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Chinese Legislation and Theoretical Basis for Patent Parallel Import: Consideration of Parallel Import of Pharmaceutical Patents During the Pandemic

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Abstract: The current Chinese Patent Law permits parallel import, but its theoretical basis is disputed. Neither the principle of domestic exhaustion of rights nor the principle of international exhaustion of rights can be used as the theoretical basis to support parallel import. Chinese legislation can set aside the traditional dispute between the principle of exhaustion of rights and the principle of territoriality, support parallel import in principle, and make exceptions in which parallel import can be prohibited if the parallel importer violates the contract or authorization agreement or conducts unfair competition to damage the legitimate rights and interests of the patentee or the consumer. The primary objective of legislation on parallel imports of pharmaceutical patented products should be better protection of public health. Permitting parallel import of patented medicine is of utmost significance to decrease the price of patented drugs and expand the accessibility of drugs. However, we should also prevent the import of fake and inferior goods. China should be cautious about permitting the parallel import of "repackaged" pharmaceutical patented products in legislation and law enforcement. Regarding administrative enforcement, the customs should set up special supervision authorities for patent import and export, and standardize the enforcement procedure for parallel import.

Keywords: Patent parallel import; Principle of exhaustion of rights; Pharmaceutical patents; Customs

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1. Introduction

Parallel import has always been the focus of international intellectual property trade practice and has long been a contentious legal issue in the academia of international trade law and intellectual property law. Meanwhile, there are some blind spots in the enforcement of intellectual property border protection for parallel imports. Owing to the COVID-19 outbreak, the public health crisis has reemerged as the frontrunner. As a crucial legal weapon to handle the public health crisis, compulsory licensing of patent and parallel import systems has been highlighted again. South Africa calls for the full implementation of TRIPS Agreement flexibilities,

such as compulsory licensing and authorization of parallel imports, in response. Countries like Vietnam are preparing to revise their intellectual property laws to permit parallel imports. Considering the external support, the implementation of the compulsory license system for medicine patents and the establishment of a parallel import system of patented drugs will assist in improving the accessibility of anti-epidemic drugs, thereby striving for more favorable opportunities and status for China to respond to international public health emergencies [1]. As compulsory licensing is a governmental action, it is likely to cause incongruities and disputes at the national level. Nevertheless, parallel import is commercial behavior and does not cause international disputes as long as it does not violate international treaties. Thus, using a parallel import system to handle public health crises has become the preferred path. However, the legal nature of patent parallel import and the rationality of a pertinent system in China have been debatable in theory and practice. This study reexamines the legality and theoretical basis of parallel import and presents reasonable suggestions to improve the relevant legislation and law enforcement in China, which will also provide a clear administrative enforcement basis for China's customs enforcement of intellectual property rights (IPRs).

2. Concept of patent parallel import

Parallel import, also known as the gray market, has no clear definition in domestic legislation and international conventions but has different expressions and definitions in theoretical bounds. Some studies claim that parallel import denotes importing intellectual property products sold in foreign markets by an intellectual property right holder or its authorized person into the home country without the permission of the intellectual property right owner of the home country, which the intellectual property rights of the products, such as copyright, patent, or trademark rights, are protected by the laws of the home country. This produces a parallel relationship between the importation of the right holder or its authorized person and the importation of others, hence called parallel import [2]. The definition highlights the parallel relationship. Some studies consider that parallel import implies the act or phenomenon of importing the products (or services) that are put on the market by or with the consent of the domestic intellectual property rights holder without authorization, or importing the intellectual property products (or services) that have homology with the rights of the domestic intellectual property rights holder [3]. This definition underlines the identity of products imported by others and products sold by the right holder, or the same identity of rights. Other studies claim that parallel import implies that an unauthorized importer of the home country buys goods from a foreign intellectual property owner and imports the goods into the home country without approval, and the intellectual property has been protected by the laws of the home country [4]; this definition is relatively straightforward.

This study argues that patent parallel import denotes the act when the same patent is granted and protected by law in different countries, an unauthorized importer of one country legally purchases the patented products from the foreign patentee or his licensee and imports the patented products into the country for sale without the permission of the patentee of the importing country. Patent parallel import might involve many parties, but the basic parties are the following three: the patentee or his licensee of the exporting country, the patentee or his licensee of the importing country, and the unauthorized importer (parallel importer).

