The access to pharmaceuticals is of significance for ensuring the right to health, which has attracted more and more attention from the world. It is widely recognized that an adequate system of intellectual property (IP) is a necessary condition for achieving access to pharmaceuticals. Due to technological lag, insufficient manufacturing capability, and weak voice in the world, developing countries need more concerns from the global society to overcome such challenges before them. Consequently, it should strengthen multilateral efforts to implement international treaties and help the poor in developing countries obtain cheaper pharmaceuticals. On the other hand, developing countries could modify their own IP systems to facilitate access to pharmaceuticals. This article discusses the coexistence between the right to health and IP rights, reviews the amendments of China’s patent law, studies how China achieves the flexibilities allowed by the Agreement on Trade-Related Aspects of Intellectual Property Rights, and analyses its implications for safeguarding public health.

**Keywords:** Access to pharmaceuticals, patent, TRIPS Agreement, flexibility

The right to health is a fundamental human right derived from the inherent dignity of the person that is recognized in a substantial number of international human rights instruments. These instruments affirm that the person ‘has the right to enjoy a standard of living adequate for the health’, and that nations should ensure this right by providing necessary and effective access to medicines. However, since plenty of pharmaceutical resources fighting against the public health crisis are held by developed countries under international intellectual property protection, such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), it is difficult to acquire them for people who living in less-developed countries where patented medicines are unaffordable and generic copies cannot be produced domestically due to lack of manufacture capacity. In the light of this situation, the World Trade Organization (WTO) Members adopted a special Ministerial Declaration at the WTO Ministerial Conference in Doha to respond to the concerns of developing countries under international intellectual property protection, such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), it is difficult to acquire them for people who living in less-developed countries where patented medicines are unaffordable and generic copies cannot be produced domestically due to lack of manufacture capacity. In the light of this situation, the World Trade Organization (WTO) Members adopted a special Ministerial Declaration at the WTO Ministerial Conference in Doha to respond to the concerns of developing countries. Fortunately, the Doha Ministerial Declaration on the TRIPS Agreement and Public Health (the Doha Declaration) greatly promotes access to affordable medicines in the interest of public health in general. Nevertheless, due to the sharp divergence between the position of developed countries and developing countries, all the attempts on achieving public health are to be implemented gradually.

This article discusses coexistence between the right to health and IP rights, reviews the amendments of China’s patent law, studies how China achieves the flexibilities allowed by the TRIPS Agreement, and analyses implications of the new China’s Patent Law (NCPL) for safeguarding public health.

**The Right to Health Coexists with IP Right**

The right to health, an inherent human right, should be appreciated as ‘a right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health’. In order to achieve progressive realization of this right, nations may take measures to improve conditions related to healthy living, which including adequate food and housing, potable water, sanitation, healthy environments, education system to preventing diseases, health facilities, goods and services, and so on.

However, sometimes, realization of the right to health is hindered by exploitation of the IP right, which allows the right holder to prevent any use of
the subject matter without his permission in general. With expansion of IP rights, there are growing critiques on excessive monopoly generated from the IP system that it limits public access to protected materials so that the public welfare is unreasonably impaired in some less-developed countries. Especially, in the pharmaceutical sector, the IP system has become a substantial barrier to public access to medicines in developing countries. This gives rise to debates on whether IP right and the right to health can coexist. In the recent years, there are generally two approaches to describe the relationship between human rights and IP rights: the conflict approach and the coexistence approach. The former holds the view that IP protection undermines a broad spectrum of human rights obligation and advocates the principle of human rights primacy where the two conflict. In contrast, the latter views human rights and IP rights as compatible, while reaching an appropriate balance within the IP system for ensuring that the public has adequate access to protected materials. Nowadays, it can be observed that the coexistence approach prevails in debates under WTO framework. The WTO notes that human rights ‘will be best served, taking into account their interdependent nature, by reaching an optimal balance within the IP system and by other related policy responses. Human rights can be used - and have been and are currently being used – to argue in favour of balancing the system either upwards or downwards by means of adjusting the existing rights or by creating new rights.’ The TRIPS Agreement confirms flexibilities to ensure public interests, including patentability, compulsory licenses, exceptions, exhaustion, and anti-competitive policies, which actually verifies the fact that the coexistence approach gained control in the existing international legal system. Subsequently, the Doha Declaration recognizes and explains the flexibilities in detail, reflecting significant efforts to promote public access to health care in developing countries. Besides, the global society continues efforts to implement the Doha Declaration and settle problems causing failure to achieve the Doha’s objectives. At the World Intellectual Property Organization Conference on Intellectual Property and Public Policy Issues held in July 2009, the topic on strengthening multilateral cooperation on IP and public health was discussed as a special issue. At this conference, Dr Margaret Chan addressed that ‘people should not be denied access to life-saving interventions for unfair reasons, including an inability to pay,’ which implies that more international cooperation should be made to help the poor acquire cheaper medicines.

