory license) in court on numerous grounds: insufficient documented evidence; uncertainty of the patent owner's ability to satisfy the demand for a medicine, etc.
1.2.2. 1.2.2. Unjustified patent owner's refusal to issue a license			
Applicant's preliminary request to the patent owner for granting a license for the use of the invention (utility model)	The licence may be granted if the patent owner has given ***a groundless refusal to issue a license*** for the use of the invention (utility model). (clause 2 of the Procedure No. 877) The request shall be accompanied by a documentary evidence of the patent owner's groundless refusal to issue a license for the use of the patented invention (utility model) ***upon the applicant's appeal.*** (clause 4 (3) of the Procedure No. 877)	In order to obtain a compulsory license, the applicant is required to contact the patent owner regarding voluntary license to use the invention (utility model) beforehand.	No special procedure exists. This may constitute a risk of challenging a compulsory license (or refusal to issue a compulsory license) in court on numerous grounds: insufficient period for review of an appeal; lack of information necessary for the patent owner to make a decision, etc.
Patent owner's refusal to issue a license for the use of the invention (utility model)	A license may be granted if: - the patent owner ***has made an unfounded refusal to permit*** the use of the invention (utility model). (clause 2 of the Procedure No. 877)	In order to obtain a compulsory license, the patent owner's unfounded refusal must be received.	Current legislation does not establish: - the procedure for reviewing the request for a license (order, terms); - signs and criteria of the notion "groundless refusal"; - the consequences of non-response received from the patent owner (it is not established whether the absence of a response can be considered a refusal). This may constitute a risk of challenging a compulsory license (or refusal to issue a compulsory license) in court on numerous grounds: lack of a written refusal, non-obvious content of a response, etc.

TERMS OF COMPULSORY LICENSING	LEGISLATION	COMMENTARIES	RISKS AND CAUTIONS
Documentary evidence of the patent owner's refusal to issue a license for the use of the invention (utility model)	A license may be issued if there is ***documented evidence*** of such circumstances. (clause 2 of the Procedure No. 877)	The circumstances must be documented.	No requirements for documented evidence of the patent owner's unfounded refusal to issue a license (form, content) are stipulated by the law. This may constitute a risk of challenging a compulsory license (or refusal to issue a compulsory license) in court due to insufficient documentary evidence or improper registration of documents, etc.
2. Main stage: submitting and consideration of an appeal for a compulsory license			
2.1. Appeal to the Ministry of Health of Ukraine			
Appeal to the Ministry of Health for compulsory licensing	An entity that may obtain a compulsory license The applicant may be: - a manufacturer of pharmaceuticals: - in its entirety; - at the final stage of manufacture using the active pharmaceutical ingredient of another manufacturer; - at manufacturing sites in Ukraine on the basis of a license for the manufacture of pharmaceuticals; - a business entity importing pharmaceuticals to Ukraine on the basis of authorisation for import of pharmaceuticals and wholesale and retail trade in pharmaceuticals. (clause 4 (1) of the Procedure No. 877) **Procedure for filing an appeal** The applicant files an appeal to the Ministry for the issue of a compulsory license by the Cabinet of Ministers (the Government). The appeal and its annexes are set forth in Ukrainian and submitted to the Ministry in three copies, one of which remains in the Ministry, and another is returned to the applicant with an acceptance seal. (clause 4 (2, 4) of the Procedure No. 877)	The legislation establishes the procedure for filing, as well as the form and content of such an appeal.	The provisions stipulating a complete list of documents that must be submitted to obtain a compulsory license violate: - Clause 4 of Procedure No. 877, which contains a list of documents attached to the appeal, is not a complete list of the documents to be submitted together with an appeal; - Clause 2 of the Procedure No. 877 provides for other documents, namely: documentary evidence of the patent owner's failure to satisfy the demand for pharmaceuticals; - It is not specified that such list of documents is exhaustive, and the Ministry has no right to demand from the applicant any documents that are not expressly stated by the legislation.

TERMS OF COMPULSORY LICENSING	LEGISLATION	COMMENTARIES	RISKS AND CAUTIONS
Подача заявителем ходатайства в Министерство о получении принудительной лицензии	**Content of an appeal** An Appeal contains the following information: - international non-proprietary name of a medical product; - name of an invention (utility model); - patent number, information about its owner(s), its(their) address or location; - applicant's name, location, signature of an authorised person; - documentary evidence of the powers of the applicant's signatory on the appeal. The following is attached to the appeal: • substantiation of the need to use a patented invention (utility model), as well as: - the circumstances of the case, and - license validity period for the patent use; • feasibility studies, terms and procedures for using the patented invention (utility model); • documentary evidence of the patent owner's unfounded refusal to issue a license for the use of the patented invention (utility model); • calculation of the compensation offered by the applicant to the patent owner made in accordance with clause 13 of the Order. (clause 4 (2, 3) of the Procedure No. 877)	The legislation establishes the procedure for filing, as well as the form and content of such an appeal.	This involves risks of: - refusal to accept an appeal, return of an appeal, request for supplementary documents, refusal to issue a compulsory license, etc.; - challenging a compulsory license (or refusal to issue a compulsory license) in court on the grounds of submission of incomplete documents.
2.2. Acceptance of an appeal by the Ministry			
Verification of the content and completeness of appeal and attached documents by the Ministry	Within five working days from the date of receiving an appeal, the Ministry returns the materials received together with the justification for such a return if the applicant has failed to comply with the requirements of clauses 3 and 4 of the Procedure No. 877 (on the content and procedure for filing an appeal). After eliminating all inconsistencies within the period established by the Ministry, the applicant may reapply. (clause 5 (1) of the Procedure No. 877)	The Ministry verifies the content and completeness of an appeal and annexes thereto within five working days and may return such an appeal to the applicant and set a deadline for eliminating inconsistencies	Legislation provides for the applicant's right to reapply. The Law does not provide a deadline for eliminating inconsistencies, the Ministry establishes the term. This creates risks of corruption and a biased attitude against some applicants and unequal terms regarding the deadlines to eliminate inconsistencies.

TERMS OF COMPULSORY LICENSING	LEGISLATION	COMMENTARIES	RISKS AND CAUTIONS
Acceptance of an appeal by the Ministry	In case the appeal is **accepted**, the Ministry sends it with the relevant request to: - the State Intellectual Property Office, requesting information about a patented invention (utility model); - an authorised body, requesting information on compliance of the compensation amount proposed by an applicant with the provisions of clause 13. (clause 6 of the Procedure No. 877)	The Law does not establish the procedure for acceptance of an appeal for consideration by the Ministry. Admission of an appeal follows from the context of clause 6 of the Procedure No. 877.	The procedure and timeframes for the Ministry to admit an appeal are not provided by law. The Ministry is not required to notify the applicant about acceptance of an appeal. This undermines the transparency of the procedure and indicates a lack of certainty about whether the appeal is being reviewed.
2.3. Submission of an appeal by the Ministry to a specific list of authorities and individuals			
2.3.1. Submission of an appeal by the Ministry to the State Intellectual Property Office			
Submission of an appeal and request by the Ministry to the State Intellectual Property Office	In the case ***the Ministry*** accepts an appeal, it shall send it with a relevant request ***to***: - State Intellectual Property Office for information about a patented invention (utility model). (clause 6 of the Procedure No. 877)	The Ministry must address the State Intellectual Property Office concerning a patented invention.	The deadline for submitting an appeal or a request for information to the State Intellectual Property Office is not provided by law. This may lead to undue delay in the appeal process.
Response of the State Intellectual Property Office	The State Intellectual Property Office, within ten business days upon receiving a request, submits to the Ministry ***information on the compliance of the data*** contained in the appeal, which has been entered into the State Register of Patents of Ukraine for inventions or the State Register of Patents of Ukraine on utility models. (clause 7 of the Procedure No. 877)	The State Intellectual Property Office checks the compliance of the patent (utility model) data contained in the appeal with the information contained in the state registers.	