Technology, labor, and other essential productive factors and their prices differ from one country to another. Besides, the patentee's pricing strategy in different countries, the changes in the international exchange rate, the government's control policies, and other factors lead to the apparent price difference of the same patented product in different countries. After purchasing products from a low-priced country and importing them to a high-priced country for sale, parallel importers can attain considerable profits; this is also a crucial reason for

patent parallel imports. In addition, with the development of economic globalization and the establishment of a multilateral trading system, trade barriers among countries are reduced gradually, markedly promoting the free flow of goods and technology in the world. All these create an evermore relaxed environment for international trade, including patent parallel import, making parallel import expand rapidly in the world.

3. The main theoretical divergence on the legality of patent parallel import

In international trade, the legality of patent parallel import is a debatable issue worldwide. The affirmative side and the opposing side support their own views mostly with the principle of exhaustion of rights and the principle of territoriality, respectively.

The foremost theoretical basis opposing parallel import patents is the principle of territoriality. The theory highlights that the intellectual property rights created according to the laws of different countries are independent of each other, and the patent rights are protected just by the laws of the country in which the patent is granted, while the application and efficacy of the patent right are only recognized within the scope of the country that has strict regional characteristics. Thus, parallel imports without the permission of the patentee of the importing country violate the legal rights of the patentee of the importing country. Meanwhile, the patent right becomes an independent right existing per the Patent Law of each country. The patent mark and trademark on the patent display the reputation of the patented product, which has different meanings in different countries and even has considerable differences. Especially when the patent right to use is transferred overseas, the patent licensee establishes an independent patent reputation on patented products through extra efforts from production to marketing. Such independent reputation of the patent right is the realistic basis of the principle of territoriality of a patent right. Undeniably, parallel import infringes the independent rights and interests of the patent licensee of the importing country.

Moreover, the opponents of parallel import contend that it harms the legitimate interests of consumers. As consumers are unclear about the patent parallel import trade and the gray market, they encounter trouble while choosing the same patented product with a noticeable price difference in the market. The after-sales service of parallel imported products is usually provided by the merchant, and the manufacturer does not provide the corresponding service and guarantee, which consumers typically do not know or notice this difference. Moreover, owing to differences in production technology and production standards among different countries, the quality of patented products produced by different manufacturers might differ even for the same patent. Thus, for products belonging to the same patent but from different sources, besides causing trouble in judgment and choice for consumers, it inevitably harms consumers if the quality of parallel imported products is, indeed, defective and there is no clear source identification. Furthermore, the dissatisfaction and disputes due to this negative consumption experience damage the good reputation of the domestic patentee in turn.

For those who support parallel imports, the main theoretical basis is the principle of exhaustion of rights. This theory proposes that once the patentee or patent licensee puts the patented products (including the products directly obtained by the patented method, the same below) into the market for the first time, the patentee no longer keeps control over the further circulation of these products, and his patent rights are exhausted. The patentee has no right to intervene or interfere with the further use or sale of the products after other people have acquired them legally. Consequently, patent parallel import is legal and does not infringe others' patent rights.

Supporters of parallel imports also highlight that parallel imports could promote domestic and international economic development. The reasons are as follows: (i) patent parallel import can promote the free circulation of related products in the international market, avert the patentee from abusing his rights and causing the artificial

segmentation of the international market, endorse the full utilization of global resources and international economic cooperation and development, and promote international trade liberalization. (ii) The competition between the parallel importer and the patentee in the importing country can prevent monopoly and promote market competition to some extent in the importing country [5]. In addition, parallel imports can provide consumers in importing countries with more and cheaper consumption options. As parallel importers usually do not need to spend on production inventory, manufacturer's after-sales service, advertising, and public relations, the prices of parallel imported goods are much cheaper, thereby bringing more benefits to consumers [6]. (iii) Regarding public health, many patented medicines are prohibitively expensive and put out of reach for patient consumers. If drugs are attained through parallel import channels, the economic pressure on consumers to purchase drugs can be reduced markedly, public health needs can be met, and social burden due to public health problems can be effectively alleviated, and public welfare can be improved.

4. The provisions of Chinese Patent Law and the flaws of the applied theory

The provisions in Paragraph 1 of Article 75 of the newly revised Chinese Patent Law on October 17, 2020, align with the provisions of the Patent Law before the revision (before the amendment, the provisions were under Article 69). That is, where any other person uses, offers to sell, sells, or imports patented products or products directly obtained by the patented process after the sale by the patentee or any entity or individual authorized by the patentee, it shall not be deemed to infringe the patent right. The provision clarifies that Chinese Patent Law permits parallel imports. Meanwhile, this provision also considers that China has recognized the international principle of exhaustion of rights [1,7-8]. After fully considering the real situation of Chinese-patented technology development and the import demand for foreign technologies, legislators hold that the importation of patented products after they have been sold to the market through legitimate channels should not be regarded as infringement; this is equivalent to recognizing that the scope of validity of "exhaustion of patent rights" should be "international exhaustion" [9]. As per the "Guide to the Third Amendment to the Patent Law" published by the Department of Treaty and Law, China National Intellectual Property Administration in 2009, the scope of the first sale of the patented products comprises both the first sale within China and the first sale outside China, which shows that Chinese Patent Law applies the principle of international exhaustion of rights on parallel imports [10].