The New Patent Law of China

Since 1985, when the China’s Patent Law was first established, China has modified the patent law three times. The First Amendment, enacted in 1992, recognized pharmaceutical compositions as the patentable subject matter. The Second Amendment, enacted in 2000, reconciled the modified patent law with the TRIPS Agreement, which paved the way for entering into the WTO. The Third Amendment, which came into effect on 1st October 2009, aims to bring many aspects of China’s patent law into further compliance with international standards. This section only focuses on the ones that have implications for public health and pharmaceutical industries, such as, a new standard of novelty, changes of compulsory license provisions, ‘Bolar’ infringement exemption, international patent exhaustion, and parallel imports.

An ‘Absolute’ Standard of Novelty

The NCPL has changed the standard of novelty. Before this new revision, a ‘relative’ standard was adopted to assess novelty, which required that the invention must not have been disclosed in any publication in China or abroad and not publicly used or known to the public in China. However, the new patent law introduces an ‘absolute’ standard to define novelty. In other words, any public disclosure prior to the filing date of the patent application, no matter anywhere in the world would it be relevant for novelty.

Adopting an absolute standard of novelty is an approach to realize flexibility under the TRIPS Agreement, which does not give interpretation on the criteria of novelty. The philosophy behind the requirement of novelty is to reward substantial innovations that make a step in advance in the related field. Therefore, flexibility under the TRIPS Agreement allows countries to decide what kinds of innovations are valuable to reward in their own domain, which implies the criteria of novelty are not rigid but variable under certain circumstances.

The new standard is expected to promote the quality of patent applications by counting against applications using existing technologies in the world. Thus, it prohibits opportunistic behaviours of finding out existing technologies that have not been publicly
used or known in the domestic domain and then filing patent applications for them. Meanwhile, some applications that could obtain patent protection previously are released into the public domain under the current patent law. Accordingly, the cost of manufacture and further research based on these technologies would be reduced since subsequent innovators can use them freely. From this point of view, this higher standard of novelty could encourage competition in the pharmaceutical industry and promote access to pharmaceuticals by reducing their prices.

Actually, the new standard brings great challenges for domestic pharmaceutical firms as well, in view that their original creative capacity is apparently insufficient compared with foreign ones. The statistical data collected by the State Intellectual Property Office of China (SIPO) show that merely 317 applications for drug patents published under the Patent Cooperation Treaty (PCT) in 2009 were filed from China, accounting for 2.6% of all the PCT applications in the same field. In contrast, more than 10,000 applications were filed by domestic entities for Chinese medicine patents during the same period.\(^\text{10}\) Probably, there are two reasons generating such a situation. The first is that the majority of domestic applications are filed for Chinese traditional medicines, which have not widely been recognized by other IP systems. The second is that the domestic innovation capacity in developing chemical medicines lags far behind foreign countries. For example, the proportion of the fundamental patents that determine the core competence only accounts for 15%.\(^\text{11}\) From this perspective, the raised threshold of novelty would urge domestic entities to improve innovation capacity.