TERMS OF COMPULSORY LICENSING	LEGISLATION	COMMENTARIES	RISKS AND CAUTIONS
2.3.2. Submission of a copy of the appeal by the Ministry to an authorised body			
Submission of an appeal and a request by the Ministry to an authorised body	If the appeal is accepted, ***the Ministry sends*** it with a relevant request t***o: an authorised body*** to certify the compliance of the amount of compensation proposed by the applicant with the data contained in clause 13. (clause 6 of the Procedure No. 877)	To consider an appeal, the Ministry is obliged to address an authorised body to verify the compensation amount.	The following is not provided by law: - an authority authorised to verify the compensation amount specified by the applicant for compliance with the requirements of Procedure No. 877; - the deadline for submission by the Ministry of the appeal and request to such authority. This actually makes it impossible to verify the calculation of compensation and, as a result, to complete the compulsory licensing procedure.
Response of an authorised body	An authorised body, within ten business days upon receipt, submits ***information on compliance of the amount of compensation*** with the requirements of clause 13 of the Order to the Ministry. (clause 7 of the Procedure No. 877)	An authorised body checks the amount of compensation for compliance with the requirements of clause 13 of Procedure No. 877.	
2.3.3. Submission of a copy of the appeal by the Ministry to the patent owner			
Submission of a copy of the appeal by the Ministry to the patent owner	A third copy of the ***appeal*** and its annexes are ***sent to the patent owner*** within 10 business days. (clause 4 (4) of the Procedure No. 877)	The Ministry informs the patent owner about receipt of a request for the compulsory licensing procedure.	The procedure for submitting an appeal to the patent owner is not provided by law.
Consideration of an appeal by the patent owner	The patent owner may submit relevant ***information about an appeal*** within 30 business days upon its receipt by the patent owner with the post mark. (clause 4 (5) of the Procedure No. 877)	Submission of information is the patent owner's right, not responsibility.	- this clause does not establish the order, content and form of submission of such information; - established terms for submission are questionable. This may be the basis for challenging the compulsory licensing procedure in light of the violation of the patent owner's right to provide information, non-compliance with time limits, etc.
2.4. Consideration of an appeal by the Ministry			
Taking into account the patent owner's information	The Ministry ***takes into account*** the information provided by the patent owner. (clause 5 (1) of the Procedure No. 877)	The Ministry considers information provided by the patent owner.	The obligation of the Ministry to justify the consideration or rejection of any patent owner's information when making a decision on the results of consideration of the appeal is not stipulated by law.

TERMS OF COMPULSORY LICENSING	LEGISLATION	COMMENTARIES	RISKS AND CAUTIONS
Formation by the Ministry of proposals in case of receipt of appeals from several applicants	If during the consideration of an appeal, the Ministry receives an ***appeal from another applicant***, the ***formation of proposals*** for selection of a person to whom the compulsory license may be granted is carried out by the ***Ministry***, taking into account the feasibility, terms and conditions for the use of the invention (utility model). (clause 5 (2) of the Procedure No. 877)	Proposals for the selection of a person to provide a compulsory license are formed by the Ministry.	Transparency and corruption risks are due to the following: - proposals are formed by the Ministry alone; - the procedure for the formation of such proposals is not established; - it is not determined whether the Ministry should inform the applicants about the decision and the proposal made.
Preparation and submission of a draft Government decision on granting a compulsory license by the Ministry to the Government	The Ministry, within ten business days from receipt of ***relevant proposals***, makes a draft Government decision on granting a compulsory license. Together with the draft decision, the following is submitted to the Government: - copies of the appeal and annexes filed by the applicant; - information received from the State Intellectual Property Office regarding a patented medical invention, together with an extract from the State Register of Patents of Ukraine for inventions or the State Register of Patents of Ukraine for utility models; - information received from an authorised body on the amount of compensation to be paid to the patent owner for the respective medicine; - whether information provided by the patent owner has been taken into account. (clause 8 of the Procedure No. 877)	The Ministry makes a draft Government decision on granting a compulsory license within ten business days.	The legislation stipulates that the Ministry is preparing a draft decision of the Government after receipt of "relevant proposals". Procedure No. 877 does not specify the proposals. Since the period for drafting a Government decision on compulsory licensing is calculated from the moment when the Ministry receives uncertain "relevant proposals", this may complicate the correct calculation of timing for drafting such a decision. In addition, the legislator defined the deadline for drafting a Government decision, but did not set the deadline for submitting a draft decision to the Government. This may complicate the correct calculation of the terms and cause unjustified delay in the procedure of appeal consideration.
2.5. Government's decision on compulsory licensing			
Consideration of the draft Government decision submitted by the Ministry	The Government considers the draft in accordance with the established procedure. (clause 9 (1, 2) of the Procedure No. 877)	The procedure for consideration of draft decisions by the Government is established by the Law "On the Cabinet of Ministers of Ukraine", the Rules of the Cabinet of Ministers, Rules for the preparation of draft acts of the Cabinet of Ministers.	

TERMS OF COMPULSORY LICENSING	LEGISLATION	COMMENTARIES	RISKS AND CAUTIONS
Order of the Government on additional consideration of granting a compulsory license by the Ministry	If necessary, the Government authorises the Ministry to consider the compulsory licensing feasibility. (clause 9 (3) of the Procedure No. 877)	If the materials provided by the Ministry do not convince the Government of the expediency of compulsory licensing, the Government may return the documents for revision.	The procedure, deadline, consequences of such an order of the Government and the results of its implementation are not defined by the law. This creates the risks of corruption, a biased attitude, unjustified delays in the consideration process, etc.
Government's decision to issue a compulsory license	Content of the Government's decision In the decision on granting a compulsory license, the Government provides for ***compensation for the use of a patented invention (utility model)***, taking into account the availability of pharmaceuticals at the lowest possible price. (clause 13 of the Procedure No. 877)	The amount of compensation to the patent owner for the use of a patented invention (utility model) is determined in the decision of the Government.	The following is not established by law: - requirements to the content of the Government's decision to grant a compulsory license (only certain provisions are specified); - a list of grounds for refusal to provide a compulsory license by the Government. This undermines the transparency of the procedure.
Informing the applicant and the patent owner of the compulsory license	Not later than three working days from the date when the Government decision on the issue of a compulsory license enters into force, the Ministry ***informs***: - applicant; - patent owner. (clause 10 of the Procedure No. 877)	The Ministry is obliged to inform the applicant and the patent owner on compulsory licensing.	Procedure No. 877 does not determine either the procedure or the form of such notification.
State Intellectual Property Office publishes the Government's decision to grant a compulsory license	State Intellectual Property Office ***publishes a decision*** on the issue of a compulsory license in the official intellectual property bulletin. (clause 11 of the Procedure No. 877)	State Intellectual Property Office is obliged to publish the Government decision on the issue of a compulsory license.	Procedure No. 877 does not determine the terms for such publication.