The principle of exhaustion of rights is the key theoretical basis for supporting parallel import. The principle of exhaustion of rights can be further subdivided into two different views. The first view assumes that once the patentee puts the patented product into the market of a country for the first time or authorizes others to do so, the exhaustion of rights is only within the scope of that country; this view is also called the principle of domestic exhaustion of rights. The second view posits that when the patentee or authorized parties introduce patented products into the market of a country for the first time, the patent rights become exhausted worldwide; this view is also called the principle of international exhaustion of rights. As for whether the principle of exhaustion of patent rights should be applied internationally, developing countries and developed countries take quite different stands [11]. Moreover, the practice of regional exhaustion of rights still exists in some regions. That is, once the patentee himself or authorizes others to put the patented products into the market in a certain region, his patent rights are exhausted within the scope of the region. This proposition is mostly reflected in the legislation and practice of the European Union and the North American Free Trade Area. This study argues that the principle of regional exhaustion of rights and the principle of international exhaustion of rights are, indeed, the same origin, both of which break through the regional scope of a country and are essentially the same

theoretical propositions.

No provision in this agreement can be invoked to address the problem of exhaustion of intellectual property rights with the settlement of trade disputes per the national treatment and most-favored-nation treatment provisions of the TRIPS Agreement [12]. This provision is in effect a tacit admission that member states can regulate the exhaustion of intellectual property rights themselves. Subsequently, Article 5 (d) of the Doha Declaration on the TRIPS Agreement and Public Health further stipulates that, based on observing the principle of nondiscrimination in TRIPS, each member is free and undisturbed to establish its own legal system of exhaustion of rights [13]. This provision further elucidates the freedom and flexibility of member states to establish their regimes for the exhaustion of intellectual property rights. Some foreign studies have reported that such flexibility is vital because the right exhaustion system of a member state determines whether it can legally participate in the parallel import of patented products. Member states could adopt different claims of exhaustion of patent rights, domestic exhaustion, regional exhaustion, or international exhaustion; however, the claim of international exhaustion is most beneficial to parallel imports [14]. This should also be the view of most scholars. In an international exhaustion system, a right owner cannot prevent the importation of products embodying its IPRs so long as such products have been put legally on any foreign market (the subject includes not only natural persons but also enterprises or institutions).

However, the principle of exhaustion of rights is not an appropriate theoretical basis for indicating parallel import legitimacy, whether it is domestic exhaustion of patent rights or international exhaustion of patent rights.

4.1. The notion of "international exhaustion of patent rights" is inherently wrong or unscientific

Apparently, territoriality is one of the basic characteristics of intellectual property; its basic meaning in patent rights is that great differences exist among Patent Laws of various countries, such as the object, content, scope, duration, and mode of protection are different. The patent rights granted according to different national laws are independent of each other. Thus, the application and validity of the patent right attained by the patent owner is only recognized in the country and does not automatically be recognized and protected in another country. Likewise, exhaustion of patent rights is only exhausted in the country that granted the patent rights, not necessarily exhausted in other countries. In summary, the principle of territoriality of patent rights comes first, followed by the principle of exhaustion of patent rights in terms of legal rank. Exhaustion of rights is only the exhaustion of the rights of the patentee to the products that have been put into the market in the country where the patent right is granted [6].In other words, the exhaustion of patent rights is only valid within a country. The theory of "international exhaustion" of patent rights proposes to throw away the characteristic of territoriality of patent rights, which is untenable from the basic theory of the Patent Law.

