



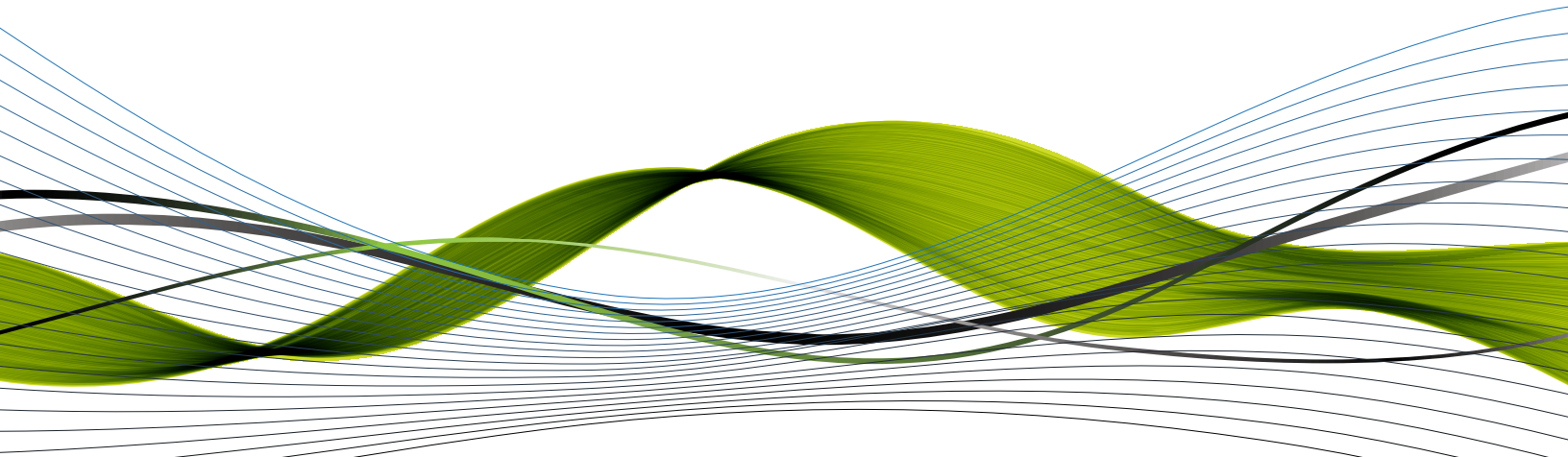
**U.S. CHAMBER OF COMMERCE**



# **中美知识产权学者对话纪要**

## **U.S.-China IP Cooperation Dialogue**

**2016**



## U.S.-China IP Cooperation Dialogue

2016

*“Scholars at the U.S.-China IP Cooperation Dialogue have deeply realized that innovation is the source of progress. A sound intellectual property rights protection regime that fully and effectively protects intellectual property rights is both beneficial to the development of domestic technology and economy and the prosperity of China and the U.S., and it can benefit mankind as a community.”*

Liu Chuntian, Co-chair of the U.S.-China IP Cooperation Dialogue

*“The Dialogue is a group of accomplished professionals who understand the foundation of innovation lies in a well-designed intellectual property system. Our work provides concrete ways to design an IP system that contributes to society and supports global prosperity.”*

David Kappos, Co-chair of the U.S.-China IP Cooperation Dialogue

The U.S.-China IP Cooperation Dialogue reached new heights of achievement in 2016, gathering together key policy leaders in support of innovation. Led by experts from the United States and China, the Dialogue explored the mechanisms in place to protect and enforce intellectual property and reached mutual understanding and consensus.

### Background

The Dialogue began in 2013 with a shared vision of the importance of intellectual property (IP). Over a span of four years, the Dialogue has convened annually in China and the United States, and has eventually matured to a point of mutual trust and understanding among the experts. The Dialogue follows the principle of “seeking common ground and reserving differences.”

The Intellectual Property Institute of Renmin University of China and the U.S. Chamber of Commerce jointly convene the U.S.-China IP Dialogue. Twice a year, these conveners invite an ever-expanding group of policy leaders to exchange views on U.S.-China IP relations, the global innovation system, and the foundation provided by intellectual property protections.

Each year, the Dialogue members engage in a wide range of activities that build a useful platform for U.S. and Chinese IP relations. This includes research, teaching, private practice of law, counseling students, engaging with the U.S. and Chinese governments, etc. Dialogue members have a deep understanding of the development of technology, the economy, the law, and the importance of U.S.-China relations. The Dialogue members believe the extensive and varied experiences of its members helps better inform its exchanges and opinions and also helps demonstrate a collective commitment to improving IP protection in the two countries. It should be noted that the Dialogue report reflects

the consensus reached in the group’s meetings and should not be attributed as the personal opinion of any individual or his or her employer or clients.

The Chinese experts reports and presents the Dialogue’s achievements to the Premier’s Office, Supreme People’s Court, Ministry of Commerce, Ministry of Education, State Intellectual Property Office, and China Law Society, among others. The U.S. experts

generate a press release in Washington, D.C., and circulates the Dialogue report within the U.S. government.

This year, members of the Dialogue are also pleased to note that its model for nongovernment expert discussion of IP challenges has been adopted for use in European-Chinese IP discussions. We look forward to exchanging views, opinions, and approaches with other countries' experts.

### **The Results of Our Work**

Through discussion, research, and understanding of the IP systems in the United States and China, the Dialogue provides a prioritized set of proposals on how to address intellectual property challenges.

The Dialogue notes that many of the topics discussed are in various stages of consideration and adoption in China. Some are being carefully studied, some have matured into pilot projects, others have sparked legislative or judicial action or other forms of meaningful activity. In this report, we list a few examples of meaningful progress that has been made on Dialogue priorities.

*Judicial Protection of Intellectual Property Rights:* In the first and second reports of the Dialogue, the experts recommended an amicus curiae system for on-the-record opinions of interested experts in a pending case, a guiding case system, or other precedential system to provide guidance for courts on well-reasoned cases and for improving the application of existing legal criteria for the award of civil damages. The goal of these efforts is to provide timely and authoritative guidance nationwide for judicial authorities and policy makers.

The Dialogue experts note promising activities on all fronts. China's Supreme People's Court has initiated a project to establish a case database system, and private law firm projects have increased access to judicial decisions. The Beijing IP Court is piloting a judicial amicus curiae system on behalf of China's Supreme People's Court. Efforts are underway by various courts to improve procedures for damage awards for IP in China's judicial system. Both the 2014 new trademark law and the new drafts of copyright and patent laws have increased damages for intellectual property infringement, including consideration of more deterrent or punitive damages.

While awaiting further legislative developments, judicial protection for IP in China has progressed to address significant changes in the marketplace and technology, to improve the consistency and uniformity of IP adjudication, and to support further positive development of market-based mechanisms for protection of private intellectual property rights.

The pilot reforms of Beijing, Shanghai, and Guangzhou IP courts are based on China's national conditions, with reference to international experience, and have blazed a trail for IP adjudication. The international community has recognized the achievements of Beijing's IP court. Dialogue experts believe that to address the lack of consistency and uniformity of IP adjudication, the establishment of a unified IP appellate court nationwide might be a rational and highly cost-effective solution.

*Patent Examination:* In its reports, the Dialogue noted that patents are critical to incentivize innovation in software and innovative pharmaceutical products. At the end of 2016, the State Intellectual Property Office released draft amendments to its patent examination guidelines that positively addressed the patentability of software. In addition, the draft amendment allows for the submission of supplemental data for pharmaceutical patent applications; this policy is necessary to support innovation in the sector and will bring China into closer consistency with best practices of other large patent offices.

*Bad-Faith Trademarks:* China's trademark office, the Trademark Review and Adjudication Board, as well as China's Supreme Court are increasingly paying attention to concrete solutions to address the pervasive problem of bad-faith trademark applications. The Dialogue members note several recent positive developments. U.S. experts note in particular a recent ruling by China's Supreme Court on the Qiaodan trademark. The court found a Chinese retail sports chain had acted in bad faith by registering the Chinese transliteration of Michael Jordan in pinyin (Qiaodan) and violated Michael Jordan's prior naming rights under China's General Principles of the Civil Code. They also believe that the attention that the Supreme People's Court has paid to this case will have an impact on other cases involving similar facts or circumstances, including by incorporation of this case into China's emerging system of guiding cases or as case precedent.

*Marketplace for Copyright:* Dialogue members discussed changing technology and business models and the importance of developing a good ecosystem and more market opportunities for copyright holders to combat piracy. China has taken important steps toward creating a more robust, legitimate marketplace for many forms of copyright content, with more licensing opportunities for major internet companies in music, increased growth in motion picture box office sales, more co-productive activities, and other examples. However, controlling the distribution of entertainment products is likely to continue to be an important factor in illegal consumer downloads.

