LEGAL REGULATION OF COMPULSORY LICENSE

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Summary. *All subjective civil rights are capable of restrictions, especially for patent rights, where the desire to ensure a compromise between the interests of patent holders and the interests of society is most relevant. One of the consequences of compliance with this balance in patent law was the constant expansion of various restrictions and encumbrances, especially the property rights of patent holders. The article considers the issues of restrictions of subjective patent rights on the example of the issuance of a compulsory license. The current legislation of Ukraine and the legislation of developed countries are considered. It was found that countries independently determine the regime of compulsory licenses for patent objects at the national level. A legal mechanism for restricting patent rights to achieve a balance between the interests of society and patent holders through the application of a compulsory license has been identified. The issuance of compulsory licenses is possible for the benefit of individuals and public entities, including for health purposes, which is especially relevant for countries at the present stage. The mechanism of compulsory licensing fully corresponds to the peculiarities of patent legal relations and does not deprive the patent owner of the protection of his exclusive right, nor does it prevent him from independently using and effectively commercializing the relevant development. Compulsory license is paid, although granted against the will of the patent owner, but is a means of securing his property interests.*

Keywords: *patent law, exclusive law, results of scientific and technical creativity, monopoly, restriction of law, compulsory license.*

The relevance of the chosen direction of research is due to the presence of a number of problematic issues in the further development of the global system of patent protection. The rights to the results of scientific and technical creativity can give a participant in economic turnover a certain market power, which is associated with the risk of patent abuse. The compulsory licensing mechanism allows the state, as a regulator, to restrict patent rights in the public interest. At the same time, the use of this mechanism can lead to a significant negative impact on a incentives for innovation. Therefore, it is necessary to establish the optimal regime of patent protection in order to achieve a balance of interests of different parties in these legal relations, the creation of effective legal mechanisms to protect property and personal non-property patent rights, taking into account the public interest.

The legal mechanism of compulsory licensing in Ukraine is provided in the Civil Code of Ukraine and a number of special legislative acts. However, since its introduction, no case of compulsory licensing has been recorded, which can be explained either by the lack of demand for law enforcement in this area, or by the inefficiency of the mechanism and the need to adjust it. Especially in the current conditions of the COVID-19 coronavirus pandemic, and the existence of the problem of ensuring the availability of new, vital technologies for society and the protection of the rights of their right holders.

The aim of the article is to clarify and study the problematic aspects of the application of compulsory licensing in the context of globalization processes, and to find the optimal regime of protection of the rights to the results of scientific and technical creativity, taking into account the necessary restrictions. The task of the article is to study the legislative possibilities of maintaining the balance of interests of society and patent holders through the application of a compulsory license, and to substantiate proposals for improving the legal regulation of the studied relations.

Scientific novelty of the research. The understanding of the system of limits and restrictions of patent rights in terms of their impact on the innovative development of society as a whole has been further developed. A legal mechanism for restricting patent rights to achieve a balance between the interests of society and patent holders through the application of a compulsory license has been identified. Proposals for improving the legal regulation of relations on compulsory licensing are substantiated.

The basis of the **methodology** of research of the chosen problem is a systematic approach, as well as dialectical, formal-logical and structural-functional methods and other general scientific research methods, as well as special legal methods: comparative law and formal law.

Analysis of recent scientific research on the outlined issues shows that the solution to the problem of

compulsory license in general has begun in the works of such scientists as V Beckmerhagen A., J. Boyle, O. Karchiya, K.U.Pillai, Potekhina, N.S. Tyler, M. Finnegan and others. But further study of the problematic issues of achieving a balance of interests (in particular, the threat of monopolization of patent rights as an obstacle to the development of innovation) does not lose its relevance to this day.

Presenting of main material. Intellectual property law, in particular patent law, is the main factor that stimulates innovation. Obtaining a patent for an invention, industrial design, utility model protects its owner from the use of these results of scientific and technical creativity by other entities without the consent of the patent owner during the term of the patent. That is, at the time of the patent, its owner has a certain monopoly on the results of scientific and technical creativity, and no one without the permission (license) of the patent owner may not put into circulation goods manufactured using the results of scientific and technical creativity, or put into operation appropriate improvements. production process. Such a patent monopoly sometimes leads to controversy over the need for such absolute protection, as it may reduce the pace of scientific and technological progress or the spread of vital technologies.

The system of legal protection and defend of objects of patent law is in essence an almost unrestricted legal monopoly on the use of the result of scientific and technical creativity. The introduction of innovative technologies in any field is inextricably linked with the need to patent inventions, utility models or industrial designs. The high level of competition in the innovation market is a catalyst for the potential risk of unfair competition, industrial espionage, borrowing ideas, as well as the use of other people's intellectual and creative results. Acquisition of the right to an invention, utility model or industrial design, authorship and exclusive right to it is certified by a patent (paragraph 1 of article 462 of the Civil Code of Ukraine).

And the existence of such absolute legal protection of patent rights will inevitably lead to a conflict of personal interests of right holders with the interests of society. Especially when it comes to the availability of new as well as vital technologies (in particular in the medical and pharmacological fields) and other innovations for society. Thus, patents are intended to reward pharmaceutical companies for investing in research and development of the latest drugs. It is important for patent holders to obtain exclusive rights to such results of scientific and technical activities in order to further commercialize them by setting high prices. The field of medicine is big business and profitable. And pharmaceutical companies (bigpharma) can decide who gets access to drugs and vaccines. That can not suit society and each of its members separately. When for a certain category of patients, medications may be vital but unaffordable.