4.2. The principle of domestic exhaustion of patent right cannot be used as the theoretical basis to support parallel import

As mentioned earlier, patent parallel import denotes the behavior when a patent is granted and protected by law in two or more countries, an unauthorized importer of one country legally purchases the patented products from a foreign patentee and imports the patented products into the country for sale without the permission of the patentee of the importing country. Parallel import primarily comprises three parties: foreign patentee (or his licensee), importing patentee (or his licensee), and unauthorized importer. Although the foreign patentee and the importing patentee hold the same patent for the same invention, there are usually three types of relations: (i) The two are not the same subject [15], completely independent of each other (this situation is relatively rare in the field of patent); (ii) the two are not the same subject but

related to each other, for example, the foreign patentee is the authorized user of the patent of the importing patentee, or *vice versa*; (3) the two are the identical subject, or have a substantially identical relationship, such as parent-subsidiary company or head office and branch offices. The "substantially identical relationship" is defined in the US Customs Statute as a "co-ownership or co-control" relationship between foreign intellectual property rights holders and domestic intellectual property rights holders. In the first case mentioned above, it is apparent that the principle of exhaustion of rights (domestic exhaustion) makes it difficult to interpret the legality of parallel imports. When a foreign patentee sells patented products, the patent rights in the country where the rights are granted become exhausted. For another unrelated entity, the patent rights of a patentee in the importing country will not be exhausted. Consequently, a patentee in the importing country has the right to prevent parallel import. In the second or third case, does the principle of exhaustion of rights apply? Our answer is "no" too. This is because the principle of intellectual property independence has always been considered a basic principle in the international law of intellectual property protection. Even if the foreign patentee and the importing patentee are the same subjects, the patent rights of the two countries are generated per the laws of different countries and their patented products have different reputations in different countries, therefore the patent rights acquired by the two countries are independent of each other. Thus, though holding the same patent, the exhaustion of patent rights of foreign patentees does not lead to the exhaustion of patent rights of importing patentees as the same subject. The decision of the importing country on whether parallel import is an infringement and thus whether to allow parallel import, does not and should not be based on the exhaustion of patent rights in foreign countries. Hence, the principle of exhaustion of rights (domestic exhaustion) cannot be applied to support the legality of parallel imports.

Briefly, neither the academic proposition of domestic exhaustion nor the academic proposition of international exhaustion of patent rights can apply the principle of exhaustion of rights to elucidate the legitimacy of parallel imports and take it as a theoretical weapon to support parallel imports. However, with the continuous development of world economic integration and legal integration, it is not ruled out that this principle could be applied in the future. But at least at the present stage, the principle of international exhaustion of patent rights cannot be applied to explicate and support parallel imports. Article 75 (originally Article 69) of Chinese Patent Law adopts the principle of international exhaustion, which is inappropriate. Even if China needs legislation to support parallel import based on its national conditions, the principle of international exhaustion of patent rights cannot be taken as a theoretical basis. At present, the practical and appropriate way of Chinese legislation is to abandon the dispute between the principle of territoriality and the principle of exhaustion of patent rights and support parallel import with certain restrictions. It is not advisable to completely permit parallel import.

5. Shortcomings of the provisions of Chinese laws on parallel import

Although the principle of exhaustion of rights cannot be used as the theoretical basis to support parallel import, in the era of economic globalization, China has established a legislative attitude of permitting parallel imports in its Patent Law in compliance with international development trends and its national conditions. However, despite supporting parallel imports, relevant legislations do not incorporate exceptions or specifically address parallel imports of patented pharmaceutical products, which is unreasonable.

5.1. Lack of restrictive provisions on infringement of the legitimate rights(interests) of patentees and consumers in relevant laws

Article 1 of the General Provisions of Chinese Patent Law clearly stipulates that the legislative purpose of the

Patent Law is to protect the legitimate rights and interests of patentees, encourage inventions and creations, promote the application of new inventions and creations, augment innovation capabilities, and promote scientific and technological progress and economic and social development [16]. The protection of the legitimate rights and interests of the patentee serves as the basis for other legislative purposes. Thus, any acting of any person, including parallel import, will not damage the legitimate rights and interests of the patentee.

Patent infringement denotes the illegal action of exploiting a patent without the patentee's authorization or counterfeiting a patent. Article 75 (1) of the newly revised Patent Law of China in 2020 states that any import of a patented product or product directly obtained by a patented process after sale by the patentee or any entity or individual authorized by the patentee will not be deemed as patent right infringement. As mentioned earlier, this provision aligns with Article 69 of the previous Chinese Patent Law. Although parallel imports are permitted before and after the amendment of Chinese Patent Law, it does not imply that parallel imports are absolutely legal, as parallel import comprises not only the infringement of the patentee's patent right but also the violation of other provisions of the patent law and other relevant laws, such as the Anti-Unfair Competition Law and the Anti-Monopoly Law, which are also an integral part of intellectual property protection.

Under the following conditions, parallel import would damage the legitimate rights and interests of Chinese patentees or their licensees and consumers. Furthermore, it might disrupt the standard market order in China.

