Research on the pharmaceutical intellectual property protection and supervision of pharmacy administration

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Abstract: The patent system plays an important role in the pharmaceutical industry. In this paper, the authors analyze the pharmaceutical intellectual property protection and supervision of pharmacy administration. The intellectual property rights of drugs shall be granted to the inventor in accordance with the law, however, the pharmaceutical industry is concerned with the public health and social welfare. Therefore, we focus on the analysis of patent compulsory licensing system in the protection of intellectual property rights. Through case studies, we can see that although many countries do not implement compulsory licensing system, but this system still can become the chip for all countries to obtain authorization or reduce drug price.

Keywords: Pharmacy administration, intellectual property protection, drug industry.

INTRODUCTION

After the patent protection for the drugs developed by the market, the patent holder has exclusive rights to the drug, which has the right to manufacture, use, sell, transfer or license others to use the drug (Altorki *et al.,* 2016). It can be seen that the patent system plays an important role in the pharmaceutical industry (Dindo *et al.,* 2004; Ghoneum *et al.,* 2015). Research shows that, if there is no patent protection, 60% of drug discovery can not come out, there will be no use of 65%. The exclusive rights of drug patent holders to ensure their profits, stimulate the investment of drugs, and promote the innovation of the pharmaceutical industry (Hu, 2013; Cahill *et al.,* 2015; Bergmann *et al.,* 2016). The significance of drugs is mainly to save lives and improve public health. Encourage drug innovation, help to improve the health of the people. But in the pharmaceutical industry development at the same time, the drug patent developed by virtue of its exclusive and exclusive patent rights, get the drug monopoly in a certain time in the market, due to the high prices of patented drugs (Chen *et al.,* 2009). Especially in the event of certain public health incidents, the demand for the drug increased dramatically, the number of people who can get the drug greatly reduced. In other words, the pharmaceutical patent protection and drug industry development direction, the social significance of the drug itself. In such a situation, it is difficult to achieve the purpose of promoting the health of the whole people to save lives by the drug market.

The intellectual property right of drugs, namely, the patent system of medicine, is the core of the invention. Within the term of protection of the patent, the patent holder may not authorize the use of his patent for the purpose of production or business operation without the authorization of the patent owner (Liu, 2013; Qin, 2015). The implementation of this system, mainly in order to make the invention of the legitimate interests of the protection, so that the patentee can monopolize the market, to obtain the proper incentive report, the creation of enthusiasm and creativity, and promote the patentee to incorporate the new technology into productivity, to create wealth. After the patent owner gets the return and the income, the funds and conditions are studied again to form a benign development (Shim *et al.,* 2010; Tsiaras *et al.,* 2016). However, the pharmaceutical industry is also involved in the public health and social welfare, the development of the pharmaceutical industry is the need to give intellectual property protection of drugs, which is a problem worthy of study (Xuan, 2015). Many countries in the early patent system is not included in the scope of patent protection, the main reason is because of the specificity of drug use, should not be granted market monopoly, so as not to affect public health.

MATERIALS AND METHODS

Intellectual property protection

The intellectual property right of drugs, namely, the patent system of medicine, is the core of the invention. Within the term of protection of the patent, the patent holder may not authorize the use of his patent for the purpose of production or business operation without the authorization of the patent owner. The implementation of this system, mainly in order to make the invention of the legitimate interests of the protection, so that the patentee can monopolize the market, to obtain the proper incentive report, the creation of enthusiasm and creativity, and promote the patentee to incorporate the new technology into productivity, to create wealth. After the patent owner gets the return and the income, the funds and conditions are studied again to form a benign development. However, the pharmaceutical industry is also involved in the public