TERMS OF COMPULSORY LICENSING	LEGISLATION	COMMENTARIES	RISKS AND CAUTIONS
2.6. Compensation to the patent owner for the use of a patented invention (utility model)			
Payment of compensation to the patent owner for the use of a patented invention (utility model)	In the decision on compulsory licensing, the Government provides for ***compensation for the use of a patented invention (utility model)***, taking into account the availability of pharmaceuticals at the lowest possible price. (clause 13 of the Procedure No. 877) Based on the decision of the Cabinet of Ministers on compulsory licensing, the patent owner receives a ***compensation*** in accordance with the economic value of an invention (utility model) ***at the expense of the person who has been granted such compulsory license.*** (clause 3 (6) of the Procedure No. 877)	Patent owner receives a compensation for the use of a patented invention (utility model) from the funds of the person who has been granted a compulsory license.	Procedure No. 877 does not establish the procedure and time limits for payment of compensation to the patent owner. This may lead to a violation of the patent owner's rights to timely compensation.

The process for declaring an epidemic under the current legislation of Ukraine

In Ukraine, the concept of an epidemic is defined in two legal acts: the Code of Civil Protection and the Law "On the Protection of the Population against Infectious Diseases". These two definitions are identical:

"An epidemic is the rapid spread of infectious disease among the population of the relevant territory within a short period of time".

The same definition of the concept is stipulated in the subordinate legislation: in the Methodological Recommendations "Implementation of state policy in the field of civil protection in the institutions of the State Sanitary Epidemiological Service of Ukraine", approved by the Order of the State Sanitary Epidemiological Service No. 42 of 27 March 2015.

The definition of the epidemic is presented by the UNAIDS Terminology Guidelines 2015:

"an epidemic refers to a disease condition affecting (or tending to affect) a disproportionately large number of individuals within a population, community or region at the same time."

However, neither criteria, nor the procedures for announcing the epidemic are established by the legislation of Ukraine.

It is worth considering a specific example of the HIV/AIDS epidemic in Ukraine. Ukraine submitted a Global AIDS Response Progress Report (GARPR Ukraine) to the UNAIDS for the 2012-2013 reporting period, stating that Ukraine has the second-largest HIV epidemic in Eastern Europe and Central Asia. Although the legislation of Ukraine does not define the criteria for an epidemic, in particular HIV/AIDS, the term "HIV epidemic" is used both in the legal acts and in the subordinate legislation, namely:

- in the National Targeted Social Program to Fight HIV/AIDS in Ukraine for 2014-2018;
- in the Resolution of the Cabinet of Ministers of Ukraine No. 1349 of 28 December 2011 "On a uni fied system for monitoring and evaluating the effec tiveness of measures aimed at preventing the spread of the HIV epidemic";
- in the Bulletin "HIV-infection in Ukraine" published twice a year by the State Institution "Ukrainian Centre for Disease Control of the Ministry of Health";
- in the national assessment of the HIV/AIDS situation in Ukraine as of early 2013, which was conducted with the participation of the Ukrainian Centre for Deadly Disease Control of the Ministry of Health.

According to laboratory research, about 30 thousand people are diagnosed with HIV annually in Ukraine, about 20 thousand people are registered with a diagnosis of HIV for the first time, and up to 12 thousand people are being removed from the records for a number of reasons, including due to death. As of 01 January 2015, there were 137 390 HIV-infected persons (HIV prevalence was 322.5 per 100 000 people) and 33 279 AIDS patients (AIDS prevalence was 77.8 per 100 000 people) under the medical supervision of AIDS health care services. The highest rates of HIV prevalence are registered in Odesa (758.7 per 100 000 people), Dnipro (736.6 per 100,000 people), Donetsk (670.5 per 100 000 people), and Mykolaiv (650.7 per 100 000 people) regions.

The HIV epidemic was the reason for the Cabinet of Ministers to issue a compulsory license to use the invention without the consent of the right holder and without mandatory prior negotiations, in accordance with Article 31 (2) of the Law "On Protection of Rights to Inventions and Utility Models" and in accordance with the Procedure No. 877 with appropriate amendments and additions.

Even though Ukrainian legislation does not contain clearly defined criteria according to which the situation with spread of HIV/AIDS could be declared as epidemic, the law and a number of by-laws incorporate provisions that indicate that there is an ongoing HIV/AIDS epidemic in Ukraine.

Consequently, it is inappropriate to issue supplementary regulatory documents that would establish this fact. What is more, some experts believe that a separate decision to recognise the epidemic is not necessary for the purposes of compulsory licensing[11].

Therefore, with regards to a general fact of the HIV/AIDS epidemic in Ukraine, the Cabinet of Ministers can apply the provision of Article 31 (part 2, para. 5) of the Law "On the Protection of Rights to Inventions and Utility Models" and grant permission to use the invention, the object of which is a medical product for the treatment of HIV infection, without the patent owner's consent, but with their obligatory notification and payment of compensation subject to a procedure that must become a part of the current Procedure No. 877.

[11] Carlos M. Correa, Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement, 2008.

DIRECTIONS FOR REFORM IN UKRAINIAN LEGISLATION ON INTRODUCTION COMPULSORY LICENSING MECHANISM FOR PUBLIC HEALTH INVENTIONS AIMED AT INCREASING ACCESS TO TREATMENT

Strategic directions for reform in Ukrainian legislation on introduction of a compulsory licensing mechanism for public health inventions

The TRIPS Agreement, the Doha Declaration, Protocol on Amendments to the TRIPS Agreement, Article 219 of the Association Agreement, Law of Ukraine “On the Protection of Rights to Inventions and Utility Models”, and Law of Ukraine “On Pharmaceuticals” are the legal basis for the development of this Concept.

Summarising the above experience of using the compulsory licensing mechanism as a means of expanding access to treatment in international practice and in the EU countries, as well as taking into account the strategic objectives of the Development Strategy 2020 aimed at harmonising Ukrainian legislation with EU law, it is crucial to reform national legislation, namely, by defining the legal grounds for issuing a compulsory license and introducing appropriate legislative amendments that can ensure lawful and unimpeded compulsory licensing.

In addition, provisions for non-commercial use by the government in the interests of society and use in the event of a state of emergency and extreme necessity require improvement.

