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REVIEW

Review on the Implementation and Impact of the Comprehensive and Progressive Agreement for Trans-Pacific Partnership on China's Pharmaceutical Economy

Examen sobre la aplicación y el impacto del acuerdo integral y progresivo de asociación transpacífico sobre la economía farmacéutica de China

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ABSTRACT

Introduction: the 'Intellectual Property Rights' chapter of the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) sets high international standards for intellectual property rights (IPR) protection, particularly with regard to pharmaceutical patents. Even though some of the provisions are currently suspended, the stringent nature of these provisions poses undeniable challenges to member states, and likewise they have become an obstacle to China's IPR negotiations when joining the CPTPP.
Objective: analyze the CPTPP drug patent rules and their application in China's intellectual property law, evaluate the adaptability and challenges of China's drug patent protection system, and put forward suggestions for improving China's drug patent protection system through comparative research.
Method: a qualitative analysis This study is a qualitative theoretical study, using text research, comparative research, and case study methods. It tracks relevant research on pharmaceutical patents in the HeinOnline database, LexisNexis, WIPO database, and Cnki, and uses the China Judgment online to search for cases related to pharmaceutical patent disputes for a comprehensive analysis.
Results: a high-standard pharmaceutical patent protection system is characterized by four critical rules established in the CPTPP. China's current pharmaceutical patent laws largely meet the CPTPP's requirements. Despite this alignment, there are notable deficiencies in the legal implementation aspect.
Conclusion: while China's pharmaceutical patent laws are fundamentally compliant with CPTPP standards, further enhancements in legal implementation are necessary to mitigate potential risks associated with joining the agreement.

Keywords: CPTPP; Pharmaceutical Patent; Undisclosed Data Exclusivity; Patent Linkage System; Patent Compulsory Licensing.

RESUMEN

Introducción: el capítulo sobre "Derechos de propiedad intelectual" del Tratado Integral y Progresivo de Asociación Transpacífico (CPTPP) establece normas internacionales estrictas para la protección de los derechos de propiedad intelectual (DPI), en particular en lo que respecta a las patentes farmacéuticas. Si bien algunas de las disposiciones están actualmente suspendidas, su carácter estricto plantea desafíos innegables a los Estados miembros y, asimismo, se han convertido en un obstáculo para las negociaciones de China sobre DPI al unirse al CPTPP.
Objetivo: analizar las normas sobre patentes de medicamentos del CPTPP y su aplicación en la ley de

propiedad intelectual de China, y evaluar la idoneidad y los desafíos del sistema de protección de patentes de medicamentos de China. A través de investigaciones comparativas, se presentan sugerencias para mejorar el sistema de protección de patentes farmacéuticas de mi país.
Método: este estudio es un estudio teórico cualitativo que utiliza métodos de investigación de textos, investigación comparativa y estudio de casos. Realiza un seguimiento de la investigación relevante sobre patentes farmacéuticas en la base de datos HeinOnline, LexisNexis, la base de datos de la OMPI y Cnki, y utiliza China Judgment online para buscar casos relacionados con disputas de patentes farmacéuticas para un análisis exhaustivo.
Resultados: un sistema de protección de patentes farmacéuticas de alto estándar se caracteriza por cuatro reglas críticas establecidas en la CPTPP. Las leyes actuales de patentes farmacéuticas de China cumplen en gran medida los requisitos de la CPTPP. A pesar de este alineamiento, hay notables deficiencias en el aspecto de implementación legal.
Conclusión: aunque la ley de patentes farmacéuticas de China es básicamente consistente con las reglas del CPTPP, la ley aún necesita ser perfeccionada para que sea operativa. para reducir los riesgos potenciales de unirse al acuerdo.

Palabras clave: CPTPP; Patente farmacéutica; Exclusividad de Datos no Divulgados; Sistema de Vinculación de Patentes; Licencias Obligatorias de Patentes.

INTRODUCTION

The formation of 'Comprehensive and Progressive Agreement for Trans-Pacific Partnership, CPTPP' begins with its predecessor 'The Trans-Pacific Partnership , TPP. During the first decade of the 21st century. The international IP protection rules has entered the so-called Post-TRIPs era. It means that countries are subject to stricter IPR standards. Prior to this, the globally prevailing intellectual property standards were dependent on the TRIPs agreement of the WTO system. But as the WTO continued to develop and grow and leave US control, the TRIPs-plus provisions that favoured the fundamental interests of developed countries could not be promoted in this system. So, the then Obama administration created a new trade system to safeguard its interests by signing the TPP agreement. However, due to the subsequent Trump administration's "America First" trade philosophy, the U.S. withdrew from the TPP, preventing it from taking effect. As a result, Japan, which has the strongest economy among the remaining members of the TPP, began to push for a new negotiation, and the TPP was transformed into the CPTPP. Eventually, 11 countries signed the CPTPP agreement in Santiago. The agreement came into effect on 30 December 2018.

Also during this period, the TRIPs agreement, a globally accepted IP standard originally based on the WTO system, was gradually overtaken by TRIPs-plus provisions in various free trade agreements(FTAs). As of August 2023, there are 182 FTA-type trade agreements in force.[1] And since 2009, all FTAs have included IP provisions.[2] Some of these FTAs are called mega trade agreements because of the volume of trade or the presence of at least one core economic power; the CPTPP is currently the third largest mega trade agreement. The first and second are the 'Regional Comprehensive Economic Partnership Agreement (RCEP)' and the 'United States-Mexico-Canada Agreement (USMCA)', respectively. As far as IP rules are concerned, although the USMCA IP rules led by the United States have very high standards, their scope of application is limited to the United States, Canada and Mexico, and the standards are too high to be universally applicable. However, its scope of application is limited to the United States, Canada and Mexico, and the standard is too high to be universally applicable. RCEP covers a wide range of areas, and the trade volume is the largest in the world, but in order to balance the regional interests and the trade volume, the standard of intellectual property protection has been greatly reduced. Compared with the TRIPs Agreement, there is some progress, but it is mainly an expansion of advocacy and not mandatory. Thus, the CPTPP is the only mega FTA that has both strong protection features and regional applicability, and it represents a new trend in the international protection of IPRs.

The patent section is one of the most comprehensive and stringent provisions in IP chapter. And because pharmaceutical inventions are more complex and costly than other inventions, and because they involve the public interest, CPTPP has also established a special chapter to provide for them. It includes rules on the protection of secondary patents, patent term compensation rules, exclusivity of undisclosed experimental data, "Bolar" Exception Rule and the Patent Linkage System. Although most of them have been suspended, this does not mean that they will not come back into force in the future. With demand for products such as medicines and vaccines being greater than at any time in the context of the COVID-19 pandemic. It is therefore of great interest to assess whether the CPTPP rules on pharmaceutical patents will affect the ability of developing Member States to access essential medicines under the flexibilities of the TRIPs Agreement,

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and whether they will create additional barriers to access in the future.