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In the process of the development of the world intellectual property system, it has been debated whether to give the patent protection of drugs, but if the patent protection is given certain restrictions are also different opinions. Before the 1995 introduction of the "TRIPS agreement", each country can develop the patent system according to different conditions of its own, but if a member of the world trade organization, and must take the same level of protection of intellectual property. Because of this, the low level of science and technology of many drugs in order to join the WTO and the country has not yet developed the pharmaceutical industry to implement drug patent system. It is patent protection in the pharmaceutical industry to stimulate innovation at the same time, the patentee with patents give exclusive rights and the exclusive right to occupy a monopoly position in the pharmaceutical market, which leads to the high price of drug patent. To AIDS, for example, the global north and South countries because of their different development levels, people's rights and interests of medicine is also very different, but also affected the lives and health of people in developing countries and the least developed countries. Today, AIDS is not without drugs can be treated, since 1995, after the introduction of highly active antiretroviral drugs, the United States AIDS mortality rate dropped significantly. However, there are still more than 5 million of the world's AIDS patients can not get treatment and care. The main obstacle of AIDS treatment in science and technology is not developed developed drugs, but in the vast majority of patients can not burden, and even some really need patent medicines to patients because no cure and death. In other words, the patent protection of drugs reduces the availability of drugs. The accessibility of drugs here refers to the degree of difficulty in obtaining relevant drugs for the treatment of a disease. That is to say, people can afford the price of drugs, acceptable and safe and effective, and convenient access to medicines and related information.

Due to obvious conflict of right to health pharmaceutical patent the patent right and the drug consumers, according to the "International Convention on human rights" human rights standards, the implementation of intellectual property system of the right to health has brought negative influence. Because of the monopoly characteristics of the patent, the patent holder has the right to control the production and sale of drugs. Drugs are expensive because of patent protection, often exceeding the scope of payment of the poor, thereby affecting the development of people in poor countries and the treatment of the disease. Because the implementation of restrictive conditions attached to the patent, the patentee has the right to prevent others from getting drugs patent technology, what is more limited in poor countries and their people get the compulsory license in the default of the government. Driven by the interests of the patent, pharmaceutical investors will be the first to develop the market's most profitable drugs, rather than consider the needs of underdeveloped countries. The requirements of the grant of the patent is novel, but a similar drug efficacy and existing patent medicines are similar, are in the hands of a pharmaceutical enterprise, gradually leading to a patent drug production and sales concentrated in a small number of enterprises.

Patent compulsory licensing system

The compulsory license of patent is one of the restrictions imposed by law on the exclusive right of the patent holder. Refers to the patent administrative authorities of a country, under certain conditions, authorized by law to meet the statutory conditions of third people awarded the license, allowing the third application of patented technology, including production, sales, import law system and other relevant patent product patent way. At the same time, the beneficiary of the compulsory license is the license of the applicant is usually subject to a certain period of time or conditions, and users usually have to pay a certain amount of compensation to the patentee. The drug patent compulsory licensing system allows third party in without permission of the patentee under the condition of production, sale, import of drugs, drug prices for patented drugs is much lower than the common, which not only reduces the price of drugs, while increasing the availability of drugs for the benefit of more patients. Therefore, the patent licensing system is recognized as an effective way to solve the contradiction between patent protection and drug accessibility.

Law is the regulator of social relations, when there are two conflicts of interest, should play an active role in the law, to coordinate the balance between the two interests. Drug patent compulsory licensing system, whether it is to see the history of the development of the patent system from the vertical, or modern relevant international treaties and the national patent legislation from the horizontal, is in the use of legal means to coordinate the patent inventor (i.e., the patentee), and patent users (i.e., drug consumers). Coordinate the relationship between interests, they represent the monopoly interests of patentee and public health interests. The balance of interests is the core of modern patent legislation, and is also the starting point of patent compulsory licensing legislation or one of the following principles. In the process of patent legislation, how to balance the interests of patent monopoly and public interest? It is necessary to make trade-offs between the various interests to coordinate, which is another patent

compulsory license to follow the principles. Throughout the relevant international treaties and national legislation, we can find that the right is the main mechanism to solve the conflict of interest.

RESULTS

Analysis on legislation of compulsory licensing of pharmaceutical patents in related countries

At present, both developed and developing countries, drug patent compulsory license is "TRIPS agreement", the "Doha declaration", "TRIPS agreement with the sixth paragraph of the Doha Declaration on implementation of" the most important specification for the elastic. Different countries have different legislation on compulsory licensing of pharmaceutical patents, which reflects the interests and needs of different countries. The author selected the developed countries in the United States, Britain, Canada and developing countries in India to do the introduction of the relevant legislation. The reason to select the four countries, the main reason is the compulsory license for drug patents in hand, the four countries representing both developed and developing countries, is the pioneer and some typical legislation and their practice. Especially in India as a developing country, other economic and social environment and the strong contrast, however, the compulsory license system in science and technology, intellectual property protection and medicine, legislation and practice in India are leading and perfect, it has great significance to our country.

