

Necessity of Implementing Pharmaceutical Patent Linkage System in China

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Abstract

Pharmaceutical patent linkage system is a result of balancing the interests of the original pharmaceutical manufacturers, generic drugs manufacturers and the public, and without infringing upon the patent rights of the original patented drug, its main purpose is to make the generic drugs on sale as soon as possible. At present, domestic scholars mostly focus on the macro level of pharmaceutical patent linkage system, and rarely analyze the reasons and necessity of implementing pharmaceutical patent linkage system from the actual situation of China. On the basis of the existing research, summary the key to the successfully implementing pharmaceutical patent linkage system in the United States, and according to the experience of the developed countries and the actual conditions of China, analyze the necessity of implementing pharmaceutical patent linkage system, and give suggestions, which is very important in science and practice.

Keywords: pharmaceutical patent linkage system, generic drugs, the original patented drugs, stakeholders

1. Introduction

As a knowledge concentrated industry, the development of pharmacy is inseparable from the protection of patent system. Although the protection of patent gives the original patented drugs for fixed monopolistic time on the market to compensate for the cost of its research, it has also created the high price of the original patented drugs, which imperceptibly leads to the contradiction between the patent system and the right to public health. Therefore, at present, the development of generic drugs has become an effective way to solve problems of public health. On the basis of respecting the patent rights of drugs, pharmaceutical patent linkage system is to speed up the process that generic drugs come into the market by reducing the infringement risk of generic drugs, and then breaks the situation of the monopoly market of the original patented drugs, which will do good to regulate the price of drugs and improve the accessibility of the public to the drugs.

In February 4, 2016, the Trans-Pacific Partnership Agreement (TPP) was formally signed in Oakland, New Zealand. The agreement clearly stipulates that the 12 TPP countries should establish pharmaceutical patent linkage system in the process of approving registration of generic drugs. Although China is not one of the TPP negotiators, there is no obligation to establish pharmaceutical patent linkage system, but it can be seen that the establishment of pharmaceutical patent linkage system has become a global trend. In October 2017, the General Office of the CPC Central Committee and the General office of the State Council issued the opinion which explicitly proposed to explore the establishment of pharmaceutical patent linkage system. At present, although provisions for drug registration in China has been revised many times with the theme of pharmaceutical patent linkage, it is still in the stage of exploration and improvement, and there are still many problems in practice, and the patent problems in the registration process of generic drugs are still outstanding. So, it can be said that there is no real pharmaceutical patent linkage in our country. Because of the lack of a perfect pharmaceutical patent linkage system, when some generic drugs whose original patented drugs are still in the patent term have been on sale, it can result in a series of patent disputes. Therefore, under the above international and domestic background, it is urgent to discuss the necessity of implementing pharmaceutical patent linkage system in China and its specific operation scheme.

In recent years, domestic scholars have paid much attention to the construction of pharmaceutical patent linkage system in China, and most of them are focused on the introduction of pharmaceutical patent linkage system in developed countries, the comparison of pharmaceutical patent linkage system in China and developed countries, the improvement of China's system and so on. However, most of these studies are focused on the macro level, and a few have a profound analysis of the reasons and necessity of implementing pharmaceutical patent linkage system from the actual situation of our country. On the basis of the existing research, this paper summarizes the key to the successful implementation of pharmaceutical patent linkage system in the United States, and according to the experience of the developed countries' pharmaceutical patent linkage systems and the actual situation of our country, analyses the necessity of implementing pharmaceutical patent linkage system in China, and gives some suggestions on the operational level.

2. The meaning of pharmaceutical patent linkage system

The pharmaceutical patent linkage system originated in the United States. After the Hatch-Waxman Act passed

in 1984, the United States Congress made a detailed provision on patent rights of drugs in the registration and approval process, and it pointed out that the patent linkage referred to the “link” between the approval of the generic drugs on sale and the patent expiration of the original patented drugs, which meant that when the generic drugs would be registered, manufacturers should pay attention to the patent of drugs which had been on sale to avoid the risk of infringement. Up to now, although some countries have established pharmaceutical patent linkage system, the academic circles have not given a precise definition. Combined with the existing research and summarized the general views of most scholars, it is generally believed that the system refers to that the registration of generic drugs should consider whether or not their applications infringe the patent of the drugs that are on sale, which can avoid the infringement and further loss.