Governments of a number of countries have repeatedly called on big farms to open their patents in exceptional cases (in the treatment of rare diseases or pandemics) so that production can be increased. However, big farms are in no hurry to take such a step, as they clearly understand that they will lose over a million in profits. For example, the most effective drugs used for coronavirus are already patented. Namely, favipiravir, which is used to treat influenza, as well as a mixture of lopinavir and ritonavir, which is sold under the brand name Kaletra for the treatment of HIV / AIDS. For example, remdisivir, an Ebola drug from biotechnology company Gilead, is limited by a patent until 2038. Recently, Gilead claimed "orphan drug" status for Remdesivir because of its potential benefit in the treatment of COVID-19 [1].

Not surprisingly, countries apply or are considering preventive measures to counter the patent monopoly in emergencies and in the public interest. Accordingly, recently the legal mechanisms of restriction of patent rights to protect the interests of society in the event of a conflict between the latter and the interests of right holders have become increasingly important. Because society must have access to advanced technologies, scientific and technical developments and other objects of intellectual property rights, especially in the scientific and technical sphere. Provided that the right holders comply with the results of scientific and technical creativity. It is through the effective achievement of the balance of private and public interest that it is possible to achieve positive changes in the direction of the development of Ukraine's innovative economy.

The Paris Convention for the Protection of Industrial Property [2] establishes the right of each Member State to grant a compulsory license in order to prevent abuses which may result from the exercise of exclusive patent rights (Article 5). The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) [3] also emphasizes the balance between the interests of right holders and society. Thus, in Art. 7 The TRIPS Agreement actually emphasizes the observance of the public interest. And already in Art. 8 of the TRIPS Agreement, the observance of public interests is defined as the first principle of legal protection of intellectual property rights. Namely, in national legislation, Member States may take the measures necessary to protect public health and nutrition and to ensure the public interest in important areas for their socio-economic and technological development. These measures allow public access to the results of scientific and technical creativity, and, accordingly, provide an opportunity to use new drugs, methods and treatments [4]. In Art. 31 provides for the right to use a patent without the permission of the patent owner but with the permission of the government in the event of an emergency in the country or in other circumstances of extreme necessity [3]. The grounds for granting a compulsory license are indicated: in the case of public health, environmental safety and other public interests. The interested person, who intends to use the patented object for the

purpose of ensuring the health of the population, is obliged to apply to the owner of the invention (utility model) for a license. However, each country can choose the terms of compulsory licensing.

In order to implement these provisions, the Doha Declaration on the TRIPS Agreement and Public Health was adopted [5]. The Doha Declaration defines the importance of implementing and interpreting the Agreement TRIPS in the most acceptable way to protect the public interest - by ensuring the availability of existing medicines for the population and creating conditions for the production of new ones. However, the status of the Doha Declaration is not yet defined, so it can be considered as a political intention that is not legally binding [6].

At the same time, the declaration states that each country independently determines the grounds for the application of compulsory licensing. Therefore, the reason for applying compulsory licensing should not be just an emergency. States are free to determine circumstances that may be extraordinary.

For example, Directive 2001/83 / EU «about the Community code relating to medicinal products for human use of 06.11.2001» and Regulation (EU) #816/2006 «about compulsory licensing of patents relating to the manufacture of medicinal products for export to countries with protection problems health» established the main purpose of such licensing, namely the protection of public health (article 1 (2)).

Therefore, in order to reduce the negative consequences of legal protection of intellectual property rights (monopolization of their use), the legislation provides for restrictions and exclusions from the patent monopoly, provided that such restrictions and exclusions do not create significant obstacles to the normal realization of intellectual property rights. Part 2 of Art. 424 of the Civil Code of Ukraine establishes a general principle regarding the possibility of restricting property rights of intellectual property, which will not be recognized as a violation of these rights. In this case, it should be noted that we are talking about the restriction of intellectual property rights, which are expressly provided by law.

Thus, when it comes to public interests, protection and defense of the human right to life and health and in connection with numerous cases of its restriction by a patent monopoly, the modern legal doctrine of intellectual property law provides a mechanism to influence the exercise of exclusive rights by state enforcement licenses for the results of scientific and technical creativity, including in the field of health care for their non-commercial use.

According to the mechanism of compulsory licensing, the state obliges the patent owner to issue a license for the result of scientific and technical creativity to a third party with the payment of fair compensation. Therefore, compulsory licensing can be seen as a possible tool to address the shortage of supply and the high price of a drug on the market. At the same time, the practice of applying this mechanism is ambiguous in terms of the effectiveness of solving these problems.

The institute of compulsory licensing fully corresponds to the peculiarities of patent legal relations and does not deprive the patent owner of the protection of his exclusive right, nor does it prevent him from independently using and effectively commercializing the relevant development. Compulsory license is paid, although granted against the will of the patent owner, but is a means of securing his property interests.