*Copyright Protection for Live Sports Broadcasts:* Professional sports broadcasting has made valuable contributions to society. It is a significant commercial endeavor that requires sizable investments, generates great economic value, and supports the dreams of athletes and leagues around the world. According to the World Intellectual Property Organization, sports broadcast and media rights are "now the biggest source of revenue for most sports organizations, generating the funds needed to finance major sporting events, refurbish sports stadia, and contribute to the development of sport at grassroots level."

Providing copyright protection for live sports broadcasts is an international common practice. It is encouraging that in the 2014 case *Beijing Sina Internet Information Services v. Beijing Tianying Jiuzhou Network Technology Co.*, a Beijing district court recognized that sporting event broadcasts are sufficiently original to warrant copyright protection, and it therefore recognized the applicability of copyright to those broadcasts under Chinese law. Although the copyright law revisions are still underway, this court case is a good sign for Chinese sports leagues, broadcasters, and all those employed in

the creative process of producing a live sports broadcast. Dialogue members look forward to a decision on the appeal of this matter from the Beijing IP court, which it hopes will support more stable copyright protection for sports broadcasting and licensing.

## **Executive Summary**

This year, the experts chose five topics for discussion: technology transfer and licensing, trade secrets, innovation in medicines, trademark registration, patentability of software, and industrial design.

The report reached the following conclusions:

- A robust IP licensing trade system requires that the relevant parties have confidence in the legal principles that will protect the technology transaction. This confidence comes from the ability to make autonomous decisions according to their mutual benefit and to maintain control of their IP without excessive government interference or dictation of terms.
- Trade secret protection is key to IP-intensive industries, and it is important to supporting research-intensive industries and legitimate global technology and product flows. It is time for China to amend and implement comprehensive reforms to the outdated trade secret regime set forth in China's Anti-Unfair Competition Law (AUCL) and related legislation.
- The biopharmaceutical industry stands out as a key driver in meeting society's health needs today and in the future, but China's regulatory regime impedes growth in this sector in several ways. It lacks a functional patent linkage regime to ensure that generic companies can obtain approval of their non-infringing products, a patent term restoration for patent term loss due to regulatory delays, and protection for treatment methods and effective regulatory data protection without regard to the country of first launch. All of these policies are critical to China's acquisition of leading-edge pharmaceutical products and to support for significant R&D investments in new treatments and cures for patients.
- Brand development in China would improve significantly from a reduction in bad-faith trademark registrations and from increased predictability and consistency in trademark adjudication—both in administrative and judicial settings.
- The patentability of software in China and around the world is critical to support innovation in ever-expanding technological fields and endeavors.
- The world's major economies have recognized the importance of industrial design, and the United States and China should collaborate to improve all forms of protection, including design patents, three-dimensional marks, applied art in copyright, and unregistered trade dress. In particular, Dialogue experts discussed the benefits of allowing applicants to file partial design claims and extending the grace period that precedes patent applications.

## Areas of Research and Collaboration

This year, Dialogue experts collaborated on a number of research projects, conducted individual research, and noted other research relevant to topics covered by the Dialogue.

- [\*Faux Amis: China-U.S. Patent Administrative Enforcement Comparison\*](#), by Dialogue experts Professor Mark Cohen, David Kappos and Judge Randall Rader (ret.), addresses common misconceptions regarding the U.S. patent administrative enforcement system in light of China's ongoing reform of its own patent law.
- [\*Interpretation of Conflicts on General Clause Concerning Grounds for Refusing Trademark Registration\*](#), by Dialogue expert Professor Li Chen, canvasses Chinese courts' divergent interpretations of statutory grounds for refusing trademark registration, including bad faith, and highlights the need for legal predictability and consistency.
- [\*Research Report on Establishing System of Linking New Drug Applications and Patent Protection\*](#), by Dialogue expert Cheng Yongshun and the Beijing Intellectual Property Institute, addresses both the current status of biopharmaceutical innovation in China and the positive effects of the adoption of patent linkage in China, providing valuable research results. This paper is attached to the report.
- [\*Copyright Extremophiles: Do Creative Industries Thrive or Just Survive in China's High-Piracy Environment?\*](#) by Dialogue expert Eric Priest, highlights the important role a strong copyright ecosystem plays in the development of creative industries in China and beyond.
- [\*China IPR\*](#), a Chinese IP law blog operated by Dialogue expert Mark Cohen, includes reports on recent IP developments such as entertainment law developments, trade fair enforcement of intellectual property, China's efforts to develop a strong IP economy, the Qiaodan case, commercial rule of law developments, and other matters.
- [\*S&T Talent Recruitment and Retention Strategies for Technology Innovation in the Beijing and Shanghai R&D Clusters\*](#), by Professor Michael P. Ryan of Georgetown University, discusses the negative implications of the proposed service invention remuneration regulations on talent recruitment and retention in China.



### Co-Chairs

**Liu Chuntian**, Professor at the Renmin University of China and Chairman of China IP Law Association

**David Kappos**, Former Director of the U.S. PTO and Partner at Cravath, Swaine & Moore LLP

### Experts

**Cheng Yongshun**, Director of the Beijing Intellectual Property Institute and Former Deputy Chief Intellectual Property Judge of Beijing Higher People's Court

**Li Chen**, Professor at the Intellectual Property Academy, Renmin University of China

**Gao Lulin**, Founder and Chairman of Beijing East IP Ltd. and Former Commissioner of the State Intellectual Property Center

**Ma Yide**, Director of Zhongguancun Intellectual Property Research Institute and a Member and the Deputy Director of the Science and Technology Committee of Beijing People's Political Consultative Conference

**Randall Rader** (ret.), Former Chief Judge for the Court of Appeals for the Federal Circuit

**Mark Cohen**, Professor at Fordham University School of Law and USPTO Senior Counsel

**Anthony Chen**, Partner at Jones Day, Shanghai

**Eric Priest**, Professor at the University of Oregon School of Law



[From left to right] First Row: Gao Lulin, Judge Rader, David Kappos, Liu Chuntian, Li Chen. Second Row: Ma Yide, Mark Cohen, Judge Cheng. Third Row: Anthony Chen, Eric Priest

# 1. Technology Transfer and Licensing

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Dialogue experts on both the U.S. and the Chinese side recognize that IP licensing issues—particularly patent and technology licensing issues—deserve more serious attention at this time.

## 1.1 Increasing the Role of the Market in China

A focus on licensing is consistent with the goals of increasing the role of the market generally in China. More specifically, the Chinese Communist Party's third plenum recognized that IP utilization is an important aspect of China's plans with regard to intellectual property.

The National IP Strategy has also committed China to increase its own technology exports to US\$8 billion by 2020. Moreover, we have observed that many of China's technology plans, in diverse areas such as “mass innovation,” “open source innovation,” cross licensing with foreign parties, going abroad, acquiring technology, and transferring technology motivated by humanitarian and charitable reasons have significant licensing components.

## 1.2 Licensing-in and Licensing-out for China

IP commercialization through licensing-in and licensing-out of China still lags far behind where one would expect it to be, given the number of patent applications filed. Dialogue experts were presented with licensing-out figures for China at the May 2016 conference, and additional studies published in October show a lower-than-expected figure.<sup>1</sup> One of those studies noted that despite a high number of patent applications, Chinese universities are not licensing inventions in large numbers. For example, Stanford University filed 252 patent applications in 2011 and licensed out 101; in that same year, Tsinghua University filed 1,883 patent applications and licensed out only 28. According to the World Bank, in 2014, Singapore's IP licensing receipts were five times larger than those of China.<sup>2</sup> Dialogue experts are interested in studying this issue further. In the 2016 Dialogue report, the experts went into greater detail on licensing-in for China.

The licensing-in of patents and know-how allows Chinese companies to acquire leading-edge technology and improve manufacturing techniques and processes, enabling them to compete effectively and more freely in global markets. IP licensors often benefit from selling manufacturing equipment through such technology transactions. A stable licensing regime also supports government-to-government science and technology collaboration. In addition, Chinese companies that are able to acquire leading-edge foreign technology will be able to develop new products more quickly, will be less susceptible to lawsuits overseas, and may be better positioned to implement global marketing strategies.

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<sup>1</sup> *The State of China Technology Transfer*, published by Sinoipro IP Management & Technology Transfer Co. Ltd., October 2016.

<sup>2</sup> <http://databank.worldbank.org/data/reports.aspx?source=2&series=BX.GSR.ROYL.CD&country=> (accessed November 28, 2016).



### 1.3 China's Technology Import/Export Regulations

The U.S. government has expressed concerns that China's technology import/export regulations in particular may be inconsistent with government-to-government technological collaboration programs, such as those involving clean energy. Moreover, China needs to acquire leading-edge technology for its private sector. For example, China is now the only country in the world where 3 companies—Huawei, ZTE, and Datang—are among the top 10 contributors to the 3GPP working group's cellular standards. These companies also require an environment where they can collaborate on a more level field, including by purchasing leading-edge foreign technologies.