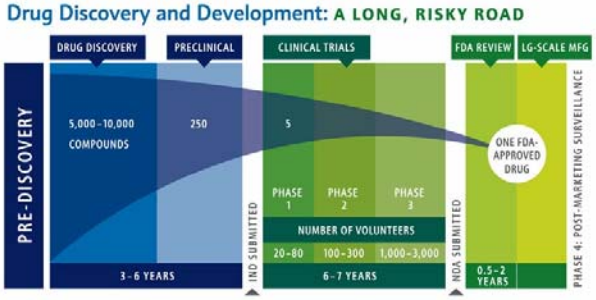

Fig. 1: Drug development process.

Canada: Canada from 1923 to 1993 signed the North American Free Trade Agreement for 70 years, the drugs are subject to special compulsory licensing system. 1935 to amend the patent law, the failure to implement the local patent, to issue a compulsory license to replace the revocation of the patent. At that time, the mandatory licensing of drugs is only required in domestic production, coupled with Canada's own market is limited, so that the number of cases of compulsory licensing less, drug patents are still firmly in the hands of a small number of people. With the rise in drug prices, the Canadian legislation in 1969 amended the compulsory licensing system for imported drugs. In 1987 Canada law (bill C-22), provisions of the compulsory licensing restrictions in the patent law to 7 years to 10 years, to Canada in 1993 through the C-91 bill to abolish drug licensing system, since Canada prices also rose rapidly. In 2005, Canada also amended its patent law, set up a "Canada drug in system" (Canadian Access to Medicines Regime), allowing Canadian generics factory manufacture and export patent medicines to occur public health crisis in the country.

Britain: The provisions of the compulsory licensing system is the earliest country promulgated "Regulations" UK Patent System in England as early as 1883 of the patent compulsory licensing provisions, the provisions of the contents of the legislation and the "Paris Convention" similar to that of the provisions in the presence of patent after the promulgation and implementation of the "no public demands are not reasonable to meet or exclude any person or the use of a new invention, can issue compulsory license. The current compulsory license is mainly concentrated in the 1977 British "patent law", the law within a certain period of time for granted patent implementation or full implementation, anyone can make the patent license to specific organs, and made detailed provisions on the subject. Of course, as a member of the European Community in China, the European court decision affect related legislation in britain. In order to connect with the "TRIPS agreement", "the patent law" was revised in 2004, especially on the part of the compulsory license made great adjustment, the patentee is divided into "WTO patents" and "non WTO patent", and give the distinction, apply different compulsory license.

United States: In the United States, such a patent, compulsory licensing and antitrust convergence. It does not stipulate the compulsory license in the patent law of the country, but it is stipulated in other laws of the country. In other words, the compulsory license is mainly when the patent holder's behavior limits the competition in violation of the anti-monopoly law, before being used. The legislation on compulsory licensing mainly includes "anti-monopoly law enforcement guidelines", "Sherman law", "the United States Code", "atomic energy law", "Clean Air Act" and some federal court cases. The legislation when the abuse of patent right, competition is limited, public health or other interests are threatened, the state in the public interest, protect the environment, have the right to patent (drugs) the implementation of the compulsory patent license, the patentee can through the specific way to obtain certain reasonable royalty. The United States of drug compulsory license and no systematic regulations, but in the event of public health crisis, set up a suitable system for emergency medicine, pharmaceutical unapproved pharmaceutical products have been approved or not approved by the use of emergency operation license.

Roche Global licensed therapy

In 2005 H1N1 influenza virus spread in the world, the WHO in 2005 revised "global influenza pandemic