There is a legal mechanism in modern international legal doctrine of intellectual property law and in most national laws [7] that allows governments to temporarily limit the legal protection of patents in case of emergency licensing in favor of specially designated persons or institutions. Compulsory licensing applies only when the harm to the public interest from a patent monopoly outweighs the benefits to the right holder [8]. The Chilean government has recently stated that a pandemic justifies the use of private licensing. Israel has issued private licenses for lopinavir and ritonavir, and Ecuador has approved a resolution proposing that the Minister of Health issue private licenses for all patents related to COVID-19. Canada and Germany have amended their patent laws to ensure the speedy granting of a compulsory license.

Thus, in Canada, many compulsory (mandatory) licenses for the import of medicines were issued, which led to significant development of industry in Canada [9, p. 2]. Brazil is in the process of amending its patent law to simplify compulsory licensing [10]. The decision to issue a compulsory license is made by the National Institute of Industrial Property. Next, the government must decide that the drugs are in the public interest. Subsequently, to negotiate with the manufacturer to reduce the price, and only in the event of their failure, to adopt another decision on the need to apply the procedure of compulsory licensing. For example, in 2003, the Brazilian government issued a license to manufacture and import generic antiretroviral drugs, including Lopinavir, Efavirenz, and Nelfinavir (INN-efavirenz for HIV / AIDS) [11].

In cases of emergency or in the need to protect the public interest, the Brazilian government may issue a compulsory licensing decision if the patent owner is unable to meet this need on his own. Compulsory licensing is not limited to specific industries, but this mechanism also applies under the following conditions:

1) the patent owner abuses his rights to the result of scientific and technical creativity or uses these rights for competitive actions;

2) the patent owner within three years after the registration of rights to the patented object did not independently establish the production process without good reason;

3) a person trying to obtain a compulsory license must be interested in using the relevant patented object on the national market;

4) the patented object is insufficiently used in the

territory of Brazil, except when it is economically impractical;

5) there is a dependence of one patent on another;

6) commercialization of a patented object does not meet the needs of the market;

7) patent holders were unable to reach an agreement on their own.

The history of the use of compulsory licenses in patent law to ensure the interests of society and protect the health of the population dates back many years. In the United States from 1941 to 1959, 107 compulsory licenses were issued [12]. But every year their number only grows. Special grounds for issuing a compulsory license in the United States are provided for in the Bayh-Dole Act of 1980 and other sectoral acts [13]. Thus, the Atomic Energy Act of 1946 provides for the possibility of issuing a compulsory license for an invention that can be used in the production or disposal of special materials for nuclear reactors or nuclear energy. The Clean Air Act of 1963 provides similar conditions for devices that eliminate air pollution. The Bayh-Dole Act provides for the possibility of issuing compulsory licenses for patented objects created with public funding or in the interests of the state. To grant such a license requires one of the following conditions:

- the right holder has not taken action on the practical application of the invention;
- the needs of the population in health and safety are not met;
- the requirements for public use of the object are not observed;
- the right holder has transferred the exclusive right to use the patented object to another person without establishing for the latter the condition of the predominant use of the object in the United States.

The U.S. Patent Act defines the grounds for compulsory licensing as a refusal to grant a license for a patented object, which creates an opportunity for a broad judicial interpretation [14]. The most common case of compulsory licensing in practice is the refusal of the patent owner to provide access to the use of the object, which was later transformed into the doctrine of essential facilities doctrine. In the case of MCI v. The ATT court determined four conditions for the issuance of a compulsory license, taking into account the doctrine of essential facilities doctrine:

1) control of the main resource by the monopolist;

2) the practical inability of a competitor to duplicate such a resource;

3) prohibition of use of the object by a competitor;

4) the possibility of providing the resource by the patent owner [15].

A similar approach was taken in the case of Otter Tail Power Co. [16], where a company that controls the infrastructure and assets that other companies can use to compete is required to license.

The American approach to compulsory licensing is interesting. Because it determines the object criterion of application of the limits of the exercise of the exclusive right, linking the possibility of granting a compulsory license with the special characteristics of the patented object. However, in this approach, the dangerous emphasis is on ensuring competition or overcoming the effects of anti-competitive practices [17]. Almost any patented objects for the use of which there is a significant consumer demand are subject to compulsory licensing. Conversely, the access to a patented object needed to support innovative progress will not be provided because the owner is not a competitor with entities that require the use of scientific and technical results.

The US government often threatens to use this mechanism as an argument in negotiations with pharmaceutical companies over the price of medicines. A well-known case of using this mechanism is the negotiations with Bayer in 2001. As a result of negotiations, the company agreed to reduce the price of the drug three times.

The German compulsory licensing mechanism is enshrined in the Patent Act in sections 24, 25, 85 and 85a [18]. The issuance of a compulsory license is carried out by the Federal Patent Court in the presence of conditions:

- the plaintiff within a reasonable period of time tried to enter into a license agreement with the patent owner on fair terms, but the latter refused to enter into an agreement;
- the granting of a license to the plaintiff is conditioned by public interests.

Or in the presence of dependent patents. The right holder retains the right to compensation from the user of the compulsory license. If the circumstances that led to the issuance of the compulsory license are exhausted, the right holder may demand the termination of the compulsory license.