Instead, the grounds for compulsory licensing, aimed to prevent anti-competitive practices on the pharmaceuticals market and medical services market that are widely used in EU countries, require a complex approach and implementation in the field of prevention of unfair competition and intellectual property law on a national level.

STRATEGIC DIRECTIONS FOR REFORM IN UKRAINIAN LEGISLATION:

1. Development of amendments to the legislation in the field of protection of the rights to inventions with a view to introducing an effective compulsory licensing mechanism.

Direction:
Amendments to the Law "On Protection of Rights to Inventions and Utility Models" and the draft new version of the Resolution of the Cabinet of Ministers "On Approval of the Procedure for the Cabinet of Ministers of Ukraine to Grant Permission to Use a Patented Invention (Utility Model) Related to the Medical Product".

Purpose:
Implementation of international law provisions on ensuring access to essential pharmaceuticals in developing countries.

Content:
1. Introduction of compulsory licensing in accordance with the provisions of Article 31 of the TRIPS Agreement:

- by the government (public non-commercial use) initiated by the government, appeal of a third party is not required;
- initiated by third party authorised by the government.

2. Implementation of the requirements of Article 31 of the TRIPS Agreement, the Doha Declaration and the Protocol Amending the TRIPS Agreement, which distinguish the grounds for compulsory licensing. Article 31 of the TRIPS Agreement provides the following grounds for the use of the patent subject matter without the right holder's authorisation, including use by the government or third parties authorised by the government:

- national emergency;
- other circumstances of extreme urgency;
- public non-commercial use;
- to remedy a practice determined to be anti-competitive.

In order to implement the above provisions, the Doha Declaration was adopted. Paragraphs 5 (b) (c) of the Doha Declaration state that each Member State has the right to compulsory licensing and is free to determine the grounds for it. Each Member State has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

The importance of the Doha Declaration is recognised in Article 219 of the Association Agreement: "In interpreting and implementing the rights and obligations under this Chapter, the Parties shall ensure consistency with the Doha Declaration."

The notion "other circumstances of extreme urgency" may be extended at the level of national legislation and include public health issues that are relevant to a particular country.

The current legislation of Ukraine states that the grounds for compulsory licensing are the need to ensure public health (paragraph one of the third part of Article 30 of the Law "On Protection of Rights to Inventions and Utility Models").

Procedure No. 877 specifies that the permission to use a patented invention without the patent owner's consent may be provided for the purpose of ensuring public health, including combatting HIV/AIDS and other deadly diseases.

Considering that Ukraine is the second in Europe in terms of cancer spread and taking into account the difficulties in ensuring access to medicines for the massive number of internally displaced population, which is aggravated by the military conflict in the East of Ukraine resulting in a significant number of injured military and civilians in need of treatment, surgery, prosthetics, rehabilitation, etc., not only the issue of counteracting social dangerous diseases is acute, but the factors above are critical to public health, and therefore they constitute circumstances of extreme urgency for the state.

In order to prevent the spread of deadly diseases in Ukraine and to take effective measures in the event of any other circumstances of extreme urgency, the following legal grounds for the use of patented inventions without the patent owner's permission are proposed to be established in the legislation of Ukraine:

- ensuring public health,
- including in the event of any circumstances of extreme urgency in the field of public health, including, but not limited to, the following:
  - HIV/AIDS, tuberculosis, hepatitis C;
  - other deadly diseases.

Thus, the above extended legal grounds need to be defined by the law (namely, in part three of Article 30 of the Law of Ukraine "On Protection of Rights to Inventions and Utility Models") in order to prevent them from narrowing through by-laws.

The detailed procedure for granting permission for the use of the invention without the patent owner's consent on legal grounds must be enshrined in a corresponding by-law. Since Ukraine does not have any compulsory licensing experience yet, the above grounds should be applied for the use of the invention without patent owner's authorisation, either at the initiative of the government, or at the initiative of third parties authorised by the government.

After accumulation of hands-on experience in government use of inventions and compulsory licensing of inventions has been developed, the issue of the feasibility of using different grounds for such use can be elaborated separately.

3. Adjustment of discrepancies and gaps in the current Procedure No. 877 must be carried out in the following directions:

3.1. The procedure for applicant's appeal to the patent owner for a license to use an invention, and documentary confirmation of such appeal;

3.2. The consequences of non-response of the patent owner (in particular, introduction of a rule according to which absence of an answer is considered a refusal);

3.3. The procedure and terms for acceptance of an appeal for consideration by the Ministry of Health, as well as notifying the applicant to the effect;

3.4. The deadlines for each compulsory licensing stage (period for elimination of deficiencies in the appeal and/or attached documents, period within which the Ministry of Health sends an appeal together with a request to the State Intellectual Property Office, etc.);

3.5. A complete and exhaustive list of documents to be filed together with an appeal for compulsory licensing, as well as the prohibition to require additional documents not provided for in such a list;

3.6. The requirements to the content of the government's decision on granting a compulsory license;

3.7. Settlement of the procedure and terms of payment of a compensation to the patent owner for the use of patented invention (utility model);

3.8. Establishing a list of grounds for refusal to issue a compulsory license.

4. Cancellation of the requirement about patent owner's "groundless refusal".

5. Cancellation of the TRIPS-plus provisions on the patent owner's failure to satisfy the demand for a medicine with the forces and capacities commonly used to manufacture pharmaceuticals.

6. Development of a mechanism for issuing an "open" compulsory license in the public interest and selecting subjects for the implementation of such a license.

7. Establishment of certain technical requirements for a pharmaceutical manufacturer under a compulsory license (GMP for a national manufacturer; FDA tentative approval, or WHO prequalification, or Stringent Drug Regulatory Authority for a foreign manufacturer).

8. Settlement of the procedure for non-commercial use initiated by the government in the interests of society.

9. Settlement of the procedure for the use of an invention without the patent owner's authorisation in the event of force-majeure (natural disaster, catastrophe, epidemic, etc.).

10. Development of a mechanism for calculating remuneration and excluding the need to agree on the amount of such remuneration with the authorised body.

11. Settlement of the issue of designating the contractor (a pharmaceutical manufacturer based on a compulsory license) if the government issues the license.

2. Development of amendments to the legislation in the field of registration of pharmaceuticals in order to ensure implementation of the compulsory licensing mechanism.

Direction:
Developing provisions and introducing amendments to the Law No. 123/96 BP "On Pharmaceuticals" regarding the registration of pharmaceuticals and access to registration dossiers of pharmaceuticals during the implementation of a compulsory licensing mechanism.

Purpose:
Enable the registration of pharmaceuticals under a compulsory license and the use of registration dossiers of pharmaceuticals (data exclusivity) when issuing a compulsory license on lawful grounds.

Content:
1. Regulation of the issue of registration of pharmaceuticals, if a permission for the use of a patented invention is granted without patent owner's authorisation.

In accordance with part one of Article 9 of Law No. 123/96 BP, pharmaceuticals are allowed for use in Ukraine after their registration with the state authorities.

The registration of pharmaceuticals for which a compulsory license was issued is virtually impossible in view of the circumstances set out below.