The experts point to several ongoing issues under the current China technology import and export regulations that have impaired or threaten to impair greater technological collaboration between China and other countries. The Chinese experts pointed out that the current China technology transfer regulations were enacted in an era when Chinese firms were not in a position to collaborate such as they are in the current era. All of the Dialogue experts believe that the freedom to contract should be honored in cross-border technology collaboration.

For example, the current regulations require foreign licensors to indemnify domestic licensees for infringement of any third-party IP; such rules discriminate against foreign licensors. Pursuant to relevant provisions under the contract law in China, domestic parties in a technology transaction are instead allowed to decide how risk of infringement should be allocated. Moreover, the rules make it difficult for a foreign licensor of an improvement to a technology that is dependent on the improvements of another party to engage in that license—unless the third party agrees to provide a suitable indemnity. The same regulation and related judicial interpretation also impose mandatory rules on the ownership of improvements that are made on top of the licensed background technologies. The current regulations essentially force licensors to give up improvements that are made by licensees—even though such improvements would not have been possible without the transfer of IP from the licensors.

The U.S. experts note that the impediments of current technology transfer regulations have partly impeded technology imports from the United States to China. Only 40% of technology transactions in China occur between U.S. companies and unaffiliated Chinese companies. Moreover, the volume of China's acquisitions of technology from the United States is disproportionately low compared with its high-tech exports or its expanding role as an innovative economy, as noted in such reports as the *Global Innovation Index* published by the World Intellectual Property Organization.

### 1.4 Global Innovation Ecosystems

Dialogue experts point to the potential impact on innovation and startup technology companies. Global innovation ecosystems provide incredible opportunities for technology entrepreneurs in China and the United States to work together. However, compulsory requirements in the IP licensing rules under the China's laws deter such cooperation. Overseas companies with leading-edge technology, particularly startups, may be unwilling to license to Chinese companies because of the mandatory obligations that are imposed on them.

Dialogue experts have noted some fundamental changes in today's technology collaboration environment. In the 1980s, state-owned companies often shared with each other when foreign technologies were imported. That technology was normally a part of a package for a manufacturing production line. However, in today's market economy, Chinese firms, whether state-owned or private, compete with each other. These companies develop new technologies, by themselves or through joint development, and it becomes part of their core competitiveness. Besides possessing advanced technology, a robust IP licensing trade system is key to boosting the confidence of those parties in the technology transaction. Typically, the companies will make autonomous decisions according to their mutual benefit and maintain control of their IP.

It is encouraging that at the meeting between the presidents of China and the United States in Hangzhou before the 2016 G20 Summit, both countries committed to avoid advancing generally applicable policies and practices that require the transfer of intellectual property rights or technology as a condition of doing business in their respective markets. Such commitments should be put into practice through progressive policies for both countries' technology transfer regimes.

## 2. TRADE SECRETS

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### 2.1 Progress in Legislative Changes

In 2016, there was new momentum in the area of protection of trade secrets in the United States and China. The U.S. Congress passed its Defend Trade Secrets Act of 2016, and China started its amendment of the Anti-Unfair Competition Law (AUCL), with a special focus on trade secrets. China and the United States also affirmed the importance of protecting trade secrets at the meeting between their presidents in Hangzhou before the G20 Summit.

This work provides a road map for future improvements. Dialogue experts believe it is important to continue raising the awareness of trade secrets protection, which is key to IP-intensive industries and important to technology development, labor mobility, and global technology and product flows. It is the time to fulfill the intended outcomes of legislative reforms in both China and the United States.

Dialogue experts have called for recognizing the importance of trade secrets from the very beginning of the Dialogue, and so they are pleased that various recommendations have been adopted and implemented. Last year, Dialogue experts recommended that the Anti-Unfair Competition law (AUCL) be revised, and they understand that a draft of the AUCL was submitted to the State Council Legislative Affairs Office (SCLAO) for review, with a public commenting period announced in February 2016. The proposed amendments shift burden of proof to the accused infringer in certain trade secrets cases, which should benefit enforcement. Still, even if these important reforms are enacted, additional reforms in civil procedure (particularly evidence gathering), criminal law, and employment law may be necessary to ensure that China's trade secrets regime can more fully help support China's efforts to become an innovative economy. Current legislative efforts are a good beginning and serve as positive evidence of the government's attention to this area.

## 2.2 Local Government Efforts

Dialogue experts note that local governments (e.g., Shenzhen) have tried various measures to increase protection for trade secrets. Shenzhen, where the Dialogue held its conference in January 2016, published draft IP enforcement measures targeted at protecting trademarks, patents, copyrights, and trade secrets. The draft measures proposed that the current liability threshold of 500,000 RMB in trade secrets cases be calculated based on the R&D investment spent by the plaintiff. Such proposals require further study and debate but are nonetheless encouraging.

Dialogue experts reviewed the Defend Trade Secrets Act that the U.S. Congress passed in May 2016. The new law demonstrates that the United States recognizes the important role of trade secrets. This significant step allows IP owners to expect uniform and effective protection of trade secrets under federal law and through the U.S. federal courts.

## 2.3 Trade Secret Legislative Action Needed in China

Dialogue experts strongly feel that the ongoing proposed legislative changes in China should provide more focus on trade secrets protection—and that these changes go beyond the traditional approach of relying on administrative enforcement. The U.S. experts have recommended in a prior Dialogue report that various measures should be adopted (e.g., steps to assist rights holders to seek preliminary injunctions, and evidence and asset preservation measures under the Civil Procedure Law). The law should ensure that administrative actions serve to protect companies' interests and that criminal enforcement is no longer routinely used wherever civil remedies might be adequate. Public awareness of trade secrets protection and improved measures for licensing technical secrets (i.e., confidential information) can help in commercializing very valuable trade secrets.

# 3. Innovation in Medicines

*(See attachment: Research Report on the Establishing System of Linking New Drug Application and Patent Protection)*

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Fundamentally, patents are a bundle of rights granted to “promote the progress of science and the useful arts.”<sup>3</sup> Today, that basic concept applies throughout the world as a foundation of patents in the biopharmaceutical industry. The biopharmaceutical industry stands out as a key driver to meeting the health needs of today and tomorrow. Strong patent protections are critical to enabling biopharmaceutical companies to make significant R&D investments and fund new treatments and cures for patients. After the patent expires, the generic industry is able to enter the marketplace at a much lower cost, as it does not have to replicate the R&D or expansive and expensive clinical trials of the innovator. When balanced properly, this approach creates an ecosystem that supports the innovative and generic sectors alike.

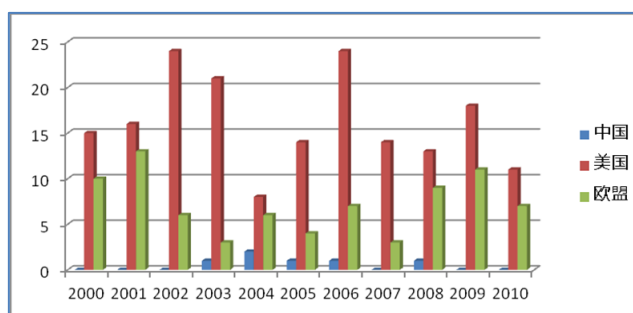
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<sup>3</sup> U.S. Const. art. I, § 8.

### 3.1 The Status of Biopharmaceutical Innovation in China

Dialogue experts note that this is a historic time for China to provide incentives for the development of new life-saving medicines and simultaneously support a vibrant generic market in China. In the past, Chinese companies had been solely focused on generic drug manufacturing, largely by state-owned enterprises, but now many in the industry have begun investing in innovative product lines. China has the benefit of a large market, an abundance of funds, and a large talent pool to make this successful. However, innovators face challenges in China's regulatory environment, which provides disincentives to innovation—and apparently the climate is getting worse. The latest draft amendments to the Drug Registration Rules make the creation of new life-saving medicines a losing proposition in China.

The experts analyzed policies in the United States and other countries that contributed to strong innovative sectors and thriving generic markets. For example, innovative achievements of Korean drug companies have surpassed those of Chinese companies. License royalties from Hanmi amounted to \$6 billion in 2015.

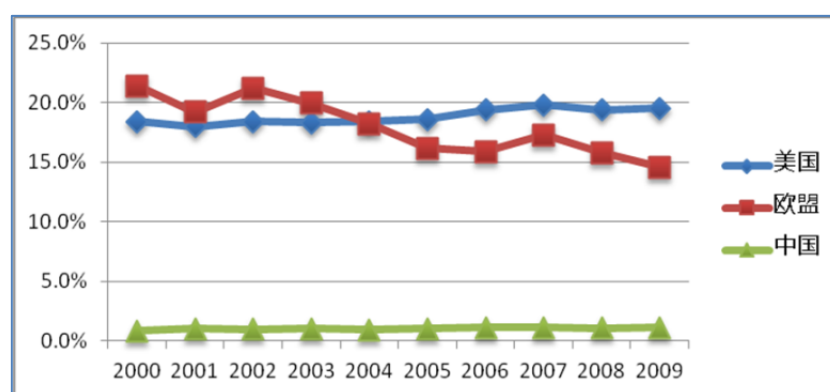


Annual Number of Marketed New Drugs of Each Country (Organization)<sup>4</sup>  
[China in Blue; U.S. in Red; EU in Green]

China's 12<sup>th</sup> Five-Year Plan envisioned an expansive growth for biotechnology, including the development of 30 new chemical entities and improved R&D output. Although the total number of innovative drugs produced in China in the past decade is less than a quarter of that of the United States—and far behind that of the **European Union** as well—things may be changing. For example, China-based BeiGene just raised \$158 million in its **IPO**, multinationals are investing in R&D facilities in China, Chinese clinical research organizations are globally integrating, and 187 novel therapeutics of Chinese origin are in clinical trials. So, it is clear that the **CFDA**'s current proposed approach is on a collision course with the trajectory of Chinese industry players and China's long-term development goals.