In addition to the above conditions, the issuance of a compulsory license is provided by antitrust law. Thus, according to the decision of the Supreme Court of Germany in the case № KZR 39/06 - Orange Book Standard of May 6, 2009 [19] it is determined that the defendants who illegally use the patent can justify their position as follows: (1) the right holder has a dominant position on market, and (2) it refuses to enter into a license agreement on fair terms. According to the case law, a positive effect on public welfare is also a prerequisite for the issuance of a compulsory license.

In the Polyferon case [20], the German manufacturer of the active substance IFN-gamma, which was used to create the arthritis medicine Polyferon, applied to the right holder for a reasonable license. The patentee refused and filed a lawsuit for violation of his exclusive right. The manufacturer applied to the Federal Patent Court and obtained a compulsory license, as the patent owner had not yet registered a new drug in Germany, and the lack of a drug based on IFN-gamma could adversely affect the health of citizens. Although the Supreme Court subsequently overturned the Federal Patent Court's ruling on the grounds that there were analogues of the drug based

on other active substances on the market, the application of a compulsory license did not ensure the availability of the disputed drug [21].

Taking into account the position of the Supreme Court, in 2016 the Federal Patent Court granted the requirement to grant a compulsory license for a drug intended for the treatment of HIV / AIDS, the patent of which belongs to Shionogi & Company Ltd., Merck & Co. The latter has already started production, but Shionogi & Company Ltd refused to enter into a license agreement on fair terms [22]. In view of the established production process of the medicinal product and the public need, the court ordered Shionogi & Company Ltd to issue a license to Merck & Co.

Another noteworthy case is Standard-Spundfass [23]. In which the court determined that in the presence of additional conditions, the anti-competitive behavior of the right holder may be grounds for granting a compulsory license. In fact, the German law enforcer also reached the *essential facilities doctrine* in determining the grounds for granting a compulsory license. The normative basis in this case was not patent, but competition law. Of course, this decision was determined not by the desire to subject intellectual relations to the rules of anti-competitive law, but to preserve the inviolable basic postulates of intellectual property rights. Indeed, the exercise of rights to indispensable patented objects for the creation of certain innovative products may lead to the holder of unfair competitive advantages [24].

The Switzerland Compulsory Licensing Mechanism established the Federal Act of June 25, 1954, on Patents for Inventions [25]. The issuance of compulsory licenses is regulated by the Switzerland Federal Council in the following circumstances:

- availability of dependent patents (article 36);
- insufficient use of the patent (articles 37, 38);
- in the public interest (articles 32, 40);
- for inventions in the field of semi-conductor technology, a nonexclusive licence may only be granted to remedy a practice held to be anti-competitive in court or administrative proceedings (article 40a).
- any person who intends to use a patented biotechnological invention as an instrument or means for research is entitled to a non-exclusive licence (article 40b).
- for inventions concerning a diagnostic product or procedure for humans, a non-exclusive licence shall be granted to remedy a practice held to be anti-competitive in court or administrative proceedings (article 40c).
- any person may bring an action before the court to be granted a nonexclusive licence for the manufacture of patent-protected pharmaceutical products and for their export to a country that has insufficient or no production capacity of its own in the pharmaceutical sector and which requires these products to combat public health problems, in particular those related to HIV/AIDS, tuberculosis, malaria and other epidemics (beneficiary country) (article 40d).

In Switzerland, only two cases of court decisions on the issuance of compulsory licenses for the use of dependent patents are known [26].

In India, in accordance with Articles 84 and 92 of the Patents Act, 1970, the following cases of application of the compulsory licensing mechanism are possible [27]:

any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely: (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or (b) that the patented invention is not available to the public at a reasonably affordable price, or (c) that the patented invention is not worked in the territory of India.

A circumstance of national emergency; or a circumstance of extreme urgency; or a case of public non-commercial use, which may arise or is required, as the case may be, including public health crises, relating to Acquired Immuno Deficiency Syndrome, Human Immuno Deficiency Virus, tuberculosis, malaria or other epidemics Central Government may issue a compulsory license to a third party (Article 92);

Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India (Article 92A).

In this regard, it is worth pointing out two court decisions that may change the approach to the regulation of the public interest in private international law [28]. For example, in 2011, the Indian company Natco Pharma Limited applied to the patent authority for a compulsory license to use the drug Bayer Corp [29] for the treatment of liver, kidney and blood cancer Glivec [30]. Intellectual Property Appellate Board, IPAB On September 14, 2012, Bayer AG refused to revoke the decision of the Patent Office of India. The court also later dismissed Bayer AG's lawsuit against Bayer AG, which sided with cheap local generics (Natco, Cipla, Hetero and Ranbaxy) [31]. Thus, he supported the issuance of a compulsory license on the basis of public interest, as Indian generics are much lower than the drug Glivec Bayer AG, the sale of which can cause significant damage to the health care system in India [32]. The compulsory licensing mechanism is common in India.