The Law No. 123/96 BP does not provide for the possibility of filing a government decision on granting a compulsory license instead of a patent or a license for the use of a patented invention for a medicine.

According to part 16 of Law No. 123/96 BP, to carry out registration of pharmaceuticals based or related to intellectual property objects for which a patent was issued in accordance with the laws of Ukraine, an applicant submits the following documents:

- a certified copy of a patent or a license authorising manufacturing and sales of registered medicine, as well as a document confirming the patent validity in Ukraine;
- a letter stating that third party rights protected by a patent or assigned under a license are not violated in connection with the registration of a medicine.

Therefore, Law No. 123/96 BP does not provide for the possibility of filing another document – the government decision to grant a compulsory license – instead of a patent or license.

This means that an authority that carries out the registration of pharmaceuticals will have legitimate grounds to refuse the registration of a medicine if the applicant submits a compulsory license instead of a patent or license. In order to ensure registration of pharmaceuticals for which a compulsory licensing procedure was applied, appropriate changes must be made in the part of the procedure and a set of documents submitted for the registration of such pharmaceuticals.

2. Regulation of the issue of access to the data of the registration dossier of pharmaceuticals for which a compulsory license was issued.

Clause 12 of the Procedure No. 877 stipulates that, based on a decision made by the government on granting a compulsory license, during the registration of a medicine, an entity may refer to the information specified in the registration dossier of the respective medicine for which a compulsory license was issued.

However, it is virtually impossible to refer to the registration dossier, since Law No. 123/96 BP does not provide for the possibility to refer to the information specified in the registration dossier of a relevant medicine for the use of which a compulsory license was issued.

According to Article 9 (10) of Law No. 123/96 BP, the information contained in the application for registration of a medical product and its annexes is subject to state protection against disclosure and unfair commercial use in accordance with the provisions of this Law and other legal acts of Ukraine.

The above requirement does not apply if the applicant has obtained the right to refer and/or use the registration information of the reference medical product/originator in accordance with the law (Article 9 (1) of Law No. 123/96 BP). Therefore, Law No. 123/96 BP allows using the registration dossier only if the applicant has the right to refer to such information under the law.

In this case, the right to refer to the information contained in the registration dossier of the medicine for which a compulsory license was issued, according to the government decision on granting a compulsory license, is set forth in clause 12 of the Procedure No. 877. However, Procedure No. 877 is a by-law of the Government, not the law of Ukraine.

In order to eliminate contradictions and to ensure the right to refer to the registration information during registration of a medical product for which a compulsory license was issued for the use of a patented invention, the amendments to Article 9 of Law No. 123/96 BP are required.

3. Development of legislative amendments in order to ensure the compulsory licensing mechanism for the prevention of anti-competitive practices

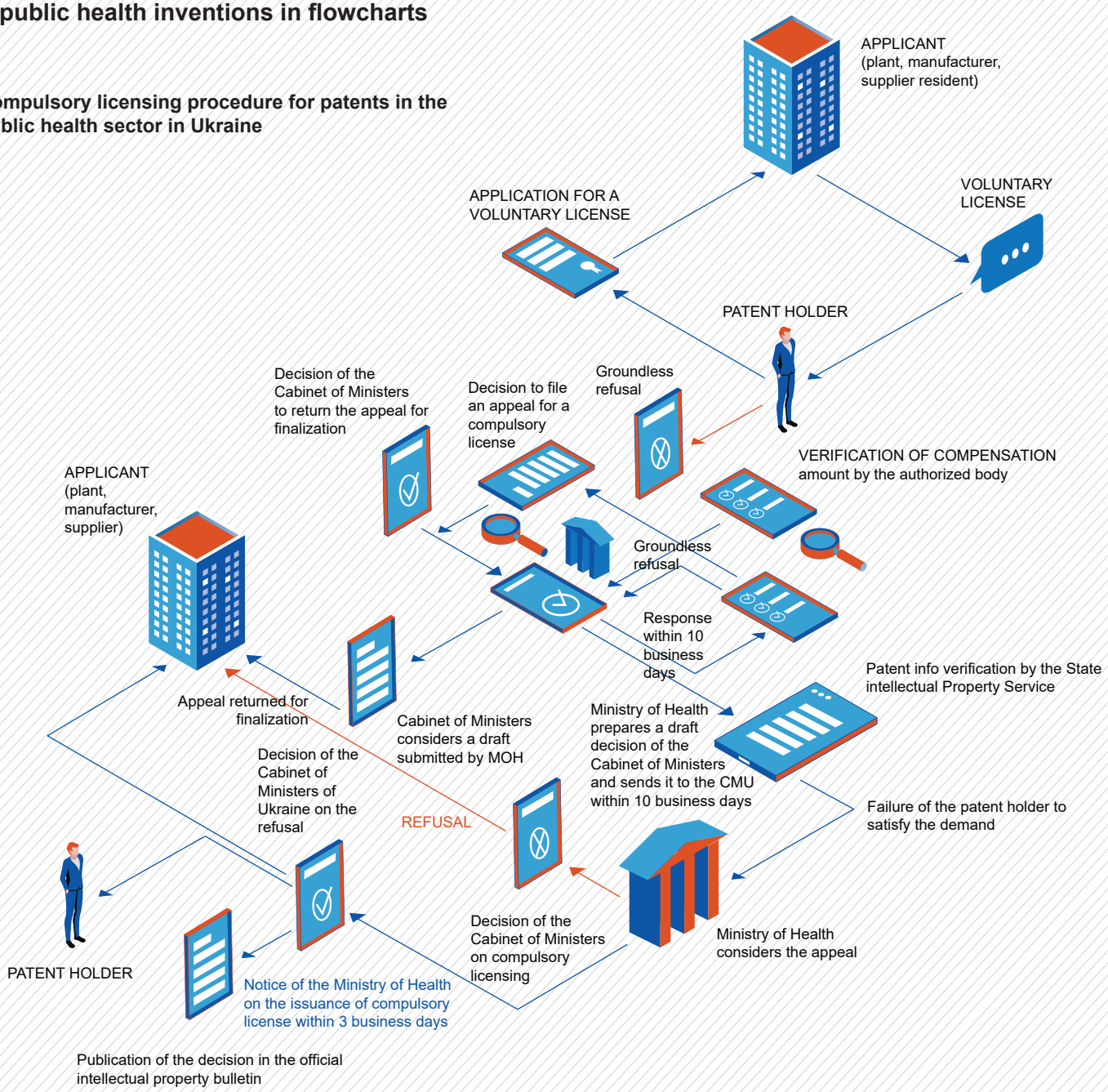
Direction:
Development of a Draft Agreement on amendments to the Law “On Protection of Rights to Inventions and Utility Models”, the Law “On the Protection of Rights to Marks for Goods and Services”, the Law “On Protection against Unfair Competition”, the Law “On Pharmaceuticals”.

Purpose:
Anti-competitive practice as a basis for compulsory licensing should be determined among actions that are not considered to be violations of rights arising from a patent when taking measures aimed at eliminating acts of unfair competition that violate the interests of society, in particular in the field of public health.