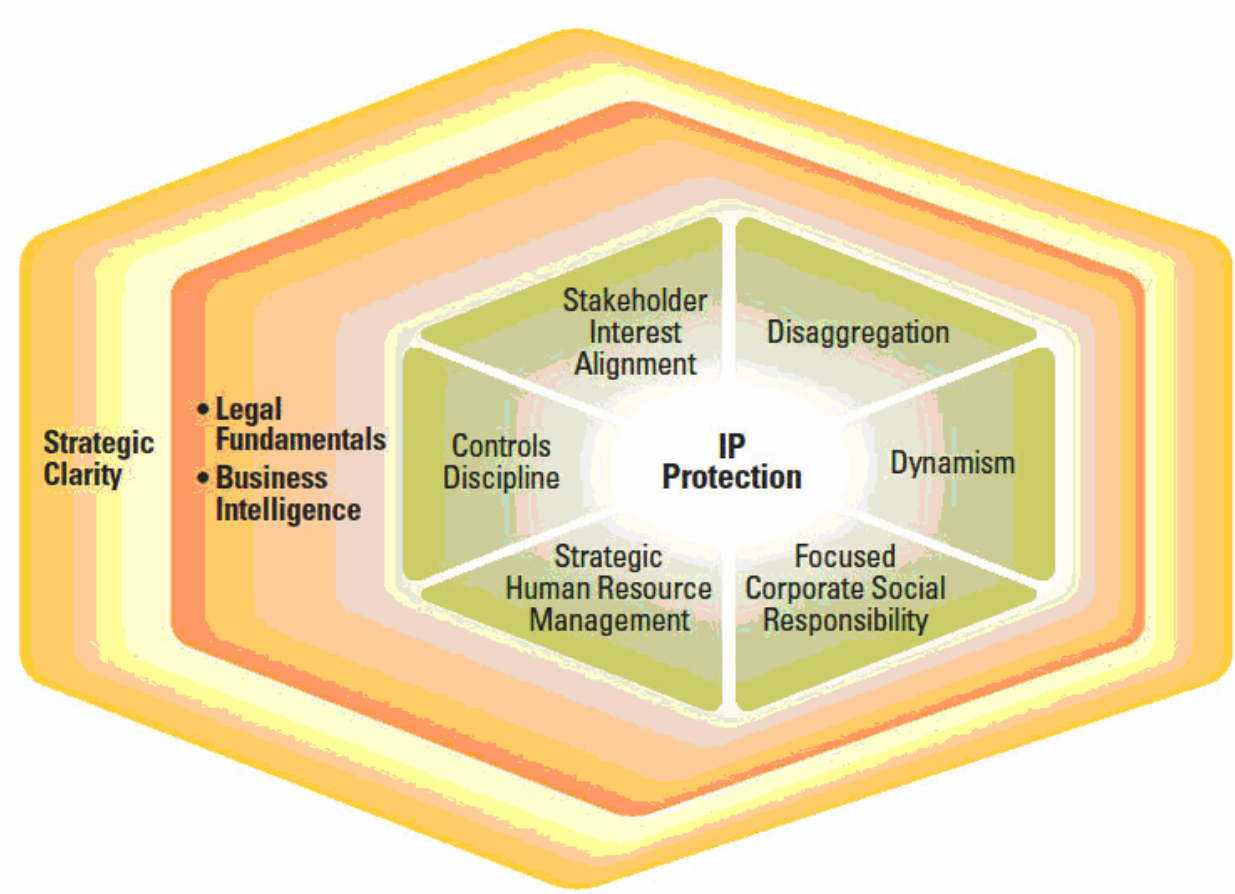

Fig.2: Intellectual property protection.

preparedness plan", from the beginning of January 2004, has been in line with the "global pandemic alert period" (pandemic alert period) third, proposed individual countries should assess the future "pandemic" period, whether they can adapt to antiviral agents. WHO also suggested that countries should be required to pre stockpile antiviral drugs. At that time, a stream of H1N1 virus has not been effectively spread between people, but the scope of the animal epidemic continues to expand and began to spread to humans. The prevention and treatment of Roche pharmaceutical production Tamiflu as recommended by the WHO and effective drugs, at the time the hot scenes, countries in order to cope with the crisis led to large accumulation of Tamiflu, Tamiflu in short supply. Because Roche is the world's only with the production of Tamiflu pharmaceutical patent pharmaceutical Group (which owns the Tamiflu patents and production rights to 2016), in the spread of influenza at the same time, many governments have asked Roche to give up its own patent.