(1) The parallel importer violates the contract or authorization agreement and damages the legitimate rights and interests of the patentee

If the patented products are prohibited in a specific area according to the terms of the patent sales contract, selling these patented products to that area by a parallel importer would violate the provisions. This action is clearly contrary to the subjective will of the patentee. Especially when "reverse repurchase" is still performed even when the patentee does not allow it. For instance, even though the market price in country B is relatively low, a Chinese patentee exports the patented product manufactured in China directly to country B for sale to tap into the market there or to differentiate markets based on the company's development strategy, and the sales contract stipulates that "reverse sale" of the patented products to the Chinese market is not allowed. However, some parties purchase the patented products in country B and sell them back to China. Such parallel import clearly goes against the original intention of the Chinese patentee to explore other markets or differentiate markets, which damages the legitimate rights and interests of the Chinese patentee, so it should be prohibited.

Moreover, if the patentee has granted an exclusive or sole license to exploit the patent to an enterprise in China when the patentee manufactures and sells the patented products in a foreign country, and the third party intends to import the products into China, could the exclusive or sole licensee in China request the customs to stop such import? According to the abovementioned legal provisions of Article 75 (1) of the newly revised Chinese Patent Law, parallel imports in this case are not considered infringement; thus, the customs cannot stop such import. Clearly, this is a flaw in Chinese patent legislation. As per the patent exclusive license contract, the patent licensee and patentee (namely the licensor) can manufacture, use, and sell the patented products in the Chinese market, and no other third party has the right to implement the patent. Moreover, according to the sole license contract, only the sole licensee can manufacture, use, and sell the patented product in the Chinese market, and neither the patentee nor any third party has the right to implement the patent. Nevertheless, according to Article 75 (1) of Chinese Patent Law, parallel importers can import the patented products and sell them in the Chinese market and their rights not only exceed those of authorized importers but also the

patentee, which is unacceptable. Such parallel import is explicitly prohibited in some countries, such as the United States [17]. Even when the domestic patent and the foreign patent are owned by the same entity, if a third party in the United States is granted the exclusive right to exploit the patent, so parallel imports can be prevented. The rationale provided by the United States courts is that, following the issuance of an exclusive license, the patentee is already prohibited from selling the patented products in the United States. Consequently, the individual purchasing (and importing into the United States for sale) the patented products cannot acquire rights over the patentee [18].

(2) The parallel importer conducts unfair competition and damages the legitimate rights and interests of the patentee or the consumer

Article 2 of the General Principles of Chinese Anti-Unfair Competition Law stipulates that in production and business activities, operators shall follow the principles of voluntariness, equality, fairness, and integrity, and abide by laws and business ethics [19]. This article is the general provision of the Chinese Anti-Unfair Competition Law and dominates other provisions of the Anti-Unfair Competition Law.

When a business operator competes with other operators by means that are illegal or contrary to the universally recognized business ethics to earn profits, which harms the legitimate rights and interests of other operators or consumers, it is called unfair competition. In the parallel import trade of patented products, the infringement behavior of parallel importers is more reflected as unfair competition, which damages the interests of other operators, primarily the interests of domestic patentees who compete directly with them in the market of importing countries. In parallel import trade, unfair competition chiefly manifests in the following situations.

The origin of the parallel imported patented products should be clearly displayed on the packaging of the products; however, the parallel importer does not do so, which causes confusion among the consumers. The second case is that there is a difference in quality between the product provided by the parallel importer and the product of the domestic patentee in the importing country, but the difference is not clearly marked. The third case is that the product provided by the parallel importer differs from the product of the domestic patentee of the importing country in terms of service and warranty, but the difference is not explicitly indicated. In the fourth case, parallel importers engage in unfair practices by exploiting the brand reputation established by the patentee of the importing country. This includes actions like “free-riding” on the advertising and brand maintenance efforts of the domestic patentee, as well as behaviors that actively undermine the brand reputation of the importing country’s patentee. These behaviors listed above are distinctive unfair competition behaviors in parallel import trade activities. However, there is no explicit prohibition of these behaviors in Chinese legislation.

5.2. Lack of emphasis on the parallel import of pharmaceutical patented products in legislation

Pharmaceutical patented products are related to public life and health. To maintain public health, there are two aspects of pharmaceutical patented products that need to be addressed: The first aspect is to ensure the availability of pharmaceutical patented products, and the second aspect is to prevent the sale and import of fake and shoddy goods to avoid harming consumers’ lives and health.