In general, the legislation of different countries in terms of provisions on public interest in this area are similar. A typical example is the Patent Act of Japan [33.]. This Compulsory Licensing Act sets out the following requirements. First, negotiations on the possibility of granting a license with the right holder

must take place. If such negotiations are unsuccessful or impossible at all (for example, the patent owner evades negotiations), the applicant may request directly from the Minister of Economy, Trade and Industry (if there is public interest in the patented object) or from the Director General of the Patent Office. decide on the issuance of a non-exclusive license [34]. Which should be issued in the following cases:

1) where a patented invention is not sufficiently and continuously worked for 3 years or longer in Japan, a person intending to work the patented invention may request the patentee or the exclusive licensee to hold consultations to discuss granting a non-exclusive license; provided, however, that this shall not apply unless 4 years have lapsed from the filing date of the patent application in which the patented invention was filed. (ст. 83 Patent Act of Japan);

2) when the patentee or exclusive licensee for their use exploits another patented invention, utility model or industrial design of another right holder, claimed or registered before the date of filing the patent application (Article 92 of the Patent Act of Japan);

3) where the working of a patented invention is particularly necessary for the public interest (ст. 93 Patent Act of Japan).

Thus according to Art. 93.1 The Patent Act of Japan under the public interest means the following cases in which: the invention is necessary to ensure the safety of life and property of Japanese citizens or directly related to human life. Or when the patented invention hinders the development of the field in which the present invention was created, and can significantly affect people's lives in a negative way.

Thus, the legal mechanism of compulsory licensing in almost all countries is based on the following principles:

- the invention is essential to ensure national or public interests;
- compulsory license is issued by the government or an authorized person in the prescribed amount and a certain number of persons;
- lack of unreasonable permission from the right holder to use the patent on fair terms. Provided that the person concerned has attempted to obtain such permission within a reasonable period of time;
- there is a dependence of one patent on another;
- used in the domestic market;
- a compulsory license is non-exclusive, and the person who received it cannot transfer the license to other persons.
- the payment of a fair fee to the patent owner when granting a compulsory license is maintained;
- the decision to issue a compulsory license and the conditions for its issuance may be appealed in court.

An effective means of ensuring the balance of interests of patent holders is the threat of using the mechanism of compulsory licensing in order to ensure the health of the population and counteract anti-competitive actions. For example, in 2000, Roche applied to the German government for a compulsory license for a blood / HIV / AIDS screening device patented by Chiron. A year later, Roche and Chiron independently signed a license agreement, the price of which suited both parties. Roche made concessions to the government, as a result of a 40% reduction in the price of Virasept (INN - Nelfinavir) avoided compulsory licensing of the drug. This example is evidence that the very fact of having the legal tools to issue a compulsory license and actively demonstrate the relevant political will in the state are quite influential mechanisms for finding a balance of public interests and patent rights.

We should also mention the active position of the French Patients' Union on the excessive price of the breast cancer test, a patent for which belonged to Myriad, which in 2004 forced a legislative initiative and amendments to the Intellectual Property Code. The amendments to Article L 613-17 provided that, in the field of health care and in the absence of voluntary consent, a compulsory license for a medicinal product, a medical device for in vitro and in vitro diagnostics could be issued at the request of the Minister of Industry and the Minister of Health. vivo and related therapeutic products. The mechanism of compulsory licensing to ensure the interests of society, violated by anti-competitive actions, was successfully used in Italy in 2005. The Competition and Market Committee (AGCM) has issued a compulsory license for the antibiotic Imipenem cilastatina to Glaxo. In 2007, the committee obtained Merk's voluntary license for finasteride two years before the supplementary protection certificate expired.

The legal basis for the issuance of a compulsory license for a patented medicinal product is currently Part 3 of Article 30 and Part 2 of Article 31 of the Law of Ukraine "On protection of rights to inventions and utility models", Art. 9 "On Medicinal Products"[35], Resolution of the Cabinet of Ministers of Ukraine of 14.01.2004 № 8 "On approval of the Procedure for granting by the Cabinet of Ministers of Ukraine permission to use a patented invention (utility model) or registered topography of an integrated circuit" [36] and Resolution of the Cabinet of Ministers of Ukraine № 877 of 4.12. 2013 "On approval of the Procedure for granting by the Cabinet of Ministers of Ukraine permission to use a patented invention (utility model) related to a medicinal product" [37].

National legislation defines the following grounds for issuing a compulsory license for a patented object as a result of technical creativity:

when the invention (utility model) is not used or insufficiently used in Ukraine for three years from the date following the date of state registration of the invention (utility model), or from the date when the use of the invention (utility model) was terminated, any person , who is willing and willing to use the invention (utility model), in case of refusal of the right holder to enter into a license agreement may apply to

the court for permission to use the invention (utility model) (Part 1 of Article 30 of the Law of Ukraine " On protection of rights to inventions and utility models ");

in the case of a related patent, the patent owner is obliged to grant (license) the use of the invention (utility model) to the owner of the later issued patent, if the invention (utility model) of the latter is intended to achieve another purpose or has significant technical and economic advantages and may not be used without infringing the rights of the owner of a previously issued patent (Part 2 of Article 30 of the Law of Ukraine "On protection of rights to inventions and utility models");

in order to ensure public health, state defense, environmental safety and other interests of society, the Cabinet of Ministers of Ukraine may allow the use of a patented invention (utility model) to a person designated by him without the consent of the patent owner (Part 3 of Article 30 of the Law of Ukraine invention and utility model ").