The preliminary results of our research provide an explanation for why China has fallen behind in innovation for this sector. China's regulatory regime lacks a functional patent linkage regime, compensation for patent term loss, and protection for treatment methods and effective regulatory data protection. These policies provide incentives to innovators and confidence to investors that their efforts will be rewarded. Without these regulatory protections, investment in this sector in China will continue to lag behind that in the United States, Europe, Japan, and Korea.

<sup>4</sup> Original citations provided in Attached *Research Report on Establishing System of Linking New Drug Application and Patent Protection*, BIPI Research (2016) No.002 published December 15, 2016, page 37 Fig.9.



Fund investment in R&D in the pharmaceutical industry<sup>5</sup>  
[U.S. in Blue EU in Red China in Green]

### 3.2 U.S. System of Patent Linkage

The reform of the U.S. regulatory environment—embodied in the Hatch-Waxman Act in 1984 resulted in a strong innovative sector and a strong generic sector, both of which continue to thrive. Before Hatch Waxman, innovative activities took place primarily in Europe, but now the United States is the foremost site for the development of new medicines. In addition, the generic industry's share of the U.S. marketplace went from 18.6% to 86% and is expected to climb to 90% in the next few years.

Before Hatch Waxman	After Hatch Waxman
Innovation activities took place in Europe.	Among 5,000 new drugs invented around the world, 3,400 were invented in the US, with an increase of 40% since 2005. <sup>6</sup>
Generic drugs represented about 18.6% of the prescription drug market. <sup>7</sup>	The generic drug portion of U.S. market increased to 86%. <sup>8</sup> The generic drug market in the US represents about 45% of the global generic drug market—amounting to \$43.5 billion in 2013, with an expectation of more than a 10% increase in 2018. <sup>9</sup>

Adoption of patent linkage in the United States resulted in many positive developments for both innovators and generics. For one, it allowed for patent disputes to be settled before the generic invested in and delivered the drug to the marketplace. Resolving disputes before large investments are made offers stability and predictability for investors. In the United States, there has been a large increase in these pre-market challenges by generics, and the rate of patent infringement cases involving generic drugs already approved in the marketplace amounted to only 6% of all accepted cases between 1984 and 2004.

<sup>5</sup> Original citations provided in Attached *Research Report on Establishing System of Linking New Drug Application and Patent Protection*, BIPi Research (2016) No.002 published December 15, 2016, page 40, Fig.11.

<sup>6</sup> See Medicines in the Pipeline (<http://www.phrma.org/pipeline>); See Also Pharmaceuticals, Small Business and IP, Available at <http://sbecouncil.org/2014/07/11/pharmaceuticals-small-business-and-international-ip/>

<sup>7</sup> See Generic Drug Savings in US, Available at [http://www.gphaonline.org/media/cms/GPhA\\_Generic\\_Cost\\_Savings\\_2014\\_IMS\\_presentation.pdf](http://www.gphaonline.org/media/cms/GPhA_Generic_Cost_Savings_2014_IMS_presentation.pdf)

<sup>8</sup> Id.

<sup>9</sup> See US Generic Drug Market Outlook 2018, Available at <http://www.prnewswire.com/news-releases/us-generic-drug-market-outlook-2018-300035606.html>

Time Period	1984-1991	1992-2001	2001-2004.10	2010-2016.1
No. of New Drugs Challenged in the US <sup>10</sup>	26	104	123	299

Dialogue experts compared the regulatory systems in the United States and China and found that current policies in China lack systemic and operable protections for innovative medicines.

First, in China, the patent information of innovative drugs is not transparent, so there is no reliable warning system for innovators or generics of potential disputes. Second, there are virtually no grounds for seeking protection for an innovative drug when a generic company applies for marketing approval. Therefore, disputes occur only after a generic drug is in the marketplace—which is after the generic has made significant investments, putting the generic at risk for bankruptcy. A complete and operable patent linkage system provides an early resolution mechanism for both parties, predictability for all market participants, and a harmonious environment.

The chart below describes some of the patent linkage and other regulatory differences between the United States and China.<sup>11</sup>

	US	China	Result of Comparison
S u b s t a n c e	Patent information published in Orange Book	Article 18.1 of Provisions for Drug Registration	Similar contents; while Chinese provisions is not operable without procedural guarantee
	Bolar exception	Bolar exception	The same
	ANDA for generic drugs	Work plan of reform on classification of chemical drug registration	Substantial contents are basically the same
	Paragraph I-IV certification	Article 18.1 of Provisions for Drug Registration	Similar contents; while Chinese provisions is not operable without procedural guarantee
	Section 271(e)(2) artificial infringement		No such regulation
	30-month automatic stay	Article 18.2 of Provisions for Drug Registration: disputes will be dealt with under the Patent Law	1.No artificial infringement in China 2.No clarification of influence of results of infringement cases on drug registration approval
	180-day generic marketing exclusivity		No such regulation
p r o c e d u r e	Patent information by ANDA filers submitted to USPTO by FDA for review	No similar procedure	
	ANDA filer, after submitting paragraph I-IV certification, will serve notice to patent holder or new drug owner within 20 days	No similar procedure	
	Patentee brings lawsuit within 45 days upon receiving the notice	No similar procedure	
	After expiration of 30-month automatic stay, FDA decides on whether to grant approval based on judicial decision and technical conditions of generic drug	No similar procedure	

### 3.3 Patentability of Biopharmaceutical Innovation

In the last few Dialogue reports, the experts identified public policy issues and key legal issues related to data supplementation for patent applications. China has drafted an

<sup>10</sup> *Research Report on Establishing System of Linking New Drug Application and Patent Protection*, BIPI Research (2016) No.002 published December 15, 2016, page 26, Chart 2.

<sup>11</sup> *Research Report on Establishing System of Linking New Drug Application and Patent Protection*, BIPI Research (2016) No.002 published December 15, 2016, page 51, Chart 4.



amendment to the examination guidelines, which brings China further into harmonization with other IP5 countries (United States, Japan, Korea and the EU) and could provide the necessary support for biopharmaceutical innovation in China. This will bring China's patent system in step with the realities of drug discovery and will introduce certainty and balance to support the fragile ecosystem for biopharmaceutical innovation. The experts look forward to adoption of the improved examination practices regarding data supplementation in the revised patent examination guidelines.

To justify the significant commitments of time and money to transform a basic compound innovation into a safe, effective, and approved medicine, innovators rely on the ability to acquire patents globally and to reliably enforce them in legal systems globally.

### 3.4 Data Supplementation

To stimulate those investments needed to pursue the risky drug development process, a careful balance of interests has been struck by the United States and other members of the IP-5. Patents are required to contain disclosures that represent a social contract: The government agrees to grant rights to exclude others from practicing an invention for a limited time in exchange for a disclosure of that invention, which will enable the public to practice the invention once the patent expires.

The acceptance of data after a patent application's filing date is among the policies that result from balancing the need to grant rights early in the product development timeline and the public interest in the protected innovation entering the public domain for all to use. This is particularly important in the context of compound claims, where the subsequent data merely substantiate a property that is inherently a part of that compound.

The policy of accepting supplemental data is also based on an understanding that standards for demonstrating the inventiveness, novelty, and utility of a biopharmaceutical compound are quite different from the standards for demonstrating the safety and effectiveness of compound inventions. The patent system and the regulatory system serve different purposes: one provides incentives and the other ensures efficacy and safety. Because of those different objectives, there are significant differences between the standards of patentability and the standards of marketing approval for therapeutic drugs.

We suggest that China's long-term interests as well as the innovator's commercial interests are best served by aligning practices and policies on data consideration with those of the other IP5 countries. Those policies have been proven over time to promote development of an innovative sector and the introduction of new products into countries. China, like the United States, can become a world leader in medical innovation with the right balance of policies that have been proven successful elsewhere.

## 4. Trademark Registration in China

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The Dialogue experts attach great importance to trademark rights. The trademark system

is part of a suite of rights that encourages inventors, designers, and entrepreneurs to invest in creating products that both delight consumers and keep them safe. In order to support brand development in China, Dialogue experts offer observations on China's trademark system and some key challenges in the marketplace.