Permitting parallel import by law is crucial to guarantee the availability of pharmaceutical patented products; however, it is necessary to prevent the entry of fake and shoddy commodities into the domestic market. Parallel import trade increases the opportunities for counterfeit and substandard products to enter the

market, thereby amplifying the health and safety risks for consumers [20]. In practice, patented products could be parallel imported after "repackaging." In some cases, to enter the market of another country, the products need to be repackaged to fulfill the requirements of the local language or customs. Several cases have emerged across Europe involving parallel imports of "repackaged" pharmaceutical products. In many cases, repackaged products not only include changes in language, size, and outer packaging but also change trademarks [21].

Chinese Patent Law permits the parallel import of patented products, which promotes the availability of pharmaceutical-patented products. However, the fact that parallel import trade may increase the risk of counterfeiting and substandard products entering the domestic market is overlooked.

6. Legislative attitudes that Chinese law should uphold and suggestions for improvement

In the era of economic globalization, based on the international development trend and its own development needs, China has established a legislative attitude of permitting parallel imports in its Patent Law. Nevertheless, the practice of permitting parallel imports is flawed. Thus, while supporting parallel import in principle, Chinese legislation needs to provide for exceptions.

6.1. Supporting patent parallel import

Although the principle of exhaustion of rights cannot be used as a theoretical basis to support parallel import, Chinese Patent Law should still adhere to the legislative attitude of permitting parallel import. Normally, the inventor will be the one who applies for a patent and becomes the owner of the patent right. Thus, the patentee of the same patent in different countries is usually the same person, unless the patent right has been transferred. This differs from a trademark because the owners of the same trademark in different countries can be the same person or different person. Moreover, the trademark can be owned by many people because the trademark could be rush registered overseas; another case is that a multinational company designates different applicants for registration in different countries based on its business strategy. When the patentee is the same person, it is easier for the right holder to regulate the production, publicity, sales, service, and other links of the product. Even if the products are produced or manufactured in different countries, the quality and service are essentially the same. Thus, parallel imports of patented products will not harm consumers in the importing country. By permitting parallel import, the patented products with guaranteed quality and competitive price can be imported into the domestic market, which not only brings increasingly affordable choices to the consumers of the importing country but also breaks the monopoly of the patentee on the domestic market and promotes competition.

International intellectual property conventions, including the Paris Convention and TRIPS Agreement, do not explicitly regulate the issue of parallel imports, leaving the legality of parallel imports to each member to decide by themselves. Currently, each country has different legislative provisions. As a developing country, although the number of domestic patent applications has been rising, China is still far from ideal in terms of intellectual property rights. While most economists would agree that having intellectual property protection is necessary, this does not mean that the stronger the protection the better the outcome [22]. Based on the needs of Chinese national conditions, while protecting the intellectual property rights of the patentee, China explicitly stipulates in the Patent Law that parallel imports are permitted, which is a correct approach per the needs of China's national and social interests at the present stage.

6.2. Prohibiting acts that infringe legitimate rights and interests of patentees and consumers

Various infringements of patent rights through parallel import mentioned in **Section 5.1** will not only damage the legitimate rights and interests of the patentee and consumers but also disrupt the normal market competition order in China, which hampers the development of the Chinese market economy. Although intellectual property law belongs to private law, which focuses on protecting the private interests of intellectual property owners, Anti-Unfair Competition Law belongs to public law, which focuses on encouraging and protecting fair competition; however, the two belong to the same way in promoting the healthy development of the market economy. Chinese Patent Law does not make any restrictive or prohibitive provisions regarding the abovementioned infringements in parallel imports. In the enumerative provisions on "anti-unfair competition acts" in Chapter II of Chinese Anti-Unfair Competition Law, except for behavior that causes confusion by the parallel importers, which might fall into Article 6(4) of this chapter "behaviors that might cause the consumers to associate the product with another product," the other clauses of this chapter do not address infringements in parallel import trade, so there are no regulations on these infringements in Chinese Anti-Unfair Competition Law. Despite having a general clause, such as Article 2 of the Anti-Unfair Competition Law, which states that "managers should be honest in their production and business activities and follow the law and business ethics," its application remains unclear, which may lead to disputes in actual practices. Such a lack of legislation directly affects administrative law enforcement, resulting in the lack of law enforcement. About the infringements mentioned in **Section 5.1.**, the customs have no basis for law enforcement, leading to the entry of parallel imported goods that might harm the rights of domestic patentees or consumers. Thus, to address this issue, we should first make clear prohibitive provisions in Chinese Patent Law. The deficiencies of Patent Law should be covered by Anti-Unfair Competition Law. Generally, Intellectual Property Law is superior to Anti-Unfair Competition Law. Intellectual Property Law is more specialized while Anti-Unfair Competition Law is more general. For example, Chinese Patent Law should provide clear rules that prohibit the act of selling the products back to China after purchasing them from another country. If the patentee has signed an exclusive or sole license contract with others in the Chinese market, parallel import should be prohibited. This necessary legislative restriction can protect the patentee from rights infringement.