More importantly, China is now actively negotiating, and the patent rules part is bound to be one of the focuses of the IP negotiations. In terms of China's situation, on the one hand, China is a big country of generic drugs, and 95 % of China's 90,000 drug approvals in 2022 will be for generic drugs. Generic medicines are the basic foundation for citizens' health protection. On the other hand, China has also made great progress in drug R&D, with 12 of the top 20 drug patent holders being Chinese companies in 2022.[3] Therefore, it is a challenge for China to innovate its patent law in order to meet the high standards and at the same time to take into account the interests of the originator drug companies and the generic drug companies, as well as the interests of the patent holders and the public health and safety.

Analysis and evaluation of the CPTPP rules on pharmaceutical patents

The CPTPP pharmaceutical patent rules are detailed and comprehensive and form a complete legal protection system. The system consists of four main parts of rules: secondary patent rules, rules on extension of the term of patent protection, mechanisms for early resolution of patent disputes, and rules on compulsory licensing restrictions. Among them, the extension of the term of protection is divided into: extension due to unreasonable shortening of time and indirect extension due to data exclusivity. The early resolution mechanism of patent disputes includes the "Bolar" exception rule and the patent linking system. (See figure1) The author will examine them one by one in the following paragraphs.

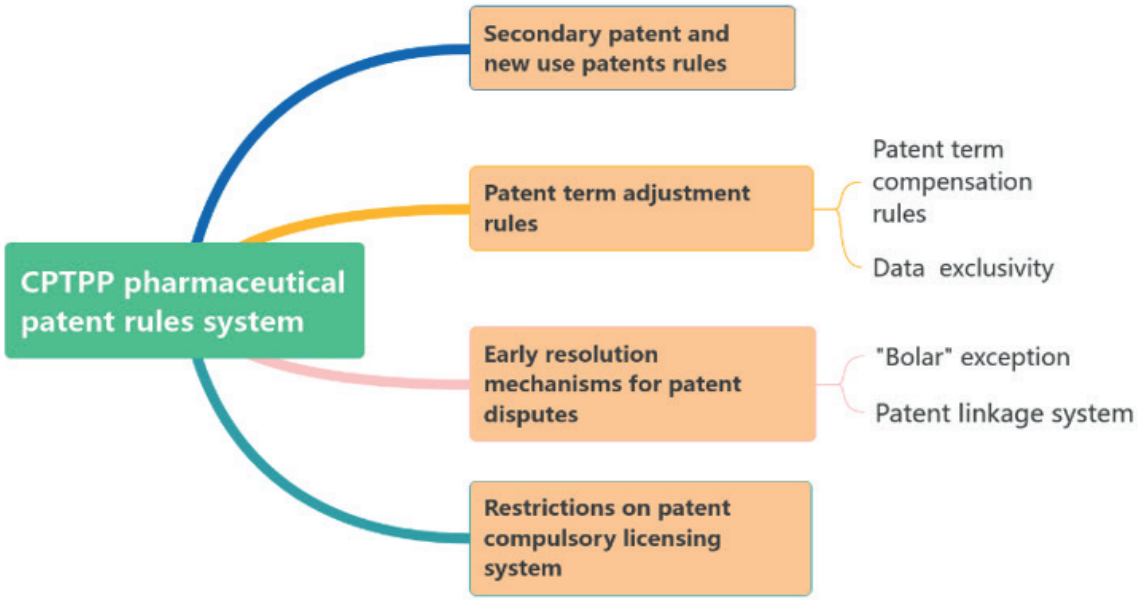

Figure 1. CPTPP Pharmaceutical patent rules system
Source: Summarized by the author in accordance with article 18.37(2), 18.46, 18.48, 18.50, 18.51, 18.53 and 18.6 of the CPTPP Agreement

The secondary patent and new use patents rules

Article 18.37(2) of the CPTPP extends the scope of patentability to new methods and processes for known products. Generally, for an invention to be considered novel, it must be new and not have been disclosed to the public prior to the date of the patent application. However, CPTPP considers that even if the product itself is not new, it can be patented if the use, method or process has been "modernised". This is known as "secondary patenting". Of course, this rule is not the first of its kind in the CPTPP, as the United States, Australia, Japan,, New Zealand and Canada, which are parties to the CPTPP, have stipulated secondary patent rules in their domestic laws based on the flexibility of TRIPs. Later, they were incorporated into the bilateral FATs promoted by the United States. The CPTPP is of interest as one of the few mega trade agreements to introduce this provision. This is because it has significant implications for pharmaceutical patents in the countries of the region. As long as the originator company can demonstrate that some improvement to the drug is a "new" use, method or process, they can apply for new patents on a minor improvement to the original product, even if those improvements do not significantly improve efficacy. Once the number of "new patents for improvements" grows, it is easy to form a "patent thicket ".[4] Based on the "patent thicket ",

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the original drug company can extend the patent protection period of the drug based on the thicket it owns, so that the drug can remain in a monopoly position in the market for a longer period of time and exclude the competition from other generic companies, and have the opportunity to save additional social costs, namely the cost of the delay in entry of generic competition.[5]

The antitrust class action lawsuit against AbbVie's drug Humira is the most representative example of this.[6] The plaintiffs , a group of purchasers and ultimate payers of Humira in the United States, alleged that AbbVie had filed numerous "sham" patents for Humira in order to maintain its monopoly on the drug, (Humira's underlying patented composition of matter patent expired on 31 December 2016. However, AbbVie filed 247 other patent applications relating to Humira, of which 132 have been granted and 90 % of which have been granted since 2014). The plaintiffs argued that the patents were not really innovations or inventions, but were designed to create a "patent jungle " that would make it difficult for rival generic companies to enter the market. Thereby they were paying too much for Humira. The defendant AbbVie, on the other hand, argued that its patent portfolio was valid and enforceable and met the criteria for the grant of a patent. These relevant patents were granted in 53,4 % of the applications and were successful in the majority of the inter partes reexamination proceedings. Ultimately, the US court held that AbbVie's patent application was not objectively unfounded and was not aimed solely at excluding competition and was not an act of trade monopoly. Although the case ended in favour of the defendant, the dispute arose out of the rule under US law that patents may be applied for on new methods and processes for known products.

Currently, IP powerhouses, in an effort to counteract the negative effects of secondary patents, are adopting new criteria in their domestic laws for assessing the "novelty" of a new use. For example, the United States Patent and Trademark Office (USPTO) determines novelty by analysing whether: (1) the new use is a non-obvious improvement over a known use; and (2) the new use involves a non-obvious improvement over a known drug. Whether the new use is different in kind from the known use is determined by analysing whether the new use involves a function, property or feature of the known drug that is clearly different. Now, most of the member states that do have such a provision have adopted a similar approach in their domestic law to avoid the risk of reduced novelty as a result of the expansion of the scope. The CPTPP, as a trade agreement, is less detailed and gives contracting states room to legislate.