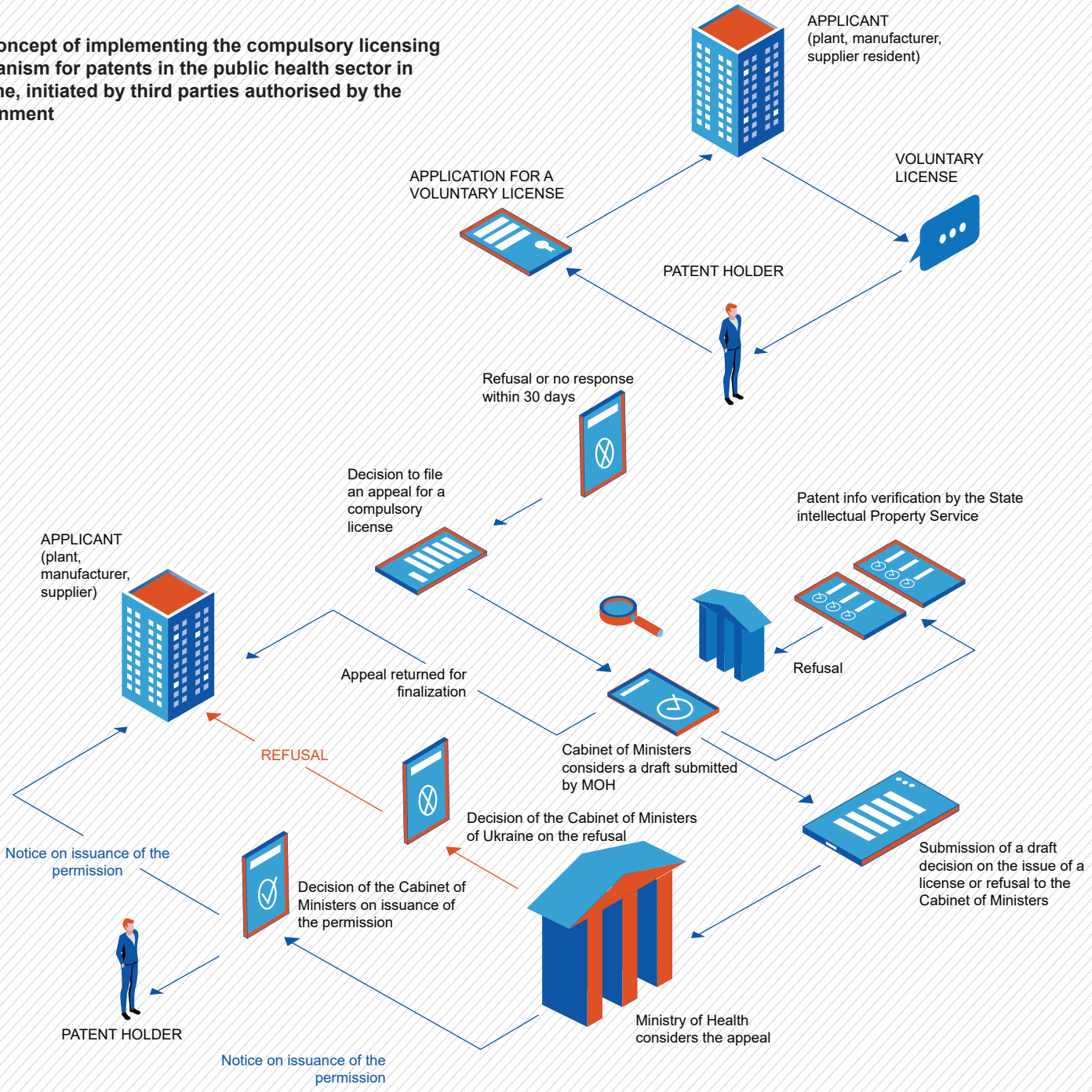
Content:
To indicate the creation of conditions which restrict access to pharmaceuticals, diagnostic and therapeutic techniques because of high prices or unavailability on the market as one of the actions that are considered unfair.

Compulsory licensing mechanism for public health inventions in flowcharts

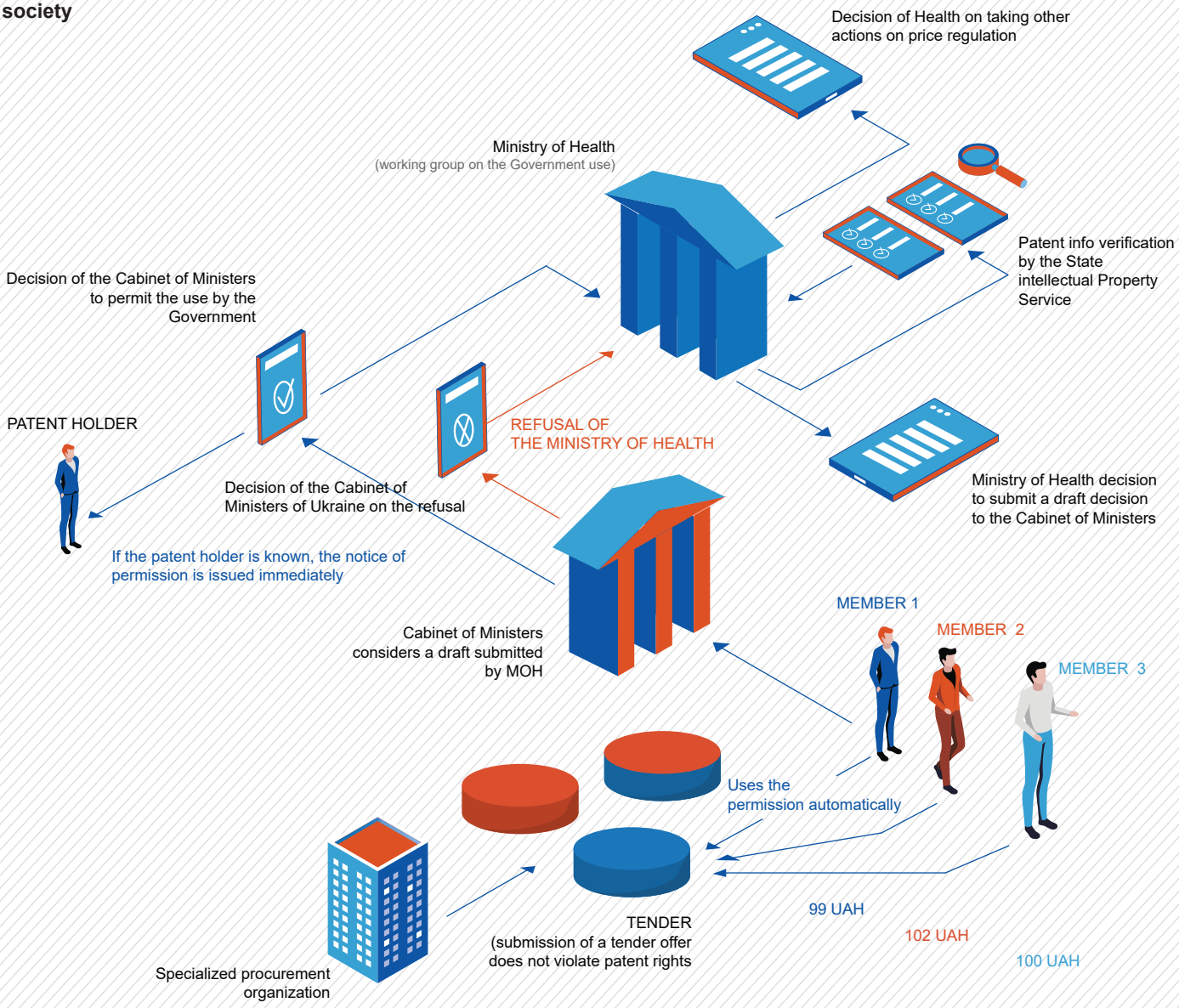
Compulsory licensing procedure for patents in the public health sector in Ukraine