3. The key to the pharmaceutical patent linkage system

The key to the pharmaceutical patent linkage system is that the approved generic drugs can not infringe the patents of drugs that are on sale. In the case of American experience, the United States is the first country in the world to establish pharmaceutical patent linkage system, and when this country's pharmaceutical manufacturers submit ANDA (Abbreviated New Drug Application), they also should submit patent statements on the basis of the Orange Book. There have statements: without the existence of patents, expired patents, or the statement that generic drugs manufacturers promise that the generic drugs are sold after the patent is due, If generic drugs manufacturers make at least above one statement for each patent involved in a generic drug application, the ANDA application can enter the review stage smoothly. If the patent of the reference preparation contained in the Orange Book is valid, and the generic drugs manufacturers still want to make their drugs come into the market (considering that the generic drugs that they make do not infringe relevant patents or related patents are invalid), the patent holders may decide whether to sue the generic drugs manufacturers within 45 days after receiving the notice. In this stage, the US FDA will not approve the generic drugs for sale.

The system in the United States can make the ANDA whose involved patents do not exist or have expired go into the review stage directly, and at the same time, the ANDA that the generic drugs contained still want to be on the market in the patent term can have a legal way of approval. As long as the generic drugs manufacturers challenge patents successfully, the generic drugs can come into the market, and break the monopoly of the original patented drugs to gain huge profit.

The Hatch-Waxman Act is the basis for the establishment of pharmaceutical patent linkage system in the United States. Before the Hatch-Waxman Act, the United States had not formed a major industry of the generic drugs, but now, the United States not only has the largest industry of the original patented drugs in the world, but also the most developed industry of the generic drugs in the world, such as Mylan, Greenstone, Par Pharma, and so on. From the scale of the current Pharmacy in the United States, the implementation of the Hatch-Waxman Act is indeed successful. It balances the interests of the original pharmaceutical enterprises and the generic drugs enterprises, and also balances the interests between the original pharmaceutical enterprises and the public. In the United States, the result of implementing pharmaceutical patent linkage system is that the proportion of generic drugs to prescription rises from about 20% in 1985 to 83% in 2015. It can be said that generic drugs have become conventional drugs for the treatment of diseases in the United States, and are used almost in all treatment of diseases. In addition, IMS expects that compound annual rate of growth for the generic drugs in the U.S. will grow up to 9.1% over the next few years, and the sales expected will exceed \$110 billion by 2020. The development of generic drugs not only brings benefits to the pharmacy and the public, but also contributes to the medical insurance in the United States. In recent years, rate of economic growth in the United States has slowed down, and the country's medical expenditure is mainly by commercial insurance, and supplemented with the government healthcare. Therefore, based on this situation, the demand for low-cost generic drugs in the United States is increasing. With the development of the generic drugs industry, health system in the United States had saved about \$1 trillion and 700 billion from 2005 to 2014, greatly slowing the pressure on healthcare in the United States.

4. Necessity of implementing pharmaceutical patent linkage system in China

In the context of the absence of corresponding international obligations and the background of the domestic pharmacy mainly produced generic drugs, thus, whether China needs to implement pharmaceutical patent linkage system can only be based on its own actual needs. The implementation of pharmaceutical patent linkage system will inevitably affect many interests of related stakeholders, therefore, this paper analyzes the necessity of implementing pharmaceutical patent linkage system in China from four stakeholders that are the original pharmaceutical manufacturers, the generic drugs manufacturers, the public and the administrative departments of supervision.

4.1 The original pharmaceutical manufacturers

The research of new drugs need a lot of time and money, so the manufacturers need the support of government's

policies that can encourage their innovative enthusiasm, and pharmaceutical patent linkage system can be used as an incentive.

Once the manufacturers lose the protection of pharmaceutical patent linkage system, they can only use their own power to safeguard their patent rights. However, even if the infringement of generic drugs are investigated, they can not interfere with the review processes of the generic drugs, and only when the generic drugs are on the market can they safeguard their legal rights. However, after the establishment of pharmaceutical patent linkage system, if the first generic drugs want to submit registration applications, the manufacturers must notify the original pharmaceutical manufacturers and provide invalid patent or statements for no infringement. This procedure can enable the original pharmaceutical manufacturers to master the trend of the generic drugs on the market in time so as to plan the strategy of safeguarding legal rights as soon as possible to protect their own rights and interests. The pharmaceutical patent linkage system makes the original patented drugs able to know the threat of generic drugs in time, and make them do a good job of prevention and avoid further loss. It can be said that the pharmaceutical patent linkage system strengthens protection of intellectual property of drugs, and gives the original pharmaceutical manufacturers more profits.