Overall, the experts stress the need to reduce bad-faith trademark registrations and increase predictability and consistency in the adjudication of trademarks—both in administrative and in judicial settings.

Dialogue expert Li Chen published an article on trademarks that summarizes some of the inconsistencies and current debate surrounding interpretation for provisions of the Trademark Law. The ongoing work of the Supreme People's Court in drafting a judicial interpretation on trademark prosecution would be helpful, and the Dialogue experts offer these observations to assist in the study of China's trademark system.

#### **4.1 Bad-Faith Trademark Registrations**

China's trademark system was designed to protect consumers and businesses, but it is now frequently abused in order to generate unwarranted profits for bad-faith registrants. Epidemic levels of bad-faith trademark cases are straining the resources of trademark offices and judicial bodies, creating insurmountable difficulties for up-and-coming brands and putting consumers at risk. Globalization of trade and culture, and the rapid rise of e-commerce and social media, has facilitated the cross-border reach of brands; however, these factors have also created opportunities for those who abuse the territorial nature of the trademark system for short-term personal gain.

In China, trademark rights are typically acquired through registration. Thus, the first entity to file a trademark application with the Chinese trademark office can become the trademark owner, even if that entity does not own the trademark elsewhere in the world. This affords registrants the opportunity to monitor the global marketplace for popular and emerging trademarks and “squat” on them in bad faith by filing to register them first with the trademark office. The Chinese and international brand owners then discover upon entering the market in China that they do not own their mark. Cases in which bad-faith registrants—including unscrupulous “trademark squatters”—seek to extort huge sums from existing brands are so common that a black market or cottage industry has developed.

One way to address many common bad-faith registrations is to focus on the use of the trademark. Currently, the trademark system places its focus primarily on registration as the value created; however, it is, in fact, commercial use of the mark and development of the brand that creates the real value. This requires a change in the mindset of the organizations that protect trademarks.

Article 32 of the 2014 Trademark Law does forbid registration of preexisting trademarks in an “unfair manner,” but significant practical barriers to implementing this standard remain. In some cases, one individual registers hundreds of trademarks that are variations of existing brand names. However, the trademark office has refused to allow mark owners who face massive amounts of unfair registrations to combine their complaints into one case. So brand owners must challenge each registration one by one.

This places a huge burden on brand owners and on government resources.

#### **4.2 Effect of Bad-Faith Trademarks on the Globalization of Chinese Brands**

Bad-faith trademark registrations harm innovation and the market in China. Creating unique brands with the ability to obtain rights in key markets is important to the future of brand development in China. Trading off the rights of established brands delivers short-term benefits in the domestic market but is a roadblock to entering the global marketplace.

Protecting this short-sighted strategy will only perpetuate the practice. To address this issue, China needs broader protection for prior rights and naming rights and interests, liability for bad-faith filers with knowledge, and broader interpretation of relevant trademark classes and the likelihood-of-confusion standard.

#### **4.3 Standards of Bad Faith**

Problems persist because the standards for bad faith are unclear and inconsistently applied by courts. For example, while the law now provides the grounds for legally recognizing well-known marks, the standards for determining well-known marks are unclear and are applied too infrequently and inconsistently. Articulating clear standards for bad-faith and well-known marks—and consistently applying those standards in the adjudication of trademark rights—is an important step in creating a pro-innovation ecosystem for brands in China and for supporting China’s goal of developing globally successful brands.

Business activity should be guided by ethics and fair practices. Reflecting this ideal, trademark law developed out of the law of unfair competition. Good faith has always been a bedrock principle of unfair competition law and indeed is a fundamental principle of civil behaviors established by civil laws. Although Article 32 of the current trademark law includes a requirement that trademark filings be made in good faith, it is not a clearly actionable basis for rejecting an application, filing an opposition, or canceling a trademark. So interpreted, the good-faith standard provides no meaningful deterrent for unethical behavior.

Because of the lack of clear guidelines in the statutory text, judicial opinions diverge markedly on what is required for showing “bad faith” in a registration. Moreover, judges often fail to consult prior decisions or otherwise seek guidance or consensus around these concepts, leading to tremendous inconsistency and unpredictability in cases involving bad-faith registrations. Dialogue experts believe that, at present, the effective measure might be imposing sanctions to bad-faith trademark registrations, which serves as a warning to others through judicial judgments or “judicial interpretations.” Judges should interpret the trademark law according to standard unfair competition principles requiring good faith. The Experts note that China’s Supreme People’s Court efforts in the Qiaodan case discussed immediately below, has drawn extensive attention.

#### **4.4 A Recent Judicial Decision**

The Supreme People’s Court issued a decision in December 2016 finding bad faith on the part of a Chinese company, Qiaodan Sports, which opened up a chain of sports stores

using “乔丹” (the Mandarin translation for Michael Jordan) and his silhouette logo, among other uses that were confusingly similar to Jordan’s name and likeness. The Supreme Court reversed the prior decisions of the Trademark Review and Adjudication Board and the lower courts by finding that Michael Jordan had prior rights to the mark in the form of naming rights.

The U.S experts believe that the court carefully studied well-established principles of trademark law from jurisdictions around the world in order to render its decision. The court rejected the heretofore unheard of “definitive association” standard created by the lower court and adopted a broad standard of “stable association” between Michael Jordan and the Chinese characters “乔丹”. The SPC also admitted evidence of Jordan’s fame in China, which the lower court simply refused to consider without explanation. Such survey evidence is commonly used in courts around the world to establish fame.

#### **4.5 Quality of Examination**

Two provisions in China’s recent amendments to the trademark law were intended to clear out the backlog. First, China’s trademark office is now required to complete examinations of trademark applications within nine months, and the office has committed to speeding up examinations and clearing the significant backlog within three years. Dialogue experts note that in recent years, the number of trademark registrations underwent a huge increase, which brings challenges to the examination work. The experts believe that to avoid subsequent disputes, attention should be paid to the quality of examination during the improvement of efficiency.

Dialogue experts note that efforts are underway at the Trademark Center to improve quality control and training, and our comments are provided to inform the center of our current concerns. We support these efforts and look forward to working with the Center and the trademark office to help address any difficulties and concerns.

## **5. Patentability of Software and Protection of Designs**

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### **5.1 Patentability of Software**

The Chinese and U.S. experts give full support for the patentability of software in both countries. The experts note the importance of software in an ever-expanding list of industries and fields of study as well as the positive impact of patentability, which provides incentives for technological development. China’s recent proposed amendments to its Patent Examination Guidelines offer more clarity to China’s protection of software, and the experts support these improvements.

### **5.2 Industrial Design**

A critical objective of the Dialogue this year was to discuss the growing recognition that innovative design creates economic value and protects consumers. At the end of 2015,

the five largest patent offices in the world<sup>12</sup> established the Industrial Design 5 (ID5) in recognition of design's importance and with the goal of improving the protection of designs.

Companies in the United States and China invest in the production of innovative designs and products and therefore need clarity and consistency in what tools are offered to them as options for IP protection. The experts suggest allowing applicants to file partial design claims and suggest extending the grace period that precedes patent application.

Dialogue experts discussed design patent systems that allow for three primary types of claims: whole article, part article, and partial. The experts reached a consensus that the Chinese design patent regime lacks the fundamental instruments to allow for partial patents. Improving the Chinese IP regime by permitting applicants to file partial design patents is in the proposed amendments of Article 2 of the fourth Chinese Patent Law. In order to understand the importance of adopting such an amendment, it is critical to first have a strong understanding of the differences between the three forms of design patents.

Whole article design patents have a major downside in the context of highly technical designs: They offer protection over the entirety of the design but not over alterations to individual components of an article. Therefore, if any distinct component of a product differs from the patented product, the former may be copied without legal consequences under “whole article” design patent protection—despite the existence of any strong similarity between the items. This is not possible if the patented product is protected by a “part article” design patent. The defining feature of “part article” protection is that it ensures that another product cannot feature a distinct component of the patented product. However, “part article” protection does not restrict imitators from simply moving the protected “part” of the patented product to a part of the product not covered by “part article” design patents. If a manufacturer intends to prevent this type of imitation, then it must seek “partial” design patent protection, which restricts the ability of an infringer to move the protected part to a new section of the product to escape liability.

In addition, the experts discussed extending the grace period to include a broader range of disclosures for design patents and for extending the grace period to at least one year for a wider range of activities. This change will facilitate collaboration between foreign and Chinese researchers; enable Chinese researchers to obtain patents in China despite inadvertent disclosures; help improve patent quality, based on comments on inventions disclosed in peer-reviewed publications; and help address problems associated with pre-application disclosures of new industrial designs. Finally, such efforts will also assist in further harmonization of patent practices among the major patent offices.

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<sup>12</sup> The ID5 is modeled after the IP5 (largest patent offices) and the TM5 (largest trademark offices) that were created over the past decade.