The concept of implementing the compulsory licensing mechanism for patents in the public health sector in Ukraine, initiated by third parties authorised by the government



The concept of implementing the compulsory licensing mechanism for patents in the public health sector in Ukraine, initiated by the government in the interests of society



Analysis of specific issues regarding implementation of compulsory licensing in the public health sector in Ukraine

In order to introduce the use of inventions in Ukraine's public health sector without the permission of the patent owner, it is necessary to analyse a number of separate issues that directly influence the implementation of this mechanism, particularly:

- import of pharmaceuticals manufactured under a compulsory license;
- legal regulation of the procedure for termination of a compulsory license.

Import of pharmaceuticals manufactured under a compulsory license

As stated above, in accordance with Article 31 (1) (f) of the TRIPS Agreement, compulsory licenses (except those issued to prevent anti-competitive practices) should be issued primarily for the domestic market of the country issuing such a license.

However, with the adoption of the Decision by the WTO General Council on 30 August 2003, Article 31 (1) (f) of the TRIPS Agreement was revoked, and a new mechanism had been established. The mechanism allows WTO Members to issue compulsory licenses for export of generic equivalents of patented pharmaceuticals to countries without a pharmaceutical industry, or lacking the capacity to expand the industry.

In accordance with the changes made regarding the import of pharmaceuticals manufactured under a compulsory license, WTO Members must submit an application to the TRIPS Council with the following information: the name of the specific medical product, the amount required, the intention of Members to issue a local permission for compulsory licensing, if the patent for such a medical product is registered in this country.
The experience of applying the TRIPS provisions, in particular in Rwanda in 2007, indicates that the procedure is long-lasting. It should be noted that the Decision of 30 August 2003 does not discharge importing and exporting countries from obligation to attempt obtaining an authorisation from the patent owner in accordance with Article 31 (1) (b) of the TRIPS Agreement.

Legal regulation of the procedure for termination of a compulsory license

Grounds for termination of a compulsory license:

Article 31 (1) (c) of the TRIPS Agreement stipulates that the scope and duration of the use of a patent object without the permission of the patent owner, in particular the use by the government, should be limited to the purposes for which it was authorised.

Article 31 (1) (g) of the TRIPS Agreement stipulates that the permission to use a patent object without the authorisation of the patent owner, in particular the use by the government, is terminated if and when the circumstances which led to it have ceased and are unlikely to resume again. The competent authorities should have the right to review, on a reasoned request, whether these circumstances still exist.

Article 31 (1) (i) of the TRIPS Agreement stipulates that the legal force of any decision to authorise the use of a patent object without the permission of the patent owner, in

particular the use by the government, must be subject to a judicial review or other independent review by the relevant higher court of such an entity.

The specified TRIPS provisions are embodied in the national legislation of most WTO Members. In some countries, there are additional grounds for terminating the compulsory license established, in particular:

Lithuania	The government may declare a decision null and void if the person uses the patented invention with a compulsory license for purposes other than those for which the compulsory license was issued.
Canada	The competent authority, at the request of the patent owner, and after hearing all of the interested parties, may terminate the compulsory license if the circumstances which led to the issue of a compulsory license have ceased to exist and are unlikely to reoccur, which is the basis for the proper protection of the patent owner's rights.
Malaysia	At the request of the patent owner, the compulsory license is terminated, if the circumstances which led to its issue ceased to exist, as well as if the government or a third party identified by it uses a compulsory license contrary to the terms on which it was issued.
Australia	Upon the patent owner's appeal, the competent court may order to terminate the compulsory license. In this case, when deciding on the termination of the license, the competent court must verify if its termination violates the legitimate interests of the kingdom or the state.

Thus, when implementing the provisions of Article 31 (1) (g) of the TRIPS Agreement, some countries have expanded the grounds and terms for termination of a compulsory license.

Termination of a compulsory license

Article 31 (1) (g) of the TRIPS Agreement that defines general conditions for the termination of a compulsory license, does not establish mandatory requirements to the very mechanism (procedure) for termination of a compulsory license.

In view of the above, each WTO Member establishes a special mechanism (procedure) for the termination of a compulsory license, taking into account the particularities of the national legislation and the state system.

Taking into account the above, there are no restrictions on the introduction of a mechanism (procedure) for termination of a compulsory license in the legislation of Ukraine.

In particular, the following mechanism is proposed:

An entity that initiates termination of a compulsory license	1. Ministry of Health; 2. a patent owner; 3. a third person; 4. a licensee.
Grounds for termination of a compulsory license	• compulsory license expiration; • termination of the circumstances that were the basis for the issue of a compulsory license; • use of a compulsory license for purposes other than those for which a compulsory license was issued; • termination of the entity to which the compulsory license was issued.
An entity that decides to terminate a compulsory license	Cabinet of Ministers at the request of the Ministry of Health.
The form of termination of the compulsory license	Order of the Cabinet of Ministers on termination of a compulsory license.

Calculation of the remuneration to the patent owner when issuing a compulsory license

There are five methods for calculating compulsory licensing remuneration, chosen according to the analysis of the Ukrainian economy condition, existing methods of the intellectual property objects value assessment and the calculation of royalty for compulsory licensing indicated below. In the Remuneration guidelines for non-voluntary use of a patent on medical technologies WHO[12], four methods for calculating royalties for the purposes of compulsory licensing have been proposed, four methods are described in paragraphs 2,3,4,5 of this section as the most convenient for practical use with limited resources.

Operating profitability method

The method based on the profitability of operating activities of the pharmacological enterprises was proposed by O.V. Novoseltsev[13]. The amount of royalties is calculated according to the formula:

$$\text{Royalties} = \frac{\text{Prof} \times \text{Sh}}{(1+\text{Prof})}$$

WHERE: Royalties – represents the amount of royalties (compensation) payable to the patent owner for compulsory licensing;

Prof – represents profitability of manufacturing and sales of products;

Sh – represents a share (part) of profit in the total volume of profit from manufacturing and sales of products under a compulsory license.

The licensor's share in the profits of the licensee from manufacturing and sales may depend on the volume of transferred rights, the availability of the licensed object to carry out commercial manufacture, and of patent protection, which should reflect the amount of business risks in the commercial use of intellectual property, issue and sales of products under license, including compulsory license.