Patent term adjustment rules

In addition to expanding the scope of grantable patents, CPTPP provides complete rules for patent term adjustment. Based on the effect of both being able to adjust the patent term, the authors categorise them by reason into adjustments for unreasonable delay and indirect adjustments for undisclosed data exclusivity. The specific analyses are as follows.

Patent term compensation rules

Article 18.46 of the CPTPP provides that if the patent term is shortened as a result of unreasonable delay by the authorizing authority, a method of adjusting the term of the patent must be provided in order to compensate the patentee. The duration of the delay is also clearly defined：A delay of more than five years from the date of the application or more than three years from the date of the request for review is considered to be unreasonable. Article 18.48, which is specific to pharmaceutical patents, emphasizes the obligation of Contracting Parties to adjust the term to ensure that pharmaceutical products enjoy the full term of patent protection. In fact, this provision stems from concerns about the time taken to grant pharmaceutical patents in some countries. This is because, in the event of long delays in examination, inventors may be reluctant to invest time and resources in new R&D due to uncertainty about whether patent protection will be granted. These rules, while compensating the patentee for damages, will also encourage all parties to process patent applications in a timely and efficient manner.

On the face of it, the rule is defending the legitimate claims of rights holders, This appears to be ensuring that IP balancing attempts as part of TRIPs continue in this TRIPs-plus rules,[7] but the final effective text sets aside the provision. But the substance is not as fair as it seems. In the authors' view, the unfairness is reflected in the following three aspects:

First, it may put pressure on patent examination in developing member countries. Since the rules do not specify a maximum period for patent extensions, examining authorities will have to complete a large number of international patent approvals within a reasonable period of time in order to circumvent the problems associated with patent term extensions. The result could be the over-granting of useless patents or unsafe or ineffective medicines, which would pose a public health risk.

Second, It would directly enable the originator pharmaceutical company to extend the patent through various ways of exploiting the loopholes of patent law or regulatory review process in order to recover the high cost of R&D as a means to extend the overall period of monopoly of patented drug in the market.[8] The result is increased costs to the public, especially in developing member States. Access to affordable

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medicines is already more limited in these countries, and patent term adjustments are primarily designed to protect the interests of originator drug companies. Although generic companies do eventually have access to the market, the extended cycle of developing and testing their own versions of the drug is too costly for them to necessarily provide consumers with cheaper generic drugs.

Third, the rule does not have the effect of encouraging R&D innovation. Skeptics have pointed out that the vast majority of R&D costs are not spent on R&D but are wasted on marketing, legal fees, etc. For example, the originator of Sovaldi, a breakthrough drug for the treatment of hepatitis C, spent about $11,2 billion on the development of the drug. The final market price was $84 000 per course of treatment (12 weeks), or about $1 000 per pill. The company also pointed out that the pricing was not based on the cost of development.[9] And the cost of manufacturing the drug is only a small part of the price of the drug.[10] In other words, not all of the high fees one pays for originator drugs are used to cover R&D expenditures. Nor are the profits made by extending patent protection necessarily invested in new R&D. Overall, the benefits to developing Member States are therefore limited. The notion of essentially protecting the interests of pharmaceutical companies in developed countries is certainly not acceptable to the majority of developing countries.

Undisclosed experimental data exclusivity period rule

In addition to providing rules for adjusting the period of protection, the CPTPP also provides for a period of data exclusivity protection for undisclosed experimental data. Strictly speaking, undisclosed experimental data are not patents because they are confidential, rather than patents, which are "disclosure for protection". However, such exclusivity produces the same protection as a patent, and at the same time, the existence of data exclusivity may indirectly lead to the extension of the original patent term. Therefore, the authors summarize it in the patent term compensation rules.And, in contrast to the initiative references in the TRIPs Agreement, the CPTPP provides detailed and comprehensive rules for the data exclusivity in article 18.50 and 18.51 (see table 1), making them representative of a high level of IP provisions.

Table 1. Undisclosed test data protection provisions for pharmaceuticals and biologicals

Clause	Protection Object	Applicable locations	Protection Period (at least)	Starting Date
Article 18.50,(1)	Undisclosed trial and other data on safety and efficacy of new pharmaceutical product	(a) The first marketing approval in a Party (b) Already marketed in other party	5 years	Date of marketing approval in the Contracting Party
Article 18.50, (2) (Optional)	New clinical information submitted to support a new utility, new formulation or new method of administration of a previously approved pharmaceutical product.	The marketing approval in a Party	3 years	
	New pharmaceutical product contain a chemical entity not previously approved by the Contracting Party		5 years	
Article 18.51, (1) (2)	A new pharmaceutical product that is or contains a biologic. Also includes a protein produced using biotechnology processes, for use in human beings for the prevention, treatment, or cure of a disease or condition.	The first marketing approval in a Party	(a) 8 years, or (b) 5 years, and through other measures and effective market protection	

Source: Summarized by the author in accordance with articles 18.50, 18.51 of the CPTPP agreement.

From the above, four characteristics of the undisclosed data exclusivity rule in the CPTPP can be derived:

First, the scope of protected medicines has been expanded. The scope of medicines has been extended from chemical drugs to biologics. Within chemical drugs, protection has also been extended from only "new chemical drugs" to "non-new chemical drugs with a new potency, formulation or method of administration". And new medicines are also defined as "containing chemicals not previously authorized by a Party", which means that known or existing chemicals may also be protected.

Second, Different data protection exclusivity periods are assigned to different types of medicines. (1) Chemical drug data were subdivided into data on new drugs and data on new uses of known drugs. CPTPP provides a five-year protection period for the former and three years for the latter. The provision is largely based on standards prevailing in the domestic laws of member States. For example, Japan's Pharmaceutical Affairs Law has a six-year exclusivity period for the protection of undisclosed data on chemical substances.

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If a drug is granted orphan drug status, an additional two-year exclusivity period is granted, which actually provides several financial incentives for pharmaceutical companies to develop drugs for rare diseases actually created a number of financial incentives for pharmaceutical companies to develop drugs for rare diseases.[11] In Australia, the Therapeutic Goods Act 1989 provides for a five-year data exclusivity period for generic drugs.(2) Separate protection of biologics data and two options for protection periods. Currently, the strongest data protection for biologics is in the United States. With a 12-year period in its Biologics Price Competition and Innovation Act (BPCIA). Japan, Australia and Canada also largely provide for protection periods of around eight years. The CPTPP gives two options after combining the protection standards of member states, increasing the flexibility of the provisions while lowering the standards. Most importantly, this effectively establishes exclusive protection of biological data within the CPTPP framework.

Third, extending the "non-reliance" obligation on pharmaceutical trial data to the entire CPTPP. The obligation of "non-reliance" means that during the data protection period, competitors are prohibited from relying directly or indirectly on the undisclosed data submitted by the originator to obtain marketing authorization for a drug.[12] The CPTPP provisions apply the "non-reliance" effect to all Contracting Parties, so that even if the holders of the trial data have not obtained a marketing authorization in the territory of a Contracting Party, they still enjoy exclusivity in the territory of the Contracting Party on the basis of the fact that a marketing authorization has already been obtained in another country.