In this case:

1) permission for such use is granted based on specific circumstances (in the event of circumstances that pose a threat to public health, state defense, environmental safety, etc.);

2) the scope and duration of use are determined by the purpose of the granted permit (for the period of existence of the threat to public interests). In this case, the presence of an unreasonable refusal of the patent owner to issue a license is not required;

3) the compulsory license does not deprive the patent owner of the right to grant permits for the use of the invention (utility model) to other persons or the right to prevent the illegal use of patented objects;

4) a person who has received the right to use the objects of patent law under a compulsory license may not transfer such right to another person, unless it is transferred together with the part of the enterprise or business practice in which such use is carried out;

5) use is allowed to meet the needs of the internal market;

6) the patent owner is notified of the granting of permission to use the invention (utility model) as soon as it becomes practically possible;

7) the permit for use is revoked if the circumstances due to which it was issued cease to exist;

8) the patent owner is paid adequate compensation in accordance with the economic value of the invention (utility model) [38]. However, the law does not specify the term and amount of compensation to right holders.

Today there are no precedents for the application of this norm in Ukraine. But due to the spread of the COVID-19 pandemic, such a precedent may emerge. At the same time, extraordinary circumstances include: ensuring public health, state defense, environmental safety and other public interests. But the question remains whether these grounds are an exhaustive list or not. Therefore, classifying a pandemic as an emergency is quite possible. The use of Art. 30 is complicated by the fact that there is almost no case law on its application. In the Ukrainian legal system, this institution has not yet received significant application. In this regard, it is not possible to clearly define exactly how the courts will interpret controversial issues in this area.

In addition, the terms of a compulsory license are not based on the mutual consent of the licensor and the licensee, but are determined by the competent state authority. In the future, the public authority may terminate the compulsory license if the circumstances that led to its issuance cease to exist. However, compulsory licensing is still the mechanism that obliges the patent owner to grant a license to another party in the public interest.

The procedure for granting a compulsory license (permit) is directly specified in the Resolution of the Cabinet of Ministers of 14.04. 2004 № 8 "On approval of the Procedure for granting by the Cabinet of Ministers of Ukraine permission to use a patented invention (utility model) or registered topography of an integrated circuit" [36]. Such permission is granted in order to ensure public health, environmental safety and other public interests. However, the resolution states that the effect of this Procedure does not apply to the procedure for granting permission to the Cabinet of Ministers of Ukraine to use a patented invention (utility model) relating to a medicinal product.

There is also special legal regulation in the field of compulsory licensing of inventions and utility models in the field of health care. In particular, in accordance with Part 14 of Art. 9 of the Law of Ukraine "On Medicinal Products" from 04.04.1996, in order to ensure the health of the population during the registration of a medicinal product CM of Ukraine may allow the use of a patented invention (utility model) relating to such a medicinal product to a person designated without consent patent holder [35]. In pursuance of this norm, the Cabinet of Ministers of Ukraine adopted Resolution of December 4, 2013 № 877, which approved the Procedure for granting the Cabinet of Ministers of Ukraine permission to use a patented invention (utility model) relating to a medicinal product. In fact, the field of health care is the only area that has special legal regulation on compulsory licensing of patent rights. Because it is here that it is very important to balance the private interests of the patent owner and the public interests of the state in the field of health care. Combating HIV / AIDS and other socially dangerous diseases is an extremely important activity for the state, so the purpose of compulsory licensing, to ensure the health of the population, is justified.

However, the question arises as to which diseases are considered socially dangerous. The procedure identifies one of them - HIV / AIDS. The Doha Declaration lists malaria tuberculosis and other epidemics, although it is not part of national legislation. The Law of Ukraine "On Protection of the Population from Infectious Diseases" among "socially dangerous infectious diseases" provides for tuberculosis, sexually

transmitted infections, AIDS, leprosy. But is this list exhaustive? Is it possible to attribute COVID-19 to such socially dangerous diseases? The existence of COVID-19 and the future emergence of other socially dangerous diseases certainly make this list open.

It is also necessary to define more clearly such a circumstance as the impossibility of the patent owner to satisfy the need for the respective medicinal product with the forces and capacities normally used for the production of such medicinal product. Especially when the supply is enough, but the drugs are sold at a price too high for the population. When consumers cannot afford to buy a drug that is vital. It is necessary to define in the legislation the basis for compulsory license, as the lack of sufficient supply and high cost of drugs for the treatment of socially dangerous diseases is not provided by law. As this may lead to a monopoly position of pharmaceutical companies that have a patent for the relevant drugs. Although Ukrainian law does not provide for antitrust compulsory licensing, the need for which deserves attention from the state. From a theoretical point of view, these potential legal relationships can be considered another type of compulsory licensing. Compulsory antitrust licensing fully meets the requirements of antitrust law and reflects the growing need of the world community to shift the balance of interests towards society, violating the patent owner's monopoly on the use of patented results of scientific and technical creativity.

The person who initiated the compulsory license also needs details. Currently, it is an interested business entity that applies to the Ministry of Health of Ukraine with a proposal. This applicant substantiates the need to use the patented object, indicating the specific circumstances of the case and the required validity of the patent. However, it is possible that the applicant may be a commercially interested manufacturer that will not act in the public interest. Therefore, the sole initiator of a compulsory license should be the state in the person of the public authority, which is responsible for making the appropriate decision.