**Research Report**  
**on**  
**Establishing System of Linking New Drug**  
**Application and Patent Protection**

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# Research Report on Establishing System of Linking New Drug Application and Patent Protection

## Introduction

### I Background

Drug is a necessity for human beings to sustain life and ensure life dignity. Research and development of new drugs and decrease of drug price have been the everlasting topics. The drug research and development is characterized by long cycle, vast investment and extremely low success rate. Hence, by making use of design and formulation of relevant system, which aims at providing sufficient protection for drug-related R&D achievements as well as guaranteeing high benefits, on one hand, the continuous R&D activities with respect to new drugs carried out by pharmaceutical enterprises can be encouraged, while on the other hand, funds for R&D support can also be available. By such means, the sustainable development of drug-related R&D can be realized. According to statistics of the World Health Organization, among 315 kinds of essential drugs, only 3-5% of them are currently still under patent protection. Yet 312 of them were once under patent protection. It shows that patent protection makes great contribution to the development and research of new drugs and the patent system is a essential system to guarantee the new drug developers to get repaid from its R&D activities. The drug price is another factor in realizing accessibility, and decrease of drug price requires development of generic drugs. Providing patent protection for drugs, namely, exchanging disclosure for monopoly, is not only the requirement of drug accessibility, but also lay a foundation for manufacturing of generic drugs. The most typical case is penicillin. Penicillin was discovered in as early as 1928. At that time, its discoverer, Franklin, announced that he would like to contribute the relevant achievements, rather than seeking for patent protection. Yet the unfortunate result came out as the fact that penicillin was not put into use for the first time until 1942, while during the 14 years between 1928 and 1942, countless people died of the bacterial infection. It was a “tragic” case in which drug accessibility was not facilitated by patent protection.

Intellectual property system is an exotic for China and China’s intellectual property

system is primarily set up by taking reference of experience of foreign jurisdictions. When considering how to deal with drug-related issues, a system appropriate to China's situation can also be established by taking reference of foreign experience. In view of the international trends of promoting development of biopharmaceutical industry, Chinese authorities have enacted a series of policies in succession in the recent decade, aiming at propping up the development of pharmaceutical industry. In recent years in particular, China has, by keeping up with international trends, prioritized development of the biopharmaceutical industry as significant industry, encouraged and guided development and research of brand drugs, and accelerated industrial transformation, in order to try every effort to march from a generic drug nation towards a brand drug nation. In the general orientation of national overall planning on pharmaceutical industry, the implementation of all specific measures has become essential power for the pharmaceutical industry to achieve considerable development.

Taking account of weighing the interests between encouraging drug development and research and reducing drug price, currently, there are primarily three models with respect to drug protection throughout the world: (i) the patent linkage system represented by the United States, balancing the development of both brand and generic drugs, (ii) strong data protection system represented by Europe, focusing on protection of brand drugs, and (iii) the Indian Model. In determining what kind of system to establish in China so as to realizing the balance of the aforesaid two kinds of interests to the largest extent, a comprehensive consideration of international practices and the national situations per se should be taken into.

In view of the above, Beijing Intellectual Property Institute (hereinafter referred to as BIPI) has founded a research group to conduct a monographic study on the system of linking new drug application and patent protection.

## II Research process

In October 2015, in view of alterations in the *Patent Law of the People's Republic of China* and *Pharmaceutical Administration Law of the People's Republic of China*, BIPI reached a preliminary agreement on cooperation with U.S. Chamber of Commerce, aiming at setting up a system of linking new drug application and patent protection in China by taking reference of the patent linkage system of US. The essential target of the program is to submit legislative proposals concerning “setting up a system of linking

new drug application and patent protection in China” to legislature concerned.

After the program was initiated, in November 2015, BIPI started to set up the research team and invited experts in areas concerned to participate in. Its expert team included experts from justice, administration, and academia, some of whom had been focused on and engaged in the researches of relevant topics for quite a long time, with some research achievements being attained. Besides, in view of the mature experience in US, its research group consulted and communicated with experts from judiciary, administration and practitioners for their advices and suggestions.

During the program, its research group sought for advices and suggestions from relevant parties by organizing workshops in a variety of scales. BIPI held five seminars and workshops of different in scale in Beijing and Shanghai on January 12, April 15, May 26, June 25 and November 19, 2016 respectively. Over 100 people once attended the above seminars, including experts from the research group and from administrations and judiciary, lawyers and patent attorneys, as well as representatives from enterprises of brand drug and generic drug, research institutions, media, etc.

Now, the research report is accomplished after taking opinions of relevant parties. In addition, two legislative proposals based on the report is formulated and submitted to legislature concerned.



## Chapter I Foreign Systems Dealing with Patent Issues in Drug Registration

As was said, generally, there are three kinds of models in dealing with patent issues in drug registration throughout the world: the patent linkage system model represented by the United States, drug data protection system model represented by Europe, and the India Model, primarily characterized as excluding the drugs from patent protection. In the following part, the above three models will be analyzed specifically.

### Section I Patent Linkage System Model

#### I. United States

##### (I) Background

In 1937, sulfonamides incident happened in the United States. The drug was on sale without undergoing severe test. As a result, over 100 people died from taking the drug. In view of the incident, the US Congress adopted *Food, Drug and Cosmetic Act (FDCA)* in 1938, requiring manufacturers to equip drugs with detailed safety descriptions as well as entitling US Food and Drug Administration (FDA) to examine new drugs. New drugs should not be sold until they were certified safe by drug manufacturers. The act spared the United States from the thalidomide tragedy of a mass of children with birth defects in Europe. Later, the United States paid more attention to drug safety and adopted the *Kefauver-Harris Act* in 1962 providing that all drugs were required to be certified safe and effective before they were sold, that FDA is authorized to re-examine efficacy of drugs applying for sale since 1938, otherwise, they were not allowed to be sold any more, and that FDA is also authorized to monitor each step in new drug development and research and product manufacture. Therefore, the 1962 Amendment was also called “risk-free regulation”.



The act had significant effects on sale of brand and generic drugs. On the one hand, brand drugs encountered a sharp cut in period of market exclusivity under patent protection since they were required to conduct clinical safety and efficacy test. Studies showed that from 1966 to 1979, period of market exclusivity of brand drugs under patent protection declined from 13.6 years to 9.5 years in average. The act also greatly increased investment of brand drug manufacturers on drug development and research, which had greatly influenced their initiative in new drug development and research. On the other hand, according to the act, generic drugs, even if imitating brand drugs certified to be safe and effective, were required to conduct pharmaceutical clinical safety and efficacy research, resulting in increasingly high investment of generic drug manufacturers and grave damage on their initiative of imitation. As a result, no corresponding generic drugs came into being after the expiration of the patent protection of brand drugs and drug prices still remained high in the market. High drug price was unbearable for the public and also greatly increasing government's healthcare cost. Government's healthcare cost even reached 14% of GNP.

As calls for facilitating access of generic drugs to market increased, the US Congress adopted *Drug Price Competition and Patent Term Restoration Act*, which is also known as the Hatch-Waxman Act, in 1984. The act, on the one hand, promoted competitive capacity of generic drug manufacturers while on the other hand, greatly reduced drug expenditure of consumers. The Hatch-Waxman Act covered three aspects: firstly, term of patent protection was extended to restore time lost in routine approval of FDA for new drug application (NDA) so that the interests of the brand drug manufacturers committed to new drug development and research can be sufficiently protected and the objective of facilitating innovation can be achieved. Secondly, Bolar exemption was added so as to initiate imitation in advance and ensure that generic drugs were on sale in time. Bolar exception was incorporated in the third amendment to China's *Patent Law* in 2008. And thirdly, generic drugs were accelerated in being rolled out by patent linkage system. Subsequently, US Federal Trade Commission studied and found some loopholes in the act. Wherein, the Congress adopted *Medicare Prescription Drug and Modernization Act* and *Greater Access to Affordable Pharmaceutical Act* in 2003, aiming at improving drug patent linkage system and better balancing interests of all the parties.

Noteworthily, drug patent linkage system is simply part of the Hatch-Waxman Act while the drug patent protection system in US also covers patent term restoration system and data protection system enforced in Europe and Japan. Despite of some

differences in specific provision, the systems concerning patent term restoration and data protection in US is almost the same as those in Europe and Japan in terms of the overall system design and its substance. Considering that the research focuses on setting up a system of linking new drug application and patent protection in China, this report will not elaborate on the patent term restoration system and drug data protection system in US. Reference can be taken in the part of the report discussing the European and Japanese systems dealing with patent issues in drug registration.

## **(II) Main content**

As is mentioned, the patent linkage system in US is an important component of the Hatch-Waxman Act. From the perspective of institutional operation, the patent linkage system in US mainly includes two aspects: firstly, all patent-related information of pharmaceuticals or methods for application, term of drug exclusivity and other information covered by the new drugs should be disclosed in NDA, i.e., orange book system, which supplies references to subsequent generic drug application; and secondly, FDA decides to apply different subsequent procedures of approval based on declarations in abbreviated new drug applications (ANDAs) of generic drugs.