Fourth, it indirectly extends the period of patent protection. Since the term of data exclusivity is independent of the pharmaceutical patent, the two protection periods may co-exist in practice. Since the cycle of pharmaceutical products from R&D to clinical trials is so long, it may happen that by the time the drug is licensed to be marketed, not much of the original patent term is left, or it may even have already expired. In such cases, data exclusivity can give the drug 5 to 7 years of market exclusivity. Even if a drug is not patented in a member State, data exclusivity can to some extent serve the same purpose as patent protection.

Of course, the rule was eventually shelved. The fundamental reason is still that its content and standards were set in accordance with the wishes of developed member States, and it is not in the interest of developing member States. Most developing member countries either do not have any monopoly system of pharmaceutical data protection in their domestic laws or only have general rules without more detailed classification and special protection for pharmaceuticals. As a result, the rule is currently not truly functional within the CPTPP.

Early Resolution Mechanisms for Patent Disputes

Early patent disputes arise mainly in the years leading up to the end of the patent term. This period is a critical time for generic drugs to undergo R&D, experimentation and preparation for market launch. Generic companies need to make their generic drugs available to the market as soon as possible before the expiration of the patent protection period, and at the same time ensure that their R&D and administrative review actions do not infringe. Therefore, in order to ensure the interests of all parties at this stage, the CPTPP utilizes the Early Patent Dispute Resolution mechanism to avoid possible infringement. Two important rules in this mechanism are the "Bolar" Exception Rule and the Patent Linkage System.

The "Bolar" Exception Rule

Article 18.40 of the CPTPP provides the jurisprudential basis for the rule of the "Bolar" exception in the domestic law of each Contracting State. The "Bolar exception" is a principle of immunity from patent infringement and inspired by Roche v. Bolar in 1984. The basic meaning is that the research and testing necessary for the marketing authorization application for a generic/biosimilar or combination generic/biosimilar product, as well as any practical requirements arising therefrom, shall not be considered as infringement of the relevant patent rights.[13] Currently, all member States have relevant provisions, indicating that this rule is generally recognized in the region. However, the specific provisions and scope will vary from country to country due to differences in national circumstances: For example, Japan permits the use of another person's patented invention for the purpose of obtaining marketing approval for pharmaceuticals, medical devices and agrochemicals. However, the manufacture or sale of generic products before the expiration of the patent is not allowed; Australia allows the use of patents for the purpose of obtaining marketing approval for pharmaceuticals and agrochemicals. Behaviorally this includes clinical trials and other activities necessary to obtain approval. Canada also allows the use of patented inventions for regulatory approval of veterinary drugs. In short, on the basis of the jurisprudence provided by the CPTPP, the Contracting Parties' generic medicines can reasonably utilize the "Bolar exception" rule to avoid possible infringement disputes. Moreover, this rule and the patent linkage system can also be used in conjunction with the preparation of administrative applications in advance in order to seize a market lead when the patented drug expires.

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Patent Linkage System

The patent linkage system set out in Article 18.53 is the predominant rule in the early resolution mechanisms for patent disputes. The most important feature of this rule is that through the patent linkage of drug registration applications, possible infringement can be detected in time during the review of drug registration, nipping patent infringement in the bud. The patent linkage system in the CPTPP actually includes the generic drugs and for patentable drugs.

The generic drug patent linkage model utilizes primarily a judicial process. Generic drug manufacturers must notify the patent holder when they apply for approval of a generic version of a patented drug. For example, if a generic manufacturer wants to introduce a cheaper version of a patented drug, they must first obtain publicly available patent information through the patent linkage system, and when they confirm that they are not infringing, they can seek regulatory approval for their version of the product. If the patent holder objects, they can litigate to confirm that the generic drug falls within the scope of their patent rights. If the court rules in favor of the generic manufacturer, they can offer consumers a cheaper alternative. Conversely, the generic manufacturer may not be able to market its product before the patent expires.

A linked review system for patentable drugs is the second approach. As an alternative to the first, the review system delegates regulatory authority to the drug marketing approval authority. It allows the drug approval authority, in direct coordination with the patent agency, to proactively stop the granting of marketing authorization to any third party seeking to market a patented drug without the consent or acquiescence of the patentee.

It can be said that the patent linkage rules of CPTPP will encompass the basic contents of patent declaration rules, patent information publication rules, and linkage rules of regulatory and approval authorities, which will perfectly connect the pharmaceutical approval authorities, patent examination authorities, judicial authorities and rights holders, and lay a good foundation for the domestic laws of the member states to formulate more detailed rules and leave the space for refinement. However, in the long run, the full application of the rule could also have adverse effects. First of all, CPTPP appear to upset the balance between patent owners' rights and public interest by elevating the position of patent right.[14] For example, the obligation to confirm "infringement" to the drug regulatory authority objectively helps the patentee to realize the expansion of private rights, reflecting the current international IP protection method tends to use public power to protect the private rights of multinational corporations or other enterprises.[15] This "preferential protection" puts generic companies in a more difficult position. It is difficult to predict whether they will be delayed in entering the market because of infringement, at the expense of the average consumer. Some scholars have called this rule a pillage of the last remaining moral essence.[16] Second, the patent linkage system is the only provision in the current CPTPP system of legal protection for pharmaceutical patents that has not been suspended, so how the contracting parties, especially the developing member states, can interface it with their domestic laws becomes a considerable challenge. For example, how to establish and improve the relevant institutions with capacity in their own countries. How to maximize the protection of public health and the interests of generic companies under the system.

New restrictions on compulsory licensing of patents

The CPTPP contains an understanding of specific public health measures: it requires parties to confirm in advance their commitments under TRIPs and the Declaration on Public Health by allowing the governments of contracting parties to use patents on a temporary basis, authorizing the manufacture of a copy of the patented product as a public health safeguard. In fact, as early as in the 2001 Doha Declaration, a consensus has been formed that countries can make full use of the flexibility of TRIPS to stipulate their own compulsory licensing system to safeguard public health.[17] On the surface, the CPTPP follows this idea, emphasizing that those who obtain drugs to ensure public health can enjoy exemptions in drug patents. However, the provision adds some restrictive circumstances, including listing the types of diseases that constitute a public health crisis, stipulating that the exemption applies to national emergencies and other extreme situations, but does not define the severity of the outbreak of the disease or determine the criteria for a public health crisis, then how the contracting parties can implement compulsory licensing based on the provision becomes ambiguous. However, although the provision is more symbolic than practical, the rule objectively completes the CPTPP system of pharmaceutical patent protection.