4.2 The generic drugs manufacturers

The perfect pharmaceutical patent linkage system can effectively promote the development of the entire generic drugs industry.

First, reduce the risk of infringement of generic drugs manufacturers. If there is no pharmaceutical patent linkage system, the generic drugs manufacturers are likely to make their products come into the market without knowing whether or not they have infringed. Once generic drugs infringe the patent rights, generic drugs manufacturers are likely to be prosecuted for infringement, and then forced to stop production and sale, which would cause a series of undesirable outcomes. In addition, in the absence of patent challenge, generic drugs manufacturers will also risk making their drugs on the market, even if some generic drugs can be produced and sold, but if the final tort action is established, generic drugs manufacturers will pay the proceeds to the original pharmaceutical manufacturers for their infringement.

Second, promote the reform of generic drugs enterprises. At present, there are still many problems in China's generic drugs industry, such as low level of production, many generic drugs with inferior quality duplication and so on. Under the background of China's supply-side reform, the generic drugs industry needs to be reformed urgently. The pharmaceutical patent linkage system is equivalent to a "filter". On the one hand, it can make the products of strong generic drugs manufacturers on the market in advance to let them occupy the market as soon as possible, on the other hand, prevent the generic drugs on sale that have not challenge the patents successfully, which can avoid further loss of the generic drugs manufacturers. Therefore, the pharmaceutical patent linkage system can optimize the structure of China's generic drugs industry, and effectively reduce the unnecessary risks and losses, and also promote the strong generic drugs manufacturers to expand the scale of the enterprises.

Nowadays, many strong foreign enterprises of generic drugs, such as TEVA, Ranbaxy, Mylan and so on, all have experienced the transformation, from making the active pharmaceutical ingredient or the generic drugs to the first generic drugs or the breakthrough drugs. At present, China also has appeared some excellent local enterprises. They constantly improve their ability, and expand the market overseas to enhance the international influence of Chinese pharmaceutical enterprises. However, because there is no perfect pharmaceutical patent linkage system and monopoly system of first generic drugs in China at present, once a few generic drugs manufacturers start challenge invalid patents and challenge successfully, other pharmaceutical enterprises often take the opportunity to "hitchhike", or even take up market ahead of the pharmaceutical enterprises that have challenged successfully. Therefore, most Chinese generic drugs manufacturers choose to wait or take a risk to make their drugs on the market. So, the pharmaceutical patent linkage system can give a new way to some strong generic drugs enterprises in China. It will help these enterprises to take up the market as soon as possible, expand the scale, and then achieve the goal of the transformation of the generic drugs industry in China.

4.3 The public

The pharmaceutical patent linkage system blocks the way that the generic drugs which are in the patent term come into the market rashly. Though the system may not change the influence of the original patented drugs for a moment, and the public still have to pay higher prices to get drugs, but as time goes on, the pharmaceutical patent linkage system can solve these problems in a balanced way. Monopoly system of the first generic drugs in the pharmaceutical patent linkage system can make the drugs market transform from monopoly of the original patented drugs into a favorable situation of the competition between the original patented drugs and the generic drugs, which can effectively control and reduce the price of the drugs and improve the drugs' accessibility to the public.

From the experience of the developed countries that have established the pharmaceutical patent linkage

system, monopoly system of the first generic drugs can significantly improve the speed of research for high-end generic drugs, and it makes it possible for the public to have a greater range of choice when buying drugs. However, the first generic drugs also threaten the market influence of the original patented drugs, and the monopoly of the original patented drugs has been broken, which makes the both kinds of drugs produce benign competition of the market, and improves the availability of drugs.

4.4 The administrative departments of supervision

At present, China has not yet established a perfect pharmaceutical patent linkage system, so it will be more difficult for administrative departments of supervision to review generic drugs. If those who enter the stage of review are not suspected of infringement, all things are well. Once they are suspected of infringement, the administrative departments of supervision will have a bad effect on how to do it. If the applications of suspected drugs are approved, after the drugs are on the market, it is likely to appear lawsuits about the infringement of generic drugs. If the related applications are not agreed, the administrative departments of supervision will be criticized by the public, because their behaviors affect the public's accessibility of drugs. Therefore, the pharmaceutical patent linkage system can make the registration of generic drugs transparent and controllable, and help the administrative departments of supervision to avoid some administrative risks arising from the review of generic drugs.