In addition, the Resolution requires the applicant to provide documentary evidence of the unjustified refusal of the patent owner to issue a license to use the patented invention (utility model) on the relevant application of the applicant. Compliance with such a waiver requirement is quite problematic, as the right holder will clearly be uninterested in granting such a license. It is effective not to obtain a permit, but to warn (notify) the right holder of the intention to obtain a license, and if the right holder does not agree to the license within a certain period, the user can apply to the competent authority for a compulsory license.

Despite the existence of a compulsory licensing mechanism in the legislation, there has been no precedent for its issuance in Ukraine. In the field of medicine and pharmaceuticals, this is due to objective factors: the complexity and cost of state registration of a generic largely depends on the actions of the holder of the rights to the original drug. Thus, even in the case of obtaining a compulsory license by a court decision, the licensee is obliged to pass the state registration of the drug, which is a time-consuming and expensive process (significant costs for additional local clinical trials). It is necessary to take into account the complexity of technology transfer, which is the significant cost of re-equipment; personnel training; the duration of the procedure for launching the production of the drug; competition from the manufacturer of the original drug, which can reduce the price of the drug; etc.

Legal protection of the results of scientific and technical creativity stimulates innovative activity and is in constant conflict with the interests of society. There are interests on different scales: patent holders (monopoly exclusive right to the result of scientific and technical creativity) and the interests of society (the right of free access to the best achievements of science and technology). It should be agreed that the interests of both parties are an absolute value for the state. It is quite difficult to choose one side or the other. However, the legal protection of scientific and technical results must be considered in terms of impact on the public good.

CONCLUSION

Globalization processes in the field of the right to the results of scientific and technical creativity encourage the harmonization of national legislation in the field of protection of intellectual property rights. However, current trends in the formation of the patent law system indicate an imbalance with the public interest. Ensuring a fair balance of the interests of society and patent holders must be observed not only at the national level, but also at the international level. Compulsory licensing is an effective mechanism for balancing the interests of society and patent holders, and is designed to prevent the monopoly of patent holders from jeopardizing the health of the population as a higher social goal.

The mechanism of compulsory licensing as a means of ensuring access to new, vital innovative technologies (especially in the medical and pharmaceutical spheres) for society is effective and depends on clear regulation at the level of national legislation and the presence of political will in the state. The importance of the relevant legal regulation is due to the fact that the issuance of a compulsory license takes place without the consent of the patent owner, but in cases specified by law. That is why the procedure for such licensing should be standardized and reflect a certain balance of interests of both patent holders and society.

Compulsory licensing gives the government the opportunity to introduce compulsory licensing both in court and out of court. Despite the rather broad powers in the field of compulsory licensing, this mechanism is used very rarely. It is generally used as an argument in negotiations with pharmaceutical companies (the experience of the United States

and Brazil), as a result of which the prices of medicines are significantly reduced. That is why, before applying the mechanism of compulsory licensing, it is necessary to take part in negotiations not only with contractors, but also with representatives of state authorized bodies. It is during the preliminary negotiations that the possible benefits and losses from the issuance of a compulsory license will be assessed and, accordingly, the balance of interests of right holders and public needs will be observed.

REFERENCES

[1] Achal Prabhala and Ellen 't Hoen We'll find a treatment for coronavirus – but drug companies will decide who gets it // URL: https://www.theguardian.com/commentisfree/2020/apr/15/coronavirus-treatment-drug-companies

[2] Paris Convention for the Protection of Industrial Property. URL: https. ://zakon.rada.gov.ua/laws/show/995_123#Text

[3] Agreement on Trade-Related Aspects of Intellectual Property Rights. // URL: http://zakon2.rada.gov.ua/laws/show/981_018.

[4] Ghanotakis E. Access to Medicines for Developing Countries // Journal of Word IP. 2004. vol. 7. issue 14.

[5] Doha Declaration on the TRIPS Agreement and Public Health // URL:www.ier.com.ua/files/Projects/.../0000019100- Kuznecova_print2.pdf.

[6] The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties (James Thuo Gathii, Harvard Journal of Law & Technology, 2002 p, № 2)

[7] Pillai K.U. The role of Patent Law in Public Interest. // URL: http://www.altacit.com/pdf/theroleofpatentlaw-in_%20publicinterest.pdf

[8] Tyler N.S. Patent nonuse and technology suppression: the use of compulsory licensing to promote progress // URL:https://scholarship.law.upenn.edu/cgi/viewcontent.cgi?referer=&httpsredir=1&article=1548&context=penn_law_review

[9] Donald M. Cameron, R. Scott MacKendrick and Christina Capone Settimi Canadian Drug Patent Laws and Regulations // URL: http://www.jurisdiction.com/patweb09.pdf.

[10] Costa Rica submits proposal for who to facilitate access to technologies to combat COVID-19. // URL: https://www.presidencia.go.cr/comunicados/2020/03/costa-rica-submits-proposal-for-who-to-facilitate-access-to-technologies-to-combat-covid-19/

[11] Bragarnik A. Compulsory licensing of intellectual property in pharmaceuticals. // URL: www.legalalliance.com.ua.