An examination of the implementation of the Cptpp rules in Chinese law

Application of the Secondary or New Use Patent Rules in China

China's Patent Law, as early as the 1992 revision, included new uses of known drugs in the grantable scope. However, there were various disputes in practice due to the failure to refine the novelty examination standard. It was not until 2021, the State Intellectual Property Office of China (SIPO) revised the Patent Examination Guidelines (hereinafter referred to as the Guidelines) to clarify the key points of the examination

of inventions for new uses of chemical drugs and to prevent the lowering of the standard of "novelty":

An invention in which the new use is merely different in expression but is essentially the same as the original use does not have novelty;

A use in which the new use is directly equivalent to the original mechanism of action or pharmacological effect does not have novelty;

A use in which the new use A superordinate concept belonging to the original known use does not have novelty. For example, if a drug has been known and used to treat hypertension, and a new use is discovered for the same drug to treat a specific type of hypertension that is already considered a subtype of the original disease, then the new use may not be considered novel.

A new use is also not novel if there is a difference in the characteristics related to the use such as the mere object of administration, manner, route, dosage and time interval.

In addition, China has used administrative means to balance the impact on public health and safety of indirectly extending the term of protection through "secondary patents",[18] particularly during the COVID-19 pandemic. Taking Azvudine tablets (Azvudine) developed by a Chinese pharmaceutical company as an example, which was originally for the treatment of AIDS, and later found to be able to fight against the Corona Virus Disease, As a result, on 25 July 2022, The China Medical Products Administrational approved, with conditions, the registration application for Azulfidine with the addition of a therapeutic indication of neocoronitis.[19] Subsequently, in order to ensure that the drug was accessible to its citizens, the Chinese government utilized administrative means to negotiate the inclusion of the drug, which was still under patent protection, into the national collective purchasing system at a limited price. In short, in recent years, while China's patent law has been moving closer to international rules, it has also tried some legal and administrative means to try to eliminate the adverse effects of the high rules.

Application of the Patent term adjustment rules in China

Patent term compensation rules in China

First, China's Patent Law clearly stipulates the conditions for adjusting the patent term. If the invention patent has been granted after four years from the filing date and three years from the date of the request for substantive examination, the right holder can be applied for adjustment of the protection period. However, in practice, China's invention patent examination cycle is less than 22 months on average, and in 2023,[20] it will be reduced to less than 16 months. It can be said that China's patent examination capacity is generally capable of completing its work within the examination period, so it can be expected that there will not be too many cases in which compensation for delayed patent examination is required.

Second, the Chinese Patent Law also has specific provisions on the period of adjustment. For new drug invention patents approved for marketing in China, the compensation period shall not exceed five years, and the total valid patent right period after its marketing is not more than fourteen years. Its provisions are obviously more comprehensive than the requirements of CPTPP. It should be noted, however, that the rule applies only to human medicines, and that the patent type applies only to invention patents and can only be extended once.

Thus, the potential impact of the rule on China is not so much on the issue of interfacing with the CPTPP rules. It is more in the contradiction between China, a non-member country, and CPTPP member countries in the application of the law. Take the example of favipiravir, a drug developed by Japan's Fuji Group: the drug filed an application for a patent term extension in Japan in 2014 and was successfully extended. However, the original protection of the drug in China expired in 2019, and in February 2020 a Chinese pharmaceutical company obtained registration and clinical trial approval to produce a generic version of the drug. Since the extension granted to Fuji Group is only effective within CPTPP member countries, Chinese generic companies can manufacture and sell the drug without infringing on the patent. But in the future, if China succeeds in joining, it will be restricted from producing generics during the compensation period, which means that Chinese generic companies will have more obstacles in obtaining licenses to produce originator drugs.

The undisclosed test data exclusivity period rule in China

China's protection of pharmaceutical test data is based on the Drug Administration Law of China, together with a series of administrative regulations, departmental rules and policy documents. Its content mainly includes three aspects of the protection, protection period and protection process:

The object of protection: Undisclosed trial data submitted by pharmaceutical companies and independently obtained by them. These data are derived from innovative medicines, innovative therapeutic biologics, medicines for the treatment of rare diseases, specialized medicines for children, and medicines with successful patent challenges;

Protection period: 6 or 12 years is given to the trial data of innovative drugs, drugs for rare diseases, drugs for children and innovative biological products for therapeutic use;

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Protection Process: The application, review and approval of drug trial data, public announcement, and subsequent review of the monitoring period are all managed by the National Medical Products Administration.

Relevant laws and regulations that have been introduced in recent years show that China is paying more and more attention to the protection of pharmaceutical test data and is gradually converging with international standards, but it is objectively premature to require full alignment with the CPTPP standards.

First of all, China is a major producer of generic drugs, and a high proportion of generic drugs is the basic disk for public health protection in China. Protecting non-disclosure data actually protects the interests of the original researchers of drugs and objectively creates barriers to the entry of generic drugs into the market. Therefore, based on China's national conditions, setting too high a standard of protection may weaken China's own competitive advantage and indirectly lead to the loss of talent, technology and capital in the pharmaceutical industry.[21]

Secondly, the current legal provisions are not sound enough. This includes the low level of regulations, the scattered distribution of legal documents, and the lack of a corresponding supporting system in legislation. For example, there is no provision for a simplified procedure for marketing approval of biosimilars that balances the data exclusivity period as in the US or EU.[22] Although a 12-year data exclusivity period is formally stipulated, the lack of supporting rules makes the protection of experimental data inflexible and unbalanced. The result may be that biosimilar drugs need to invest the same high R&D costs as original drugs before marketing.[21] Ultimately, this will most likely result in a gap in the Chinese biosimilar market and a barrier to accessing cheap biosimilar drugs.

Thirdly, terms such as "innovative therapeutic biologics" and "therapeutic drugs for rare medicines" are not clearly defined, which may create obstacles in practice. Thus, while formally provided for, it is far from sufficient at the practical level. The continued refinement and development of the rule will take time.

The Application of Early Resolution Mechanisms for Patent Disputes in China

'Bolar 'Exception in China

China introduced the Bolar exception in the 2008 Patent Law: manufacturing, using or importing patented drugs or patented medical devices for the purpose of providing information required for administrative approval, and manufacturing or importing patented drugs or patented medical devices exclusively for the purpose of doing so, are not considered to be infringement of patent rights. Prior to this, the court can only rely on the provisions of Article 11 of the Patent Law, that the clinical trials of new drugs and the application for production licenses do not constitute patent infringement because they do not belong to the production and management for the purpose of the act to determine the case.[24] However, in practice, this legal basis is not very appropriate, just barely applicable. Therefore, this provision solves the judicial dilemma on the application of the previous law. The majority of generic drug manufacturers in China can make reasonable use of this rule and encourage them to start generic work in advance, to ensure that generic drugs can be listed in a timely manner after the expiration of the patent period of the innovative drugs to quickly reduce the price of the drugs, so that the patients can benefit from it in a timely manner. It can be seen that China is in line with the CPTPP requirements on this rule.