### **1. Orange Book system**

Brand drug manufacturers should submit all patent-related information of pharmaceuticals or methods of application covered by the new drugs (patent number and time of expiration of patent protection) in filing NDAs with FDA, including such patents as patents for medicinal active ingredients; patents for pharmaceutical products, including patents for preparations and compounds; patents for methods of pharmaceutical application including methods of application and indications, while excluding such patents as patents for methods of making medicinal active ingredients and patents for intermediates and metabolites. After NDAs are approved, FDA publishes the above information in the book titled *Approved Drug Products through Therapeutic Equivalence Evaluation* (since the book's cover is orange, it is also called "the Orange Book"). When considering patent issues that may be involved in generic drug registration, simply those patents recorded in the Orange Book will be dealt with.

In addition to patent-related information for pharmaceuticals or methods of

application covered by new drugs, the Orange Book also records the following information: drugs approved for sale and its holders of the approval, active ingredients, dosage forms, dosage, etc. of the said drugs, term of market exclusivity<sup>13</sup> (concerning term of market exclusivity of some drugs approved by FDA, the drug may be patented or not patented). Drugs whose terms of patent or market exclusivity have expired will be ruled out from the Orange Book. FDA annually publishes the new version and addendum version of the Orange Book. Since 1997, the e-version of the Orange Book is available on FDA website free of charge, with the supplemented and amended contents with respect to the previous month released monthly.

## **2. Abbreviated new drug application system for generic drugs**

In order to accelerate sale of generic drugs, the Hatch-Waxman Act designs a channel of abbreviated new drug application (ANDA) for the application of generic drug. In other words, the generic drugs, when applying for sale, are not required to repeatedly submit data of proof for drug safety and efficacy submitted in NDA (those data are acquired at an expense of huge amount of time and money). Instead, they are simply required to certify that generic drugs have the same active ingredients, manufacturing specifications, dosage forms, specifications and bioequivalence as brand drugs.

Meanwhile, while submitting the ANDAs, a generic drug applicant is required to submit the patent number and time of patent expiration for all the patents covering the drug and methods of manufacture<sup>14</sup> and make different types of declarations respectively concerning patents covering generic drugs illustrated in the Orange Book:

Paragraph I declaration: there is no information of drug-related patent registration;

Paragraph II declaration: drug-related patent has expired;

Paragraph III declaration: drug-related patent expires at some time;

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<sup>13</sup> Term of market exclusivity of orphan drugs (ODEs) is 7 years; term of market exclusivity of new chemical entities (NCEs) is 5 years; term of market exclusivity of pediatric drugs (PEDs) is original patent term + 6 months; term of market exclusivity for other up-to-standard revisions (supplementary applications) is 3 years; and term of market exclusivity of generic drugs is 180 days as soon as their ANDAs succeed in patent challenge.

<sup>14</sup> Ding Jinxi and Han Beibei. Comparative Study on Patent Linkage Systems in China and US, *Chinese Journal of Pharmaceuticals*, Issue 39, 2008

Paragraph IV declaration: drug-related patent is invalid or no patent is being infringed in the manufacture, application or sale of the new drug.

As for Paragraph I and II Declarations made during ANDA, FDA may directly approve the application if other requirements are complied with. As for Paragraph III declaration, FDA may approve the application after the relevant patent expires.

Where a generic drug applicant submits a Paragraph IV declaration, the applicant is required to notify each patent holder or NDA approval holder in 20 days. The notification should include declaration that bio-availability and bioequivalence report on the generic drug has been submitted to FDA and elaborate statement of facts and legal grounds for the invalidation or non-infringement of the said patent. The patent holder may institute a prosecution of patent infringement to court in 45 days after receiving the notification while the generic drug applicant may counter charge for invalidation of the patent to court. If the patent holder files a patent infringement lawsuit in 45 days, FDA will automatically grant a 30-month marketing approval stay (the spell is also called period of containment). If the court rules patent invalid or the generic drug does not constitute infringement, FDA will approve the ANDA and the first applicant will be granted with a 180-day period of market exclusivity of the generic drug, during which, FDA will no longer approve other applicants to roll out the same generic drug. If the first ANDA applicant fails to roll out the generic drug on market in 75 days after being approved or in 30 months after making the ANDA, the 180-day period of market exclusivity will be deprived. Submission of ANDA application annexed to Paragraph IV declaration is generally called patent challenge.

Key operation process in the above content is as shown in Fig. 1 as follows:

FDA will submit related materials regarding patent declaration submitted by an ANDA applicant to USPTO for the record after accepting an ANDA (Process ① in the following Fig. 1<sup>15</sup>). USPTO will examine the validity of patent and feeds information back to FDA, based on which, FDA conducts subsequent procedures (Process ② in Fig. 1). The process is exactly the linkage of the functions of FDA and USPTO.

If ANDA applicant submits Paragraph I and II declarations qualified, after the examination by USPTO, ANDA will be immediately approved by FDA; whereas ANDA with Paragraph III declaration will be approved after expiration of the drug-related

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<sup>15</sup> Ding Jinxi, Guo Xuan, and Jiang Hui. Research on Issues of Patent Linkage in Application for Approval in China and US, China Health Law, Issue 5, Vol. 19, September 2011 (Issue 114).

patent (Processes ③ and ④ in Fig. 1).

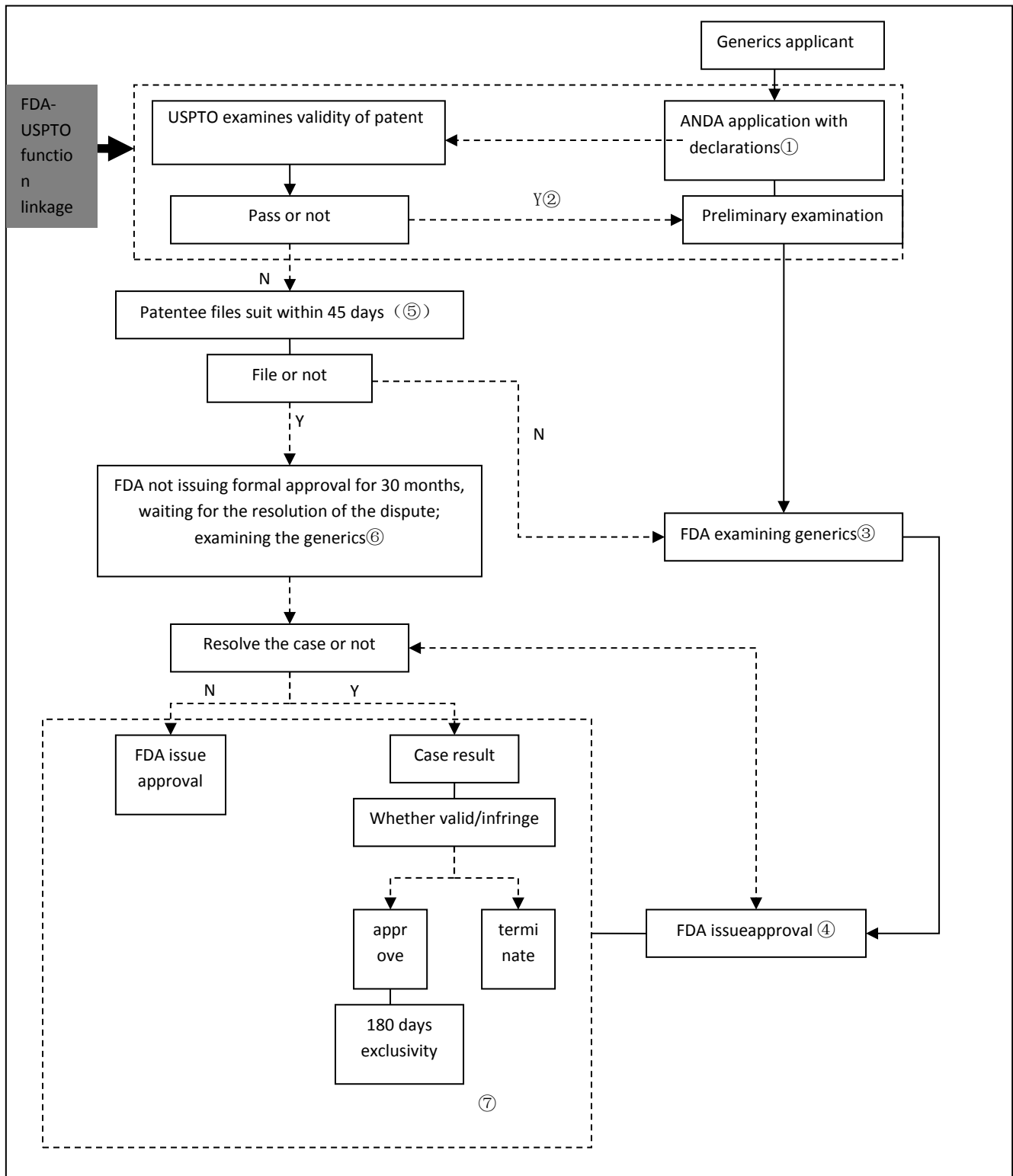


Fig. 1: Procedure of Patent Linkage System in US (Generic Drug Application part)

### **(III) Legal ground for patent linkage system**

#### **1. 271(e) in the Patent Act: Bolar exemption**

According to Bolar exemption, “information acquired, if purely for gaining approval from drug administration as specified in law, will not constitute infringement of patent in manufacture, sale, or offering for sale in the United States or import of invention awarded with patent to the United States”. The term provides a legal ground for generic drug manufacturers to acquire data required in sale approval as early as possible before the end of patent term of brand drugs, effectively facilitating generic drugs to be on sale as early as possible.