Taking into account the provisions of the Remuneration guidelines for non-voluntary use of a patent on medical technologies WHO/TCM/2005.1, it is proposed to use a rate of 4% (a licensor's share in the profits of the licensee).

Here is an example:
Sh = 0.04 (4%)
Prof = 16.8 (according to the State Statistics Service of 31 December 2015)

$$\text{Royalties} = \frac{16{,}8 \times 0{,}04}{1 + 16{,}8} = 0{,}0378\ (3{,}8\%).$$

That is, the compensation to the patent owner for the use of the invention without their consent makes:

Compensation = Manufacture volume * Royalties (3.8%)

Royalty is a part of the profit from the introduction and use of intellectual property objects, thus, it is more appropriate to use a method based on commonly financial indicators: profit and profitability.

[12] Remuneration guidelines for non-voluntary use of a patent on medical technologies WHO/TCM/2005 http://www.who.int/hiv/amds/WHOTCM2005.1_OMS.pdf
[13] Assessment of the market value of the intellectual property results, calculation of royalty rates and license prices // Innovations. – 2001. – No. 4 – 6. – P. 95-103.

This method is advantageous, as the commonly known values of profitability of the operating activity of a particular industry, calculated and summarised on the basis of the accounting and financial statements of each individual enterprise and submitted to the State Statistics Service www.ukrstat.gov.ua, may be used to calculate the royalty rate.

UNDP Rank, 2005/Canadian Export Royalty Guidelines

This method was adopted by Canada in 2005 for the guidelines for compulsory licensing patents for export of pharmaceuticals to countries that lack manufacturing capacity. According to this method, a low royalty rate is applicable in developing countries. The total royalty rate is 0.02-4.0% of the cost of products based on the UNDP Human Development Index (HDI).

The method is applicable under the formula as follows: 1 + HDI country number - HDI importing country rank. There are currently 185 countries in the HDI index. The Human Development Index is a comprehensive benchmark for life expectancy, literacy, education and living standards for countries around the world. This index is used to identify differences between developed countries, developing and less developed countries, and to assess the impact of economic policies on quality of life. For most developing countries, rates are less than 3%. For most of Africa, this rate is less than 1%. According to this principle, the rate is from 0.02 to 4% of the price of the basic product based on the HDI country rank.

The general formula for calculating royalties is as follows:
Royalties = 0,04 x [(186) – importing country rank] / 185.
Here is an example of royalty calculation for Ukraine.The royalty rate for Ukraine (a developing country) is 3%.

Ukraine HDI rank is 0,747.
Royalties = 0.03 * (186-0.747) / 185 = 0,03004.

That is, the compensation to the patent owner for the use of the invention without one's consent makes:

Compensation = Production volume x Royalties (3,004%).

Thus, the Canadian method is less useful for middle and high-income countries. In countries with very low royalties, this will lead to a reduction in investment in the development of new technologies.

Tiered Royalty Method

According to the tiered royalty method (TRM), a royalty basis is defined based on product prices in developed countries such as the United States or the European Union, and the royalties are established in accordance with the country's potential of payment for pharmaceuticals. This capacity is based either on relative income per capita or relative income per person in need for treatment. Royalty rates are easily calculated and are different in high-income and developing countries. This method prescribes for calculating the remuneration based on the license fees calculation in terms of transparency and predictability.

The TRM method will result in higher royalties calculated and payable in middle and high-income countries with low morbidity rates, and lower royalties calculated and payable in the lower income countries with the highest morbidity rates.

This method provides a more rational basis for joint R&D expenditure and is especially useful for low or middle-income countries to address common health issues.

The base royalty is calculated from the price of the product in the country of origin (often the United States or the EU, since the largest pharmaceutical companies – patent owners – are based there), and a standard royalty rate of 4%. Thus, the amount of royalty is then adjusted for different countries according to measures of affordability.

According to the TRM method, the royalty (maximum compensation amount) is calculated by the formula:

(C x 0.04 x (IU: I) = MR,

WHERE: C is the cost of the unit of the original medical product in the market of the country of origin. The cost of an original medical product can be determined from the data obtained on the Internet (for example, qualityprescriptiondrugs.com, drugstore.com, etc.).
IU – Ukraine's income per capita, according to the World Bank;
I – income of the country of the originator per capita, according to the World Bank;
MR – maximum remuneration.

Here is an example of royalty calculation for Ukraine. The royalty rate for Ukraine (a developing country) is 4%.
C is equal to 3.58 (data given in absolute values).
IU, as of 2016, makes USD 1 854.
I (for example, of the UK), as of 2016, makes USD 42 105.
Consequently, we have the following result:

MR = (3.58 x 0.04) x (1854/42105) = 0.1599

1998/JPO royalty guidelines method

In 1998, JPO published guidelines for setting royalties on government-used patents. The 1998/JPO method allows for normal royalties of 2 to 4% of the cost of the licensed product. The royalty rate depends on the amount of profit when the product is sold under a license. Method 1998/JPO has a number of factors that increase or decrease the royalty rate. According to these factors, it may be increased maximum by 2%, that is, up to 6% of the value of the product under the license. The main factor in increasing of the royalty rate is the "utilization factor", which concerns the ratio of the patented invention in the product. This approach is particularly applicable to cases where there are several patents for the same medicine and, in particular, when the product is a fixed-dose combination of various active ingredients.

This method can also be used when some products are patented and others are not under patent protection. Thus, license fees (royalties) can be calculated according to the formula as follows:

Royalty rate = value * use * increase/decrease factors * research work

WHERE:

- value or interest rate are as follows:
  - High - 4%
    (when the expected profit is 30%)
  - Average - 3%
    (when the expected profit is 20%)
  - Low - 2%
    (when the expected profit is 10%)

- utilization factor:
The "utilization factor" is applicable to determine the importance of the invention in relation to the final product. When the invention is a product, the ratio is 100%. Otherwise, the ratio is the fraction that represents the value of the part compared to the value of the whole product (the utilization factor cannot exceed 100%.)

- **increase or decrease of factors of influence.**
Increase or decrease may vary from 50% to 150%, and applies to the following cases:

(A) A patent, which is especially needed for public interest.
(B) The royalty rate is particularly high or low.
(C) The patent is not particularly new, there are other similar inventions.
(D) There are other special conditions.

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(A) A patent, which is especially needed for public interest.
(B) The royalty rate is particularly high or low.
(C) The patent is not particularly new, there are other similar inventions.
(D) There are other special conditions.

research work:
The indices can range from 50% to 100%. The lower coefficient is used when:

(A) high costs are required for the researches to commercialise the invention;
(B) high costs are required for advertising and promotion of the product.

2001/UNDP guidelines method

This method of calculating royalties is the easiest one. The usual royalty rate of 4% is recommended. Based on indices that are relevant to the therapeutic value of a product or the role of the state in financing R&D, the royalty may be increased or reduced by 2%.

Simplicity, predictability, and manageability are the benefits of the method. However, it is difficult to accurately estimate the therapeutic value of the invention.

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