Patent Linkage System in China

China has gradually established a patent linkage system since the Administrative Measures for the Registration of Pharmaceuticals in 2007, with rules such as declarations of non-infringement and time limits for approval.[25] A more complete and systematic patent linkage system with Chinese characteristics was formed in the fourth amendment to the Patent Law ,which recognizes the patent linkage system as a means of early resolution of drug disputes, and specific implementation measures were introduced in 2021.[26] To summarize, at this stage, China's patent linkage system includes four main rules:

Drug patent information disclosure system. Similar to the Orange Book system in the United States, it can be downloaded to obtain a list of all branded and generic drugs approved by the FDA and not been discontinued from marketing.[27] In China, innovative pharmaceutical companies can publish the valid patents involved in patented drugs in the drug patent information platform in order to fulfill the obligation of patent announcement for listed drugs and increase transparency.

Patent declaration rules. A declaration of non-infringement is made by the chemical generic applicant (I-IV category of declarations are available).

Patent challenge procedure. When a right holder files an opposition, the judicial or administrative authority will confirm the right. If the challenge is accepted by the judicial or administrative authority, a nine-month waiting period is granted to the chemical generic.

Generic exclusivity rule. The first generic drug company with a successful challenge is granted a 12-month exclusivity period, during which no generic drug of the same variety will be approved for marketing.

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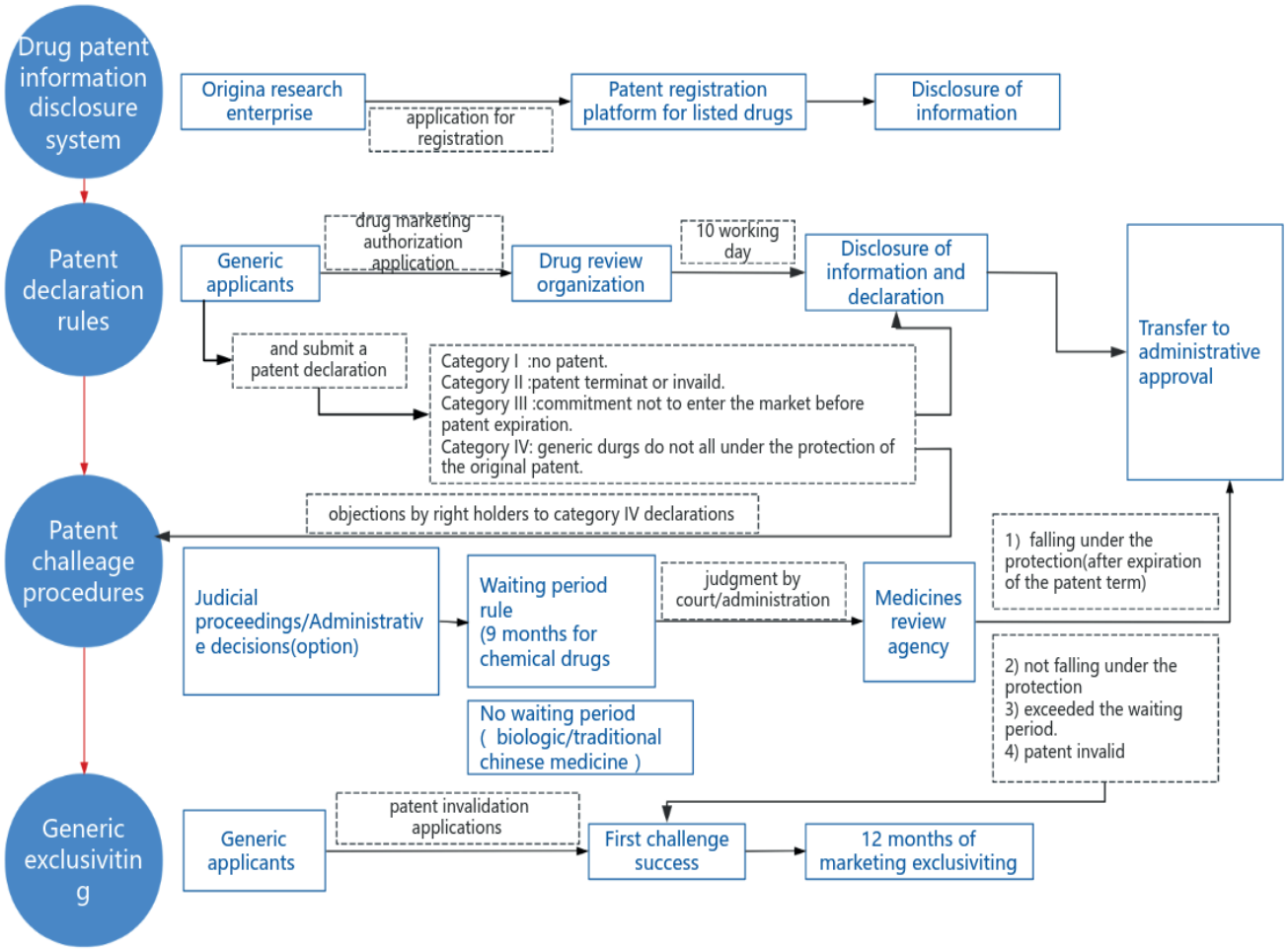

Figure 2. Flowchart of China's Patent Linkage System
Source: Compiled by the authors in accordance with the provisions of the Patent Law

As shown in figure 2 above, these four rules organically integrate the right people, the patent examination authority, the drug marketing examination authority, the judicial procedure and the administrative procedure to form a more complete patent linkage system, which provides the optimal solution for dealing with the early disputes of pharmaceutical patents, and at the same time, it also shows that China has already been on a par with the international high standard on this rule, which is in line with the requirements of the CPTPP for the member states.

China's Patent Compulsory Licensing rules

China's compulsory licensing rules have formed a more complete system in the current patent law. The content includes the object of adjustment, applicable circumstances, application limitations, relief methods and other aspects. Among them, there are two types for pharmaceutical patents: (see figure 3)

One is a general compulsory license, i.e., the direct use of national public power in the absence of the consent of the pharmaceutical patentee, to have the conditions for the implementation of the object of the patent issued to the implementation of the patent license, by the licensee in accordance with a certain standard to pay royalties to the licensor; This category includes the five applicable situations set out in figure 3.

The other is compulsory licensing in special circumstances. For public health purposes, China mandatorily grants licenses to manufacture and export eligible subjects to countries or regions that meet the requirements set forth in international treaties to which China is a party. This rule is intended to help other countries and regions alleviate the problem of drug supply from a humanitarian point of view. The circumstances of its application are relatively simple, and the content is limited to the manufacture and export of patented medicines. For exporting countries and regions, there is also the restriction of joint participation in an international treaty. This shows that the use of compulsory licensing is extremely prudent and strict.