Roche has always claimed that foreign Tamiflu production is very complex, the general pharmaceutical enterprises is difficult to grasp the technology, said the Tamiflu authorized the production of other enterprises is meaningless, and said it would strive to meet the global demand for Tamiflu. But at that time, WHO estimates, "Roche's current production capacity, about ten years of practice to produce the world's population of 20% people need Tamiflu". As Roche refused to authorize the licensing of other pharmaceutical companies to produce Tamiflu, many countries have decided to revoke the Tamiflu patent on the grounds of public health, that countries may impose compulsory licensing Tamiflu. Under pressure from all sides, Roche eventually changed its position, voluntary license for 9 countries around the world in 19 contract factory production of Tamiflu, China's Shanghai Pharmaceutical Group in December, 2005 has been officially licensed Tamiflu production license, have the right to produce generic Tamiflu. By the end of 2007 Roche's annual output of Tamiflu exceeded the global demand for Tamiflu, while also reducing the price of Tamiflu in various government procurement and low-income countries.

Through the analysis of the case, we can see that the patent compulsory license does not have to rely on the implementation of the drug can be effective, its role can also be made by the patent owner to make a voluntary license. In the case of Roche last voluntary authorization of 19 pharmaceutical companies Tamiflu production license global generic drugs, the drug supply response to

influenza a H1N1; at the same time to provide technical support to relevant information to inform the manufacturing of drugs, to promote the related pharmaceutical enterprises to raise the level of research and development.

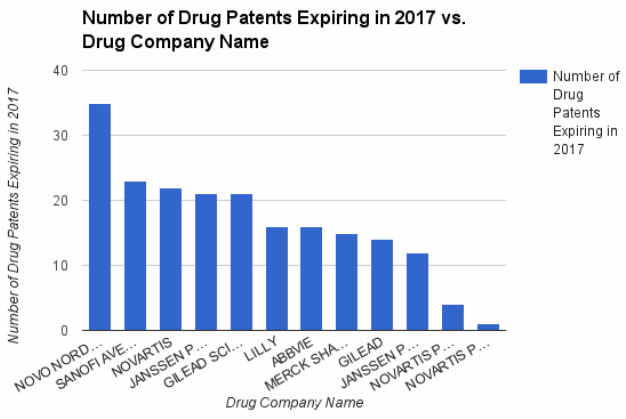

Fig. 3: Drug patent expiration 2017.

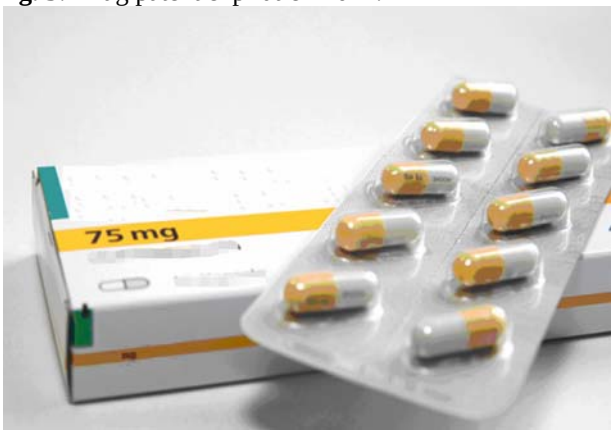

Fig.4: Tamiflu

Ciprofloxacin against anthrax virus

In 2001, the United States, Canada, anthrax outbreak occurred, and led to many deaths. Ciprofloxacin (generic name: Ciprofloxacin Hydrochloride tablets) proved to be effective against anthrax, but Germany's Bayer patented drugs, the drug in the United States is the only approved for treatment of anthrax virus drugs, the drug in the United States patent is valid until December 2003. The United States has a number of companies have copied the drug, but because the drug is still in the patent protection period, these generic requirements can only be listed after the expiry of the patent protection period. With the increase of the spread of the virus and the demand of Bayer Ciprofloxacin in short supply, high prices. The American public strongly requires the implementation of the suspension of the patent right of Bayer company set, take measures to reduce the price to ensure the supply of drugs. According to the provisions of the domestic law of the United States, the United States government has the right to use the government without the patentee agree to authorize the third party to use the patent, the third party only need to pay compensation for the patentee the patentee has the right to require the payment of federal court proceedings "unreasonable compensation". The United States also had the conditions for compulsory licensing, but after weighing the U.S. Department of health and human services tend to simply negotiate with Bayer to reduce drug prices. The United States requires Bayer to reduce the price of Ciprofloxacin to $1 / piece, or the United States will start the emergency provisions to purchase cheaper generic drugs.