### Clarifying Compulsory Licenses

The NCPL details the conditions for applying doctrine of compulsory license and introduces some new cases for granting compulsory licenses. First, it revised the provision of refusal to license. Under the previous patent law, the compulsory licensing would be available if the applicant who is capable of implementing the claimed patent cannot obtain a voluntary license on reasonable terms. This stipulation is severely criticized in that it only emphasizes unavailability of a voluntary license, but ignores that refusal to license does not by itself necessarily impair the potential market and lead to the abuse of IP rights.\(^\text{12}\) Generally, the patentee may refuse to license due to business considerations. If only such a refusal does not unfairly limit competition or impair the public interest, it should not be regarded as the abuse of rights. Therefore, the NCPL removes the previous provision, divides the abuses into two categories, namely, insufficient exploitation and anti-competitive activities, and takes the refusal to license as a necessary condition of insufficient exploitation. In detail, in case of insufficient exploitation, where the patentee fails to exploit or sufficiently exploit the patent, from three years after the grant of patent or four years after filing, the patent administrative department under the State Council has the power to grant a compulsory license.\(^\text{13}\) In order to clarify the conception of insufficient exploitation, the Implementing Regulation of the Patent Law released in 2010 gives a further explanation, according to which insufficient exploitation means a situation that the method or scale of the exploiting the claimed patent cannot meet the domestic need for the patented work.\(^\text{14}\) Moreover, the applicant for compulsory license by claiming insufficient exploitation must prove that he has made efforts to obtain a voluntary license but failed. As for the second form of abuses, anti-competitive activities, the NCPL adds a provision against them.\(^\text{13}\) Under this rule, the compulsory license would be granted, where the patentee’s use is identified as a negative monopolistic activity, to alleviate a perceived anticompetitive effect caused by such an activity.

Moreover, the NCPL reconfirms that the patent administrative department can issue the compulsory license for manufacturing patented medicines in case of national emergency or any extraordinary state of affairs, or for the public reason.\(^\text{13}\) Here, patented medicines refer to ‘any patented product or product directly obtained according to patented processes in the medical and pharmaceutical field to address public issues.’\(^\text{14}\) At the same time, it adds a clause pertaining to the compulsory license for exportation. Under this new article, a compulsory license may be issued for the public health reasons to allow manufacturing patented medicines and exporting to qualified countries under international treaties of which China is member.\(^\text{13}\) This provision confirms to the Doha Declaration. In fact, in 2005, the measures to implement public health-related compulsory licensing enacted by the SIPO had definitely allowed compulsory license for exportation.\(^\text{15}\) Although it seems that the NCPL merely repeats the
administrative regulations aforementioned, it is worth noting that the hierarchy of the provision is elevated, which offers a better foundation for implementing this doctrine.

These compulsory license provisions aim to establish a dynamic market, ensure public interests, and especially help the poor in the less-developed countries. Even though no case of compulsory license has taken place in China, successful experience of using compulsory licensing in other countries has illustrated its positive effects on promoting competition and reducing prices of medicines. First, the patentee would be challenged if he exploits the claimed patent in an anticompetitive way. For example, in the past few years, Abbott Laboratories was involved in several lawsuits due to false usage of its monopoly position over Norvir’s AIDS drug to unreasonably inflate the price. Similarly, in 2005, AstraZeneca, another leading biopharmaceutical company, was fined 60 million Euros for misusing patent systems to delay generic competitors from entering into the relevant market. Second, the provision of compulsory license may help the poor obtain cheaper medicines. For instance, since 2002, Zimbabwe issued several compulsory licenses to allow Zimbabwean registered companies to produce patented antiretroviral drug on the condition that the produced drugs should be supplied to national health institutions at a price on control terms. Another example is Brazil. After negotiation with the drug’s patentee, Merck & Co on price reduction failed, the Brazilian government used compulsory license provisions for permitting importation and production of generic drugs, efavirenz. Thus, the price per day of this drug reduced from US$1.56 to $0.45 by importing Indian generic products.

China seems quite conservative on implementing compulsory licensing provisions, which is mainly attributed to the external political pressure. In the recent years, China has been confronted with numerous challenges caused by SARS, HIV epidemic, bird flu and pandemic influenza H1N1. Even though involved in serious crisis of public health, China continuously adopts a prudent attitude towards this issue due to the possibility of retaliation by powerful nations. In fact, it is sensible for China to use compulsory licensing provisions for the public interest reason within the flexibility system of the TRIPS Agreement and the Doha Declaration. On the one hand, compulsory licensing provisions can be used as leverage in price negotiations. On the other hand, in case of actually issuing a compulsory license for manufacturing generic products, domestic generic competitors are encouraged to provide cheaper drugs for the domestic need and even for the need of least-developed countries. In a nutshell, China should exert efforts to implement this system rather than use it as an ornament.