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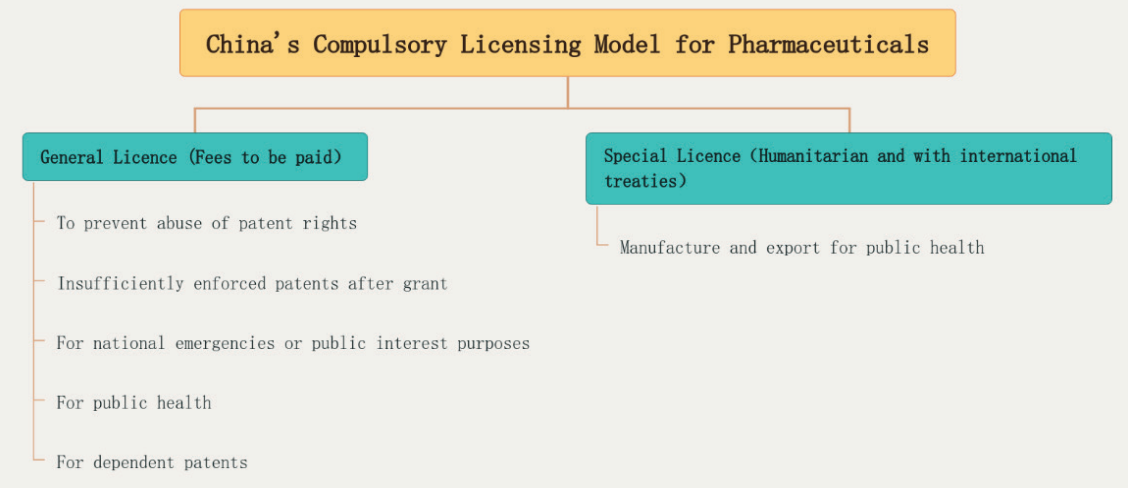

Figure 3. China's compulsory licensing model for pharmaceuticals
Source: Compiled by the authors in accordance with the provisions of the Patent Law

However, the rule lacks clarity at the operational level:

The conceptual terms "emergency", "exceptional circumstances" and "public interest", which provide the legal basis for compulsory licensing of pharmaceutical patents in response to public health crises.[28] are not clearly defined.

The qualification of the subject matter is too strict. Included:1) The individual cannot become the subject of compulsory licensing applications.[29] 2) Lacking quantifiable criteria on "conditions for patent exploitation" makes it difficult for an entity to initiate a compulsory license.[30] After all, what kind of enterprises are eligible and capable is not stated. It is difficult to define the compensation costs.

The duration of the license is not clear.

Therefore, even if the legislation meets the requirements of CPTPP, there should be more detailed regulations on the application targets, approval procedures, administrative supervision, and remedies to enhance the enforceability of the law.

Reflections on china's pharmaceutical patent protection system under CPTPP rules

Legislation is already largely CPTPP compliant

As shown in table 2 below, China's pharmaceutical patent protection is more comprehensive and specific at the domestic law level. All four parts mentioned above have relevant Ruls in China, and most of the provisions can meet the high standards of CPTPP. Among them, the patent term adjustment rules and the patent linking system are more detailed and systematized than those of CPTPP. The main gap lies in the rules on data exclusivity.

Table 2. Comparison of Patent Rules for Pharmaceuticals between CPTPP and China

Pharmaceuticals Patent Rules		CPTPP	CHINA
Patentable scope and secondary Patent Rules		New inventions (products, processes); new uses, methods and processes for known products; inventions of plant origin;	Inventions, utility models, designs, new uses and processes for known products;
Patent term adjustment rules	Unreasonable shortening	(1) Prompt processing of applications for marketing authorization of pharmaceutical products is an obligation of States parties. (2) The State party is required to adjust the patent term for unreasonable shortening. However, there is no specific period of time for extension.	Patents for new drug inventions are compensated for a period not exceeding five years, with a total validity period not exceeding fourteen years after marketing authorization.
	Data exclusivity	The Contracting States are obliged to provide exclusive protection for undisclosed experimental or other data. And the object of protection, the duration of protection and the scope of protection are specified in detail.(See figure 2 above for details.)	(1) The scope of data protection for pharmaceutical products is specified. (2) The protection period for innovative chemical drugs is 6 years. 12 years for biologic. However, there are no specific supporting implementation measures (3) The legal basis is an exposure draft and has not yet entered into force.;

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Mechanism for early resolution of patent disputes	The bolar exception	Article 18.40 provides the jurisprudential basis.	The use of a patent for the purpose of providing information required for administrative approval is not considered an infringement
	The patent linkage system.	(1) Marketing authorization of drugs is linked to patent protection. (2) Use of judicial or administrative procedures, etc. to seek remedies; (3) Disclosure of patent information on marketed drugs.	(1) Drug patent information disclosure system. (2) Patent declaration rules. (3) Patent challenge procedure. (4) Generic exclusivity rule.
Compulsory licensing for pharmaceutical patents		Understanding of specific public health measures	General and special licenses

Source: Summarized by the author in accordance with Articles 53 to 63 of the Chinese Patent Law.

In addition, external impetus has accelerated the reform of China's domestic patent law. Under the general environment of rising international standards of IPR protection, China has attempted to introduce rules related to pharmaceutical patents into a series of trade agreements signed with foreign countries, in an attempt to accelerate the further improvement and docking of domestic legislation through high external standards. The most typical ones are the 'Regional Comprehensive Economic Partnership (RCEP)' and the "Phase One" Economic and Trade Agreement between China and the United States', especially the rules on pharmaceutical patent protection in the latter is a game between China and the US under the US IP standard, of which Article 1.10 is to consider Supplemental data, Article 1.11 is an effective mechanism for early resolution of patent disputes, and Article 1.12, paragraph 2 is compensation for the term of pharmaceutical patents. Although some of the rules were introduced late, such as patent links, exclusive rights to undisclosed data and other provisions have not been applied much in China's practice, and the relevant supporting measures have not yet been established and perfected, but at least there is a law to follow. In terms of completeness, the requirements of CPTPP have been met.

Need for further improvement of specific rules

Data exclusivity rules need to be refined

First, the legal documents on which the rules are based lack stability. At present, the rules are basically stipulated in the 'Implementing Measures for the Protection of Pharmaceutical Test Data (Provisional) (Draft for Comments)'. The document is not legally in force and may be amended at any time in the light of comments once the consultation period has expired. Of course, temporary application is also the more appropriate approach for the time being. After all, the practice of the rule is still in its infancy, and it will take time to see to what extent Chinese drug companies will be able to resist the impact and benefit from it. However, the instability of the rule will ultimately have a significant impact on the sustainability of the implementation of the law.

Second, there are no specific provisions for special approval procedures. Therefore, although it is innovative for the Chinese law to grant a special approval system to applications for biological drugs and new drugs for rare diseases, the lack of an explanation of the specific implementation steps means that the provision is currently only symbolic and not very practical.

Third, there is no clear statement on how to define "new drug" .For example, in the U.S. law, there is a clear statement on the scope of new drugs, which includes test data on new indications, and it is allowed to apply for the marketing of new drugs for new indications or new uses, and the data on the new indications will be protected without extending the original exclusive rights. In addition, new salts, new esters and new compounding are also included in the scope of protection. However, there is no mention of this in the Chinese law.