Under the compulsory license of deterrence, Bayer negotiated in the United States Department of health and human services, finally reached an agreement, agreed to $0.95 / piece price to the U.S. government to provide 3 million pieces of Ciprofloxacin to the hardness of the anthrax crisis. Prior to this, the retail price of 5~7$, the U.S. government's purchase price is $1.77. Canada Ciprofloxacin after compulsory licensing, Bayer company to protest against the government of Canada, Canada that the compulsory license suspension of patent infringement, will reduce the enthusiasm of pharmaceutical enterprises, while Bayer also persuaded other generics listed companies. All kinds of pressure across Canada, the Ministry of Health announced the respect of Bayer patent on Ciprofloxacin in October 2001, and reached agreement with Bayer, Canada provisions can only buy drugs in the treatment of anthrax from Bayer, the purchase price is $0.95 per piece, Bayer Canada will ensure a continuous supply of drugs to cope with anthrax spread.

DISCUSSION

Most of the countries in the world in the field of intellectual property rights, including copyright, trademark or patent areas are almost no compulsory licensing measures. Although some countries in the domestic legislation provides a compulsory license system, but it is often limited to the strict conditions, practice is rarely taken, such as Canada issued a compulsory license Ciprofloxacin case. Through the "Roche authorized to treat H1N1 case can be drawn, although rarely initiated the system of compulsory license, compulsory license but usually by another way to play the role of deterrence has become a drug for the authorization or reduce drug prices and related pharmaceutical enterprise talks -- not as objective, but a this also means, and in recent years to protect the global importance of patent rights are closely linked. "TRIPS agreement" after decades of negotiations and compromise between developing countries and developed countries, the compulsory license for drug patents has been a relatively perfect legal framework, the previous paper has also done a special exposition. But the drug patent compulsory license one of the outstanding problems, we have already mentioned, is the specific scope of drugs involved in drug patent licensing, the disease is always hold an evasive attitude, "TRIPS agreement", "the implementation of the

resolution on" drug coverage provisions are not clear, the "public health" and "an emergency" compulsory license execution conditions, there are no uniform provisions. Due to the different economic technology, health care and understanding, make compulsory licensing related provisions and interpretation vary greatly, resulting in various countries especially the developed countries and developing countries in the implementation of compulsory licensing standards differences. For example, India, Thailand as the representative of the developing countries as heart disease, diabetes and drug treatment of diseases included some public health problems involved in their own medicine; while the United States is that it does not comply with the "TRIPS agreement" in detail; the EU recommendations listed a list of the important public health problems.

In this way, some countries, especially developing countries, even in the legal system in the pharmaceutical patent compulsory license system, does not mean that the real use of the system to deal with the actual problems. Compulsory licensing of drugs requires more skill and judgment in the absence of clear legal standards, especially in developing and least developed countries. Patent protection balance the patent compulsory license system and public health benefits, improve the positive role of drug accessibility is recognized, but the lack of relevant drug patent compulsory license standard is one of the main causes of differences between developed and developing countries. In another aspect, the drug patent compulsory license are the countries concerned in order to solve the public health crisis facing the country and take on the drug patent restrictions, it will infringe the interests of the patentee. Today, drug research and development is basically controlled by several multinational pharmaceutical companies in developed countries in Europe and the United States, the development of Chinese furniture has a certain number of R & D capabilities only a few, China is one of them. The difference of the level of drug patent technology and the standard of the global protection of intellectual property rights make the conflict between the developed countries and the developing countries on the patent protection of drugs.

CONCLUSION

The drug patent compulsory license system is to balance the patent right of private rights and interests of the public health system, it focuses on the protection of public interests and share the medical advances of violations of the legitimate private rights, therefore, drug patent compulsory license must be established in the necessary circumstances, be legal, reasonable, implementation of this right in legislation to force expressly limits the compulsory license expressly authorized person is the beneficiary of the obligation, such as compensation fees, patent transfer restrictions and other aspects of the problem. We know that the drug patent compulsory license is in an emergency public health crisis, the emergency most are sudden and difficult or unpredictable, that is to say the implementation of compulsory license for drug patents are often accompanied by the urgency and the lag of. This requires us to fully prepare for the public crisis. At present, China's legislation on public crisis response mechanism, drug development and other aspects of the lack of. Coupled with the administrative and judicial division of labor is not careful, it is easy to have the right to have no matter whether the phenomenon, which is also an important aspect of the preparation of public health crisis.

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