Another important issue related to compulsory license is the reasonable level of remuneration to the patentee. The NCPL provides that the entity that is granted a compulsory license of using the patent should pay a reasonable royalty to the patentee; nevertheless, it does not go further to explain the standard of the reasonable royalty. Besides, due to lack of general standards of an equitable royalty in the international law, approaches vary from one country to another country. Overall, developed countries are more likely to require a higher level of royalty to compensate the loss of the patentee. For example, in the case of Gargoyles, the court held a 10% royalty as compensation and asserted that ‘because recovery is based on eminent domain, the proper measure is what the owner has lost, not what the taker has gained.’ Similarly, in IMS Health, the European Commission noted that compulsory licensing should not cause the patentee to suffer an unreasonable loss of income. Besides, developed countries would like to underscore marketing factors in determining a reasonable royalty, which include the scope of licensing, the portion of product profitability, benefits of the licensed patent, and other factors that may be considered in a hypothetical negotiation on this licensing. By contrast, developing countries are generally reluctant to set a high standard of the royalty. For instance, the patentees were entitled to a 0.5% royalty on generic sales where the government of Thailand issued compulsory licenses for antiretroviral drugs. These opposite situations usually arouse controversy among different countries. Prof Cahoy proposed a three-level system to settle this problem. Within this system, a higher compensation should be appropriate for industrialized countries, where the utility of market rates should be considered as a default approach for measuring royalty. However, developing countries could set the standard based on their own conditions; and least-developed countries could even use compulsory license free of royalty in case of public health emergency. This proposal seems optimal since it is compatible to the provisions of the TRIPS
Agreement which offers additional assistance for developing countries and least-developed countries. Consequently, China, as a developing country, should adopt an appropriate standard of royalty considering its development stage. Although royalty would be determined case by case, it is necessary to note that the scope of compensation should not be expanded excessively. In detail, it would be sensible to entitle royalty for marketable products allowed by compulsory licensing rather than for the total cost of research and development investment.

**Introducing ‘Bolar Exemption’**

‘Bolar exemption’ is stipulated in the NCPL, under which the manufacture, use and importation of patented drugs or medical devices for the limited purpose of obtaining regulatory approval are exempted from infringement. Therefore, pharmaceutical companies are allowed to use patented drugs to obtain regulatory approval prior to their expiry without the patentee’s license. Without ‘Bolar exemption’, pharmaceutical companies would get entangled in disputes if they use the patented work without permission for regulatory approval. Before this amendment, a case related to clinical trial has attracted widespread attention as to whether the use of the patented work for obtaining regulatory approval constitutes a patent infringement. In this case, Sankyo Company of Japan and Shanghai Sankyo Pharmaceutical Company accused Beijing Wansheng Drug Company of using patented matter without patentee’s permission. The court finally dismissed plaintiff’s claims based on its finding that the defendant used patented matter merely for the purpose of research and regulatory review. Due to the absence of ‘Bolar exemption’ provision, the court asserted that using a patent for research and regulatory review does not constitute infringement because it does not fall into the category of infringement described in Article 11 that requires a business purpose. Apparently, the court recognized that the complex and time-consuming process of seeking regulatory approval for a new drug would delay generic drugs from entering the market, thereby actually extending the life of the patent and distorting the original legislative intention. However, it is unconvincing to argue that seeking regulatory approval has no business purpose at all. The Article 11 of the Patent Law 2000 prohibits any use of the patent for business purposes without patentee’s permission, while it does not define the scope of business purpose. It is undeniable that using patented drugs for regulatory approval is ultimately targeted at the success in sales. In this regard, it would be more objective to state that seeking regulatory approval does not involve direct business purposes. Therefore, the new provision of ‘Bolar exemption’ offers a clear guidance on this issue by explicitly allowing exploitation of patented drugs or medical devices for the limited purpose of obtaining regulatory approval. It would benefit public access to pharmaceuticals by facilitating generics competitors entering into markets.

‘Bolar exemption’ has been reconfirmed in the case of the Canadian Pharmaceuticals, where the WTO Panel held that the regulatory exception does not violate requirement of the TRIPS Agreement. This case would encourage generic drug companies to engage in research and development before expiration of the patented drugs so that new products can launch without an unfair delay.