Forth, The meaning of "successful patent challenge" and its corresponding protection period are not clarified. For example, whether data protection can only be obtained if the first generic drug is successfully challenged. In fact, the relevant provisions of the patent challenge procedure in the patent linkage system are also relevant here. The interface and coordinated application of the different rules is likewise an area that is currently lacking.

Patent linking system has many problems that need further adjustment.

First, the normative requirements for disclosure of information and patent declarations are not sufficiently clear. As for the content of the registration, the National Medical Products Administration(NMPA) does not make substantive judgment but only examines whether the form is qualified. Then once the patentee is wrongly registered, because the patentee may not be able to accurately determine the relationship between the patent and the drug, it may have a greater impact on the generic drug companies applying for listing. Although the law stipulates that the registrant shall be responsible for the authenticity and completeness of its registration information, and the generic applicants should be held accountable for submitting inaccurate declarations.

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However, in actual operation, the patent platform has not yet set up the objection and modification procedures of patent declaration, and there is still a lack of corresponding rules on how to resolve disputes arising from objections to the declaration by both parties.

Second, the "two-track" patent challenge process has resulted in an uneven distribution of disputed cases. The law allowed right holders to choose between the IP courts and the China National Intellectual Property Administration(CNIPA) to initiate a patent challenge. Thus, the CNIPA became one of the adjudicators in early patent disputes, and the NMPA had to decide whether or not to stop prosecution based on its rulings (this is actually the core of the patent linkage system). In practice, however, rights holders mostly preferred the CNIPA to the IP courts. Because the review cycle of the CNIPA is much shorter than that of the court, and the review cycle of an invalidation case is about six months after the filing of the case. This leads to a backlog of cases in the CNIPA. In addition, the problem of inconsistent standards of adjudication arises due to the different adjudicating bodies.

Third the waiting period rule is a sham. The law provides for a nine-month waiting period. But even if the NMPA's review cycle is shortened to 16 months in 2023, it is still significantly longer than nine months. Compared to the 30-month containment period in the U.S., China's waiting period rule does not constitute a substantial obstacle to the speed of drug approval, so it is meaningless.

Forth, settlements in litigation may result in reverse payment agreements. That is, the plaintiff pays the defendant a certain amount of money in exchange for the defendant delaying or forgoing entry into the market. Once such settlements are reached, they amount to promoting a united front between the two parties, which undoubtedly undermines the original purpose of the drug patent linkage system set up.

Fifth, the actual effectiveness of patent linkage systems is reduced by administrative measures. The centralized purchasing system implemented in China to ensure drug accessibility will result in a general and significant reduction in profit margins for all types of companies. Then even if generic companies successfully launch their products by resolving patent disputes at an early stage through the patent linkage system, they may not be able to obtain the expected market benefits. As a result, early dispute resolution mechanisms have not had the desired impact in actual operation.

Other pharmaceutical patent rules also require further integration.

China's data exclusivity rules do not provide for a simplified filing procedure rule for generic drugs similar to the one in the U.S. Patent Act. This rule, as a supporting system for the data exclusivity rule, can better balance the interests of originator and generic drug companies. This is where the current legislators need to reflect. In addition, the pharmaceutical patent linkage system is mainly stipulated in the Measures for the Administration of Drug Registration, the "Bolar Exception Rule" is mentioned in Article 69(5) of the Patent Law, and the data exclusivity rule is stipulated in the Regulations for the Implementation of the Drug Administration Law and the Measures for the Administration of Drug Registration. These regulations are characterized by disconnection, low convergence and poor integration due to different legislative subjects, different management departments and different effectiveness of the rules. Therefore, it is a great challenge to link these rules organically to form a unified protection mechanism.

China Needs to Prevent Risks and Shape its own legal paradigm

Macroscopically, the risks brought to China by the CPTPP drug patent rules are twofold: first, Chinese generics will be blocked from the pharmaceutical market in the CPTPP region by the strict protection standards of the CPTPP, and the member states in the region all maintain huge trade with China, so that the generics produced in China will have a greater impact on exports. For example, the CPTPP data exclusivity rule makes Chinese generic companies have to invest extra cost or time in the R&D process to defend against the impact of not being able to use existing data. Second, rising drug prices in the CPTPP region could jeopardize China's accessibility to imported drugs. Since China has not yet established a comprehensive social health insurance system, a rise in the price of imported drugs would directly increase healthcare costs. Therefore, Chinese pharmaceutical companies should strengthen their awareness of risk prevention against possible legal risks. The Chinese government should establish and improve the mechanism of overseas intellectual property protection, guide and help pharmaceutical enterprises to establish the mechanism of overseas intellectual property protection, and take effective measures to help Chinese pharmaceutical enterprises to improve their own intellectual property protection and utilization through various means.

In addition, it is necessary to establish the paradigm of the legal system of pharmaceutical patents with Chinese characteristics. Nowadays, whether or not to have a set of relatively stable and clear legal system is a sign of a country's level of economic and trade rule-making and international discourse power.[31] China has actually entered the era of strong protection of IPR after a new round of revision of the patent law. It is expected that China will sign more trade agreements similar to CPTPP in the future, so for IP rules, China should no longer simply reject or passively accept the "Pacific Model" promoted by the United States,

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but should use China's domestic law as a benchmark to analyze and identify, and strive to establish a legal system for pharmaceutical patents with Chinese characteristics. In this process, the following issues need to be understood: (1) An overly high standard pharmaceutical patent system represents the interests of only a few patent-powerful countries to the detriment of global public health. (2) China should build a balanced system of protection for the pharmaceutical patent system with the public health interest as the fundamental concern. (3) Chinese characteristics should be retained in the Chinese paradigm, such as the patent protection system related to traditional Chinese medicine. Prevent developed countries from using their international influence and mature legislative techniques to deprive our country of a voice in legislative protection in this area.[32]

CONCLUSIONS

Most of the rules related to pharmaceutical patents in the patent chapter of the CPTPP are suspensive provisions, which shows that it is characterized by high standards and strict requirements. Its protection system consists of secondary patent rules, pharmaceutical patent term compensation rules, early dispute settlement mechanism and compulsory licensing system in cooperation with each other. Against the background of China's accession to the CPTPP, this article examines the above rules and their application in Chinese law and concludes that China's domestic law basically conforms to the requirements of the CPTPP, and that there is not much obstacle to the legal transformation of the construction of the rules on pharmaceutical patents. However, in application of the law, China's pharmaceutical patent rules are only in the establishment period, and the degree of perfection of the rules, the cooperation between the rules, and the matching between the rules and China's national conditions are all a certain gap from the international high level of protection advocated by the CPTPP. Therefore, there is still a long way to go in integrating the rules that are currently floating on the surface to form a legal system of pharmaceutical patents with Chinese characteristics.

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