[12] Finnegan, Marcus (1977). The folly of compulsory licensing. Licensing Executive Society (LES), June, 128–147. // URL: https://ipmall.law.unh.edu/sites/default/files/BAYHDOLE/IatkinPDF/The_Folly_of_Compulsory_Licensing_by_Marcus_B._Finnegan,_6-1977_.pdf

[13] Bayh-Dole Act of 1980; Public Law 96-517. // URL:https://uscode.house.gov/statutes/pl/96/517.pdf

[14] United States Code Title 35 – Patents // URL: https://www.law.cornell.edu/uscode/text/35

[15] MCI v. ATT 512 U.S. 218; 114 S. Ct. 2223; 129 L. Ed. 2d 182 (1994). // URL: https://www.lexisnexis.com/community/casebrief/p/casebrief-mci-telecomms-corp-v-at-t-co

[16] Otter Tail Power Co. v. United States, 331 F.Supp 54, 58 (D. Minn. 1971), 410 U.S. 366 (1973) // URL: https://supreme.justia.com/cases/federal/us/410/366/

[17] Examples of Compulsory Licenses of Intellectual Property in the United States» (James Love and Michael Palmedo, 2001). // URL: http://www.cptech.org/ip/health/cl/us-cl.html

[18] Patentgesetz (zuletzt geändert durch Gesetz vom 31. Juli 2009) // URL:http://www.wipo.int/wipolex/en/text.jsp?file_id=401424

[19] KZR 39/06 – Orange Book Standard // URL: http://www.ipeg.com/blog/wp-content/uploads/EN-Translation-BGH-Orange-Book-Standard-eng.pdf

[20] Federal Court of Justice № X ZR 26/92, 5 December 1995, BGHZ 131, 247. // URL: https://dejure.org/dienste/vernetzung/rechtsprechung?Gericht=BGH&Datum=05.12.1995&Aktenzeichen=X%20ZR%2026%2F9

[21] X ZR 26/92 от 05.12.1995. // URL:https://www.jurion.de/urteile/bgh/1995-12-05/x-zr-2692/

[22] Vorozhevich A.S. Compulsory licensing of pharmaceuticals: why FAS Russia initiatives are dangerous for the industry and consumers // Economy and life. 2017. № 1.

[23] Case № KZR 40/02. Judgment of 13 July 2004. BGHZ 160, 67. // URL: https://dejure.org/dienste/vernetzung/rechtsprechung?Gericht=BGH&Datum=13.07.2004&Aktenzeichen=KZR%2040%2F02

[24] Beckmerhagen A. Die essential facilities doctrine im US-amerikanischen und europaischen Kartellrecht. Baden-Baden, 2002. S. 25. 407p.

[25] Federal Act of June 25, 1954, on Patents for Inventions // URL: http://www.wipo.int/wipolex/en/details.jsp?id=16802.

[26] Questionnaire on Exceptions and Limitations to Patent Rights: // URL: http://world-intellectual-property-organization.com/scp/en/exceptions/replies/suisse.html#Q9

[27] Patents Act, 1970 // URL: http://www.wipo.int/wipolex/ru/text.jsp?file_id=295102

[28] Chatterjee P. India: Balancing Public And Private Interests In The Intellectual Property Regime // URL: http://www.ip-watch.org/2012/09/18/india-balancing-public-and-private-interests-in-the-intellectual-property-regime/

[29] The text of the compulsory license // URL: http://www.ipab.tn.nic.in/223-2012.htm

[30] Natco vs. Bayer (controller of patents, 2012) case analysis // URL: http://www.academia.edu/6744000/Natco_vs._Bayer_Controller_of_Patents_2012_Case_Analysis.

[31] Novartis loses landmark India patent case on Glivec // URL: http://in.reuters.com/article/2013/04/01/india-drugs-patent-novartis-glivec-idINDEE93000920130401

[32] Hermann R.M. Novartis Before India's Supreme Court:

What's Really At Stake? // URL: http://www.ip-watch.org/2012/03/02/novartis-before-india%E2%80%99s-supreme-court-what%E2%80%99s-really-at-stake/

[33] Patent Act of Japan (Act No. 121 of 13 April 1959, as last amended by Act No. 16 of April 18, 2008) // URL: http://www.cas.go.jp/jp/seisaku/hourei/data/PA.pdf

[34] Wakui M. Intellectual Property Rights and Antimonopoly Act // URL: http://www.jftc.go.jp/eacpf/05/jicatext2/0907Ant.pdf

[35] On medicines: Law of Ukraine of 04.04.1996 p. № 123/96-BP. // URL: https://zakon.rada.gov.ua/ laws/show/123/96-%D0%B2%D1%80.

[36] On approval of the Procedure for granting by the Cabinet of Ministers of Ukraine permission to use a patented invention (utility model) or registered topography of an integrated circuit: Resolution of the Cabinet of Ministers of Ukraine from 14.01.2004 № 8 // URL:https://zakon.rada.gov.ua/laws/show/8-2004-%D0%BF#Text

[37] About the statement of the Procedure for granting by the Cabinet of Ministers of Ukraine of the permission for use of the patented invention (utility model) concerning a medicinal product: Resolution of the Cabinet of Ministers of Ukraine № 877 від 4.12.2013 // URL: https://zakon.rada.gov.ua/laws/show/877-2013-%D0%BF#Text

[38] On protection of rights to inventions and utility models: Law of Ukraine. URL:https://zakon.rada.gov.ua/laws/show/3687-12#Text