At present, the generic industry has begun to take giant stride with the increasing expiration of drug patents. A variety of blockbuster drugs will lose the patent protection in 2010 and the next few years. Chinese generic drug companies, which contribute to China’s prominent position of the global generic drug industry, should pay more attention to seizing such market opportunities by using ‘Bolar exemption’. Accordingly, more efforts should be directed into patent information retrieval, market acquaintance, further research and development, and so on.

**Accepting International Patent Exhaustion**

The NCPL re-affirms patent exhaustion and accepts international patent exhaustion. The Article 69 of the NCPL definitely states that where a product is sold or licensed to be sold by the patentee, such a product can be used, offered for sale, sold, or imported. The right to import under the doctrine of patent exhaustion is newly added, which demonstrates that parallel imports of a patented product would not be deemed as infringement. This amendment is expected to open the window for parallel imports and promote access to the patented products from cheaper international sources.

The international exhaustion policy allowing parallel imports would have important implications for Chinese patients and China’s pharmaceutical industry. The fact that many international leading pharmaceutical manufacturers adopt price
discrimination policies across different markets makes the parallel trade meaningful for increasing access to important medicines in China. The direct benefit of parallel imports is that the public in developing countries including China, where some blockbuster drugs are sold in small volumes at high prices, may obtain cheaper drugs from foreign markets. Moreover, like compulsory licensing, parallel imports can be utilized as negotiating leverage in that original manufacturers might agree to supply at lower prices when faced with the threat of parallel imports. On the other hand, this policy may also have some potential negative impacts on access to pharmaceutical resources, especially for the long run. First, parallel imports would raise prices in exporting countries because the original manufacturers can restrict the supply of the patented products. Second, enthusiasm for new research would dampen due to free ride permitted by parallel imports and profit reductions suffered by original manufacturers. Nevertheless, overall, benefits would outweigh the disadvantages at the current stage, considering that China is a low-income country, where a lot of poor people cannot afford expensive life-saving drugs and domestic firms have insufficient innovation capacity for developing new drugs.

Conclusion

The access to pharmaceuticals is of significance to ensure the right to health. This issue has attracted more and more attention from the world. The adequate access to pharmaceuticals is to be achieved under a series of conditions, including sufficient quantity of drugs, reasonable price of drugs, effective and dynamic markets, and so on. However, achieving these conditions, sometimes, are impeded by the technological lag, limited capability of manufacture, and expanding exclusive power of IP rights. In order to overcome such challenges, especially for developing countries, it is necessary to provide a reasonable IP system that not only works for protecting the intellectual creation, but also provides sensible flexibilities to balance the right to health and the IP right. Fortunately, flexibilities within the IP regime have been recognized from the international instruments to domestic IP laws. Further efforts to facilitate access to medical resources in least-developed countries are still expected. For example, the domain of ‘public health problems’ should be expanded from the traditional epidemics to more diseases that affect large population, such as heart disease and cancer. Accordingly, more drugs should be targeted by the program of promoting access to pharmaceuticals. In addition, the procedure of granting compulsory licenses should be simplified to alleviate countries’ apprehension when implementing this policy. It is worth mentioning that China, as a representative of developing countries, has presented a strong intention and made an attempt to promote access to drugs during the third amendment of China’s Patent Law. Revisions, including rise of novelty standard, changes to compulsory license provisions, provision of ‘Bolar exemption’, and acceptance of international patent exhaustion, would have profound implications for ensuring access to pharmaceuticals and protecting the public health.

Acknowledgement

The author is grateful for the digital resources provided by Zhejiang Shuren University and Erasmus University of Rotterdam. Also thanks to Prof Maarten Kroeze and Prof Tobias Cohen Jehoram for their kind help.

References

1. The right to health is included in the Universal Declaration of Human Rights (hereinafter UDHR), the International Covenant on Economic, Social and Cultural Rights (hereinafter ICESCR), the Convention on the rights of the Child, the Convention on the Elimination of All Forms of Discrimination against Women (hereinafter CEDAW), and so on.
5. Substantive Issues, paras, 13, 14, 15, 16, 17.


Implementing Regulation of the Patent Law, 2010, Article 73.

Measures to implement public health-related compulsory licensing, 2005, Article 9.


Gargoyles Inc & Pro-Tec v The United States, 113 F.3d 1572, 1997.