6.3. Prioritizing the protection of public health in the parallel import of pharmaceutical patented products

Intellectual property rights are private rights that are owned by a group of people, while human rights are universal. Thus, conflicts between the two rights are inevitable, especially under the framework of the TRIPS Agreement. Concretely, intellectual property rights conflict with health rights, the right to development, and cultural rights [11]. This is because patented drugs and patented medical devices are a vital field of patented products, but they are also related to public health issues. Several international organizations including the World Trade Organization (WTO) pay great attention to the accessibility of medicines in public health issues and highlight that sovereign states can play a more crucial role in safeguarding public health protection by formulating their own policies and laws [13].

Although China has made great progress in terms of medical research, its pharmaceutical intellectual property rights are still backward compared to other countries. The country is also highly dependent on imported pharmaceutical patented products. As shown in **Figure 1**[23], the amount of imported pharmaceuticals in China has been increasing from 2014 to 2020. In this case, permitting parallel import by law can enable China to access patented pharmaceutical products at a lower price rather than paying high licensing fees. Besides, it averts the risk of rights abuse by rights holders in international patent trade to some extent. Many

countries experienced limitations in medicines and medical supplies during the COVID-19 pandemic. Even China faced severe shortages in the early days of the outbreak and needed support from abroad. Donations and imports of medical supplies from overseas played a crucial role in controlling the outbreak. As revealed in **Figure 1**, Chinese pharmaceutical imports in 2020 reached 220,000 tons, with a significant annual growth of 38.9%. The pandemic has reminded us once again how crucial it is to allow parallel imports of patented medicines, especially for developing countries like China. Parallel import of patented drugs has decreased the price of patented drugs in various countries, which in turn improved the accessibility of drugs and controlled the spread of diseases [24]. Thus, regardless of how the Patent Law is amended, Chinese legislation should insist on supporting the parallel import of patented drugs, medical devices, and other supplies.

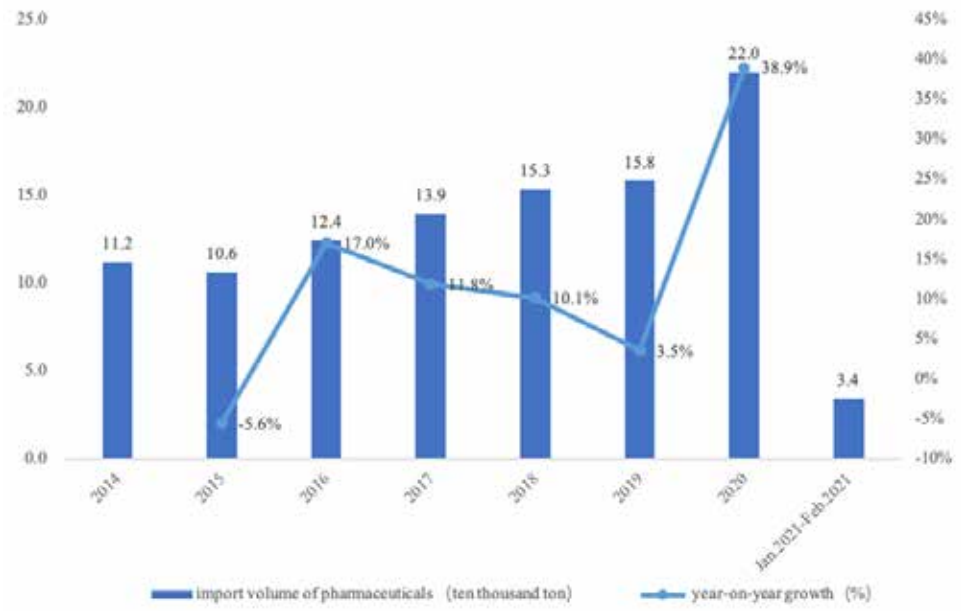

Figure 1. Amount and growth rate of Chinese pharmaceutical imports from 2014 to 2020 (Data source: General Administration of Customs of China, organized by Forward Looking Industry Research Institute)

Although Chinese legislation should encourage the parallel import of patented drugs and medical devices, it is essential to establish a special medical patent regulatory agency in the national patent administrative department. By doing so, the State can timely comprehend the demand for pharmaceutical products based on the health status of the country and various regions, assess the impact of medical patent rights on public health, and carry out necessary supervision on the parallel import trade of patented pharmaceutical products. Meanwhile, corresponding rights-responsibility mechanisms should be established to elucidate the rights and responsibilities of the regulatory agency throughout the entire process starting from identifying patent rights that may impede public health to overseeing parallel import trade. This is essential to ensure the timeliness and legality of parallel import of pharmaceutical patented products.