Through the above analysis, we can see that the perfect pharmaceutical patent linkage system can benefit the four stakeholders of the original pharmaceutical manufacturers, the generic drugs manufacturers, the public and the administrative departments of supervision. At the same time, the establishment of a perfect Pharmaceutical patent linkage system is a favorable measure to the supply-side reform of our country. Therefore, now, China needs to establish the pharmaceutical patent linkage system.

5. Suggestion for improvement

As a major power of generic drugs, the content of the existing pharmaceutical patent linkage system is not perfect. Through the above analysis, we can see that the good effect of the pharmaceutical patent linkage system is due to its perfect system. Combined with China's conditions, it is suggested to perfect the pharmaceutical patent linkage system from the following four aspects, so as to gradually establish a suitable pharmaceutical patent linkage system for China.

5.1 Perfect the registration and publicity system of drug patent information

Although the current provisions for drug registration stipulates the statement system of drugs patents, but the definition is too broad, so it can only remind the applicants to respect the patents, besides it can not play other substantive roles. Therefore, we should refine the system of patent registration, specify all the patents of new drugs and import drugs that can be registered, and also write the patent holders, the patent number, the date of authorization and so on. After the information is registered clearly, it should be uploaded to the information bank of drugs patents in time, which is for enquiries. In addition, an objection mechanism should be established to allow others to challenge the registration of patent holders. It is also necessary to specify the legal effect of the patent registration and the legal consequences arising from the lack of timely registration, which is to promote the patent holders to establish the consciousness of respecting patents and urge them to register in time.

To improve the registration and publicity system of drug patent information, it can not only make the generic drugs manufacturers understand the patents of drugs in time, which may prevent the occurrence of infringement, but also help the pharmaceutical manufacturers to select the imitated objects by public content of drugs patents, and improve efficiency of the whole pharmaceutical industry and then benefit the society and the public.

5.2 Establish a mechanism of programmatic linkage

The mechanism of programmatic linkage is the key to the whole pharmaceutical patent linkage system. This mechanism can make the generic drugs applications which are still want to be on the market in the patent term link the review of the generic drugs and the patent litigation through the system's a few own stages.

Therefore, our country can learn the experience of the United States and set up a query period that lasts 45 daies. It can allow the patent holders to have sufficient time to consider whether to prosecute the generic drugs applications that have statements of invalid patent or no infringement. For those who bring the lawsuits, we can set up the suspension period scientifically according to the trials' cycle of the patent cases in China, so as to make the majority of the lawsuits get the results in this period, and then show the rationality of the pharmaceutical patent linkage system.

5.3 Establish a linkage mechanism of relevant functional departments

China has not yet established a linkage mechanism between the supervision departments for drugs, the State

Intellectual Property Office and the courts. So, the linkage mechanism between the supervision departments for drugs and the patent management departments can be set up to ensure the smooth implementation of the pharmaceutical patent linkage system. To establish this mechanism, the first thing is to share resources. Only by sharing can all departments complement and cooperate with each other well. At the stage of patent examination, the supervision departments for drugs need the cooperation with the patent management departments to complete the examination of the patent statements; at the same time, the supervision departments for drugs should also cooperate with the patent management departments to provide relevant pharmaceutical expertise. In addition, the relevant sharing platforms of resources should be set up to share the knowledge and information in time so as to make the patent management departments and the supervision departments for drugs truly communicate regularly, which can achieve the optimal allocation of social resources.

5.4 Give the first generic drugs fixed monopolistic time on the market

The monopoly of the first generic drugs on the market refers to the fixed monopolistic time of the generic drugs that first challenge patent successfully, during this time other the same generic drugs will not be allowed to be on sale, which is to encourage them to challenge irrational patents and compensate for the loss in their litigations.

The monopoly system of the first generic drugs is an important part of the pharmaceutical patent linkage system in the United States. The system can not only solve the phenomena of injustice where generic drugs manufacturers challenge the patent successfully but other generic drugs manufacturers “hitchhiker”, but also effectively arouse the enthusiasm of the pharmaceutical manufacturers to challenge the patents. The system has undoubtedly become the “umbrella” of generic drugs manufacturers who first challenge the patents successfully. As for monopolistic time of the first generic drugs on the market in China, it should be based on China's actual conditions and a series of scientific research and demonstration. In addition, monopolistic time should be clearly defined to prevent the emergence of monopolistic behavior; and the supervision departments for drugs of our country should also improve the standards of examination and approval so that those generic drugs whose patents have expired or related patents are inexistent are eliminated as soon as possible by the market, and it can stimulate the enthusiasm of innovation of the generic drugs manufacturers.

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