In response to national pandemics such as AIDS and malaria, South Africa amended its Medicines and Related Substances Act in 1997 (Article 15[c]), which was implemented on 2 May 2003. A provision was added to Article 15 to allow parallel imports of medicines to ensure the supply of more affordable medicines. Not only does the legislation of South Africa support the parallel import of drugs explicitly but also some of its relevant practices are worth learning for China. For example, in South Africa, parallel importers of drugs must be authorized by the Minister of Health, and imported drugs must be registered. Furthermore, medicines must

be imported from companies or persons approved by the regulatory authorities to ensure that fake medicines do not take the opportunity to enter the South African market [14].

As for the parallel import of repackaged pharmaceutical patented products, because pharmaceutical products are related to life and death, and the issue of repackaging itself is complicated. Thus, whether parallel imports of repackaged pharmaceutical patented products can be permitted is debatable even in European countries that pursue European Union (EU) regional integration and apply the principle of "exhaustion" of intellectual property rights. The European Court of Justice has ruled on the principle of "objective necessity" on whether patented drugs can be repackaged and imported in parallel. However, the criterion of "objective necessity" is determined by the national courts of EU member states. Therefore, there might be a situation in which a court in a member state agrees with repackaging, while a court in another member state decides that there is no such need [23]. Therefore, China should be cautious about permitting parallel import of repackaged pharmaceutical patented products in its legislation. Even where legislation permits, law enforcement should be stricter to evade the entry of counterfeits and shoddy products that could damage the lives and health of Chinese consumers.

6.4. Establishing specialized law enforcement agencies at customs and standardizing law enforcement procedures for parallel import

Upon revising Chinese legislation, relevant law enforcement agencies and procedures should also be standardized. Imported patented products differ from ordinary commodities and other intellectual properties. Patented products may involve technical content and often suffer from hidden infringements. Since the imported products will need to go through customs, a professional law enforcement agency for the import and export of patent products should be established at customs. This agency should be equipped with experienced experts who are able to fortify the supervision and law enforcement of patent parallel imports. It is imperative to strengthen the personnel's understanding of Patent Law, Anti-Unfair Competition Law, and other laws, and enhance their knowledge on restricting or prohibiting parallel import of patented products under different circumstances. Secondly, it is necessary to standardize relevant law enforcement procedures and establish scientific and complete inspection and processing procedures. Parallel importers must provide the legitimacy certificate of the import of patented products and the provenance certificate of products, as well as the commodity quality inspection certificate issued by the authority. The customs should strengthen the inspection of the origin and quality of the parallel imported patented products, avoid confusion between the parallel imported patented products and the domestic patented products, and prevent counterfeits from posing as qualified patented products during customs clearance. Meanwhile, the crackdown on illegal activities in parallel imports should be intensified to protect the legitimate rights and interests of patentees and consumers. Finally, the administrative law enforcement resources for the parallel import of patented products should be coordinated and integrated. Besides, customs and other patent law enforcement authorities should be augmented to ensure the legitimacy of all circulation links of patented products from customs clearance to entry into the domestic market.

7. Conclusion

Patent parallel import has not only been a concern for scholars in the field of international trade law and intellectual property law for a long time but has also been a hot topic in the pharmaceutical industry and public health departments of various countries. The current patent laws in China permit parallel imports, but their theoretical basis remains dubious because neither the principle of domestic exhaustion nor the principle of international exhaustion of patent rights can be used as a theoretical weapon to support parallel imports

owing to the limitations of the theory itself. This study considers that the Chinese patent legislation can put aside the traditional dispute between the principle of exhaustion of rights and the principle of territoriality and support parallel import in principle. However, certain exceptions must be made, that is, the parallel import should be prohibited under the circumstances where the parallel importer violates the contractual agreement or authorization agreement or conducts an unfair competition, which would damage the legitimate rights and interests of the patentee or the consumer. Regarding the parallel import of pharmaceutical patented products, the protection of public health should be the primary consideration of Chinese Patent Law. Nevertheless, extra caution is needed for the parallel import of "repackaged" pharmaceutical patented products. Considering administrative enforcement, the customs should create a special supervision agency for patent import and export and standardize the enforcement procedure for parallel import.

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