#### **2. 271(e)(2) in the Patent Act: artificial act of infringement**

One important objective in the patent linkage system of US is to enable brand drug holders and generic drug applicants to ascertain the validity of the patent as early as possible and resolve patent dispute before drugs are rolled out.

Before the expiration of the patent, where a generic drug applicant files patent challenge (Process ④ in the above figure), patentee or patent holder shall file a patent lawsuit with the court based on the legal ground of artificial act of infringement established in the Hatch-Waxman Act. In other words, any new drug registration application or generic drug registration application filed with drug administration before the expiration of the drug-related patent of others shall constitute an infringement of patent<sup>16</sup>.

### **(IV) Responsibilities of relevant departments in patent linkage**

In the patent linkage system in US, there is no change in the scope and content of responsibilities of FDA, PTO and the court. Still, FDA is mainly in charge of drug safety and efficacy supervision and administration. It is not responsible for the administration and enforcement under the Patent Act; let alone the jurisdiction of ascertaining and

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<sup>16</sup> Noteworthy, according to legal precedents of the US Federal Circuit Court of Appeals, the act of simply submission of ANDA to FDA does not constitute intentional infringement of patent.



ruling “the validity of patent” or “infringement”. PTO is still in charge of examination on the validity of patent, while the court is still in charge of case trial in the light of proceedings.

In the patent linkage system, FDA and PTO are required to coordinate and cooperate in some way, as is shown in Processes ① and ② in the above figure. FDA is required of taking the ruling of the court regarding patent issues into account as is shown in Process⑥ in the above figure.

## II Canada

### (I) Background

In Canada, federal acts concerning drug application include two parts: *Food and Drug Acts* and *Food and Drug Regulations* based on it, and *Patent Act* and *Patented Medicines (Notice of Compliance) Regulations* based on thereof. The *Patented Medicines (Notice of Compliance) Regulations* links authorization of drug application of a generic drug to patent of new drugs, so it is also comprehended as patent linkage regulation of drug application authorization.

In 1993, in order to implement legislation of North American Free Trade Agreement (NAFTA) as well as get prepared for the accession into TRIPS, Canada repealed compulsory licenses to be issued to food and drugs in the *Patent Act* ; instead, the following provisions have been adopted: (1) according to Article 55.2 in the *Patent Act*, a third person (generally, a generic drug manufacturer) is allowed to use patent for the sake of application for license for drug application (the “early-working” exception) when the said drug is still under patent protection; (2) the new *Patented Medicines (Notice of Compliance) Regulations* enacted links license for drug application of a generic drug to the determination of whether constituting patent infringement. The two systems work simultaneously, aiming at balancing effective patent protection of a new drug and accession into market of a generic drug in time. On the one hand, it ensures a generic drug to access into market in time after the patent is expired; on the other hand, it provides effective patent protection through patent linkage system.

The *Patented Medicines (Notice of Compliance) Regulations* elaborates issues with respect to relations between drug application and drug-related patent, aiming at restricting the sale of generic drugs before the expiration of the said patent, and thus

resulting in infringement of patent of brand drug manufacturers. The regulation, substantially revised in 1998, 2006 and 2015, is certified to play a significant role in Canada's pharmaceutical development and research. In order to enforce the regulation, the Health Canada establishes the Office of Patented Medicines and Liaison (OPML) to take charge of the patent linkage-related work during drug registration.

## **(II) Main content**

The patent linkage systems in Canada and US share basically identical main content in spite of slight difference. Their common grounds include:

### **1. Patent Register, equivalent to American Orange Book**

Patent registration is the core of the patent linkage system as a second person (generally a generic drug manufacturer) shall be required to overcome patent registered by a first person (generally, new drug applicant, i.e., patentee or patent license holder) in the Patent Register if being authorized for sale through abbreviated new drug submission (ANDS) or supplemental ANDS (SANDS).

The first person may submit patent lists concerning medicinal ingredients, formulations, dosage forms, or use of the medicinal ingredients approved in the new drug to OPML in the light of the *Patented Medicines (Notice of Compliance) Regulations* during or after making new drug submission (NDS) or supplemental NDS (SNDS) and patent lists approved in OPML technical review are registered in the Patent Register.

The *Patented Medicines (Notice of Compliance) Regulations* has a harsh time limit for submission of patent registration. Patent registration shall be submitted simultaneously in NDS or SNDS to Health Canada or within 30 days after the patent is granted if NDS or SNDS has been made and date of patent application is ahead of the date of NSD or SNDS. Moreover, a drug patent accessed to patent registrations is required to meet harsh relativity requirements. The patent shall: (1) contain claims concerning medicinal ingredients, formulations, dosage forms, or use of the medicinal ingredients approved in NDS, or (2) contain claims concerning formulations, dosage forms, or use of the medicinal ingredients approved to be revised by SNDS. Patents for methods of manufacturing, medical equipment, and intermediates in drug manufacturing are not registered. Last but not least, if a new drug of the first person is suspended from being

sold in Canada, resulting in repeal of its batch number, the Health Canada will delete patent concerned from the Patent Register within 90 days after the batch number is repealed.

## **2. Procedures of new drug application and patent linkage review**

According to *Patented Medicines (Notice of Compliance) Regulations*, Canada's drug patent linkage, namely, demand and process for patent review on patent-related drug registration application covers the following two aspects:

### **(1) Patent linkage in the Health Canada**

As is set forth above, first person enters related patent in the Patent Register via patent lists and patent linkage is a requirements for the second person in its submission of ANDS or SANDS. Where there is a valid patent in the Patent Register, second person is required to attach *Form V* with related to declaration of patent concerned in ANDS or SANDS. *Form V* is similar to US Paragraph IV Certification, whose first and foremost part is Part 3 "Reference drugs of first person" including information concerning reference drugs, related patents, and declarations of second person concerning the said related patents. Second person may have the following options in making declarations: (i) it has been licensed by the patentee to manufacture, use, and sell the drug; (ii) it is acceptable to be authorized after the related patents are expired; (or Notice of Compliance-NOC); (iii) patentee-related declaration made by first person during the submission of patent lists is wrong; (iv) the patent is somehow invalid, (v) the patent should be invalidated; or (vi) the manufacture, use or sale of the drug does not constitute infringement of the said patent. If Health Canada approves the application of second person after examining application materials while second person fails to overcome the valid related patent in the Patent Register, the application will come to procedures of patent hold till such patent is overcome.

### **(2) Patent linkage between Health Canada and Federal Court**

If a second person selects declaration of patent invalidation or non-infringement in *Form V*, the second person shall, after filing ANDS or SANDS, provide a detailed

Notice of Allegation (NOA) supporting the declaration of patent invalidation or non-infringement to first person and submit a copy of the NOA to Health Canada for the record. The first person may file a lawsuit (NOC lawsuit) to Federal Court within 45 days after receiving the NOA, applying for banning Health Canada from granting the NOC to generic drug manufacturer. The NOC lawsuit also signifies a preliminary injunction of 24 months. During the preliminary injunction, Health Canada will continue the technical review on the ANDS or SANDS involved, but will not grant authorization to second person unless patent of the first person expires, second person wins the lawsuit or the proceeding lasts for more than 24 months, even if the ANDS or SANDS passes technical review. If the second person loses the lawsuit, the authorization will not be granted until the patent expires, unless the patent is ultimately ruled invalidate in another comprehensive patent lawsuit.

The differences between the patent linkage system in Canada and US lie in the following aspects:

- (1) The patent linkage regulation in Canada is applicable to both chemicals and biological agents while the patent linkage system in US is applicable to chemicals only.
- (2) The preliminary injunction in Canada lasts for 24 months while the period is 30 months in US.
- (3) The first second person submitting ANDS or biological generic drug application in Canada is not granted market exclusivity, which will be granted for the first generics in US and will be last for as long as 180 days.
- (4) The judgment on NOC proceedings is not final judgment with respect to the invalidation or infringement of the said patent. First person and second person are entitled to file a comprehensive patent lawsuit with Canada's Patent Act for a final ruling on whether the said patent is valid or not, or whether constituting infringement or not.

### **III South Korea**

#### **(I) Background**

The pharmaceutical industry in South Korea is primarily focused on domestic generic drug manufacture and sale. Only a few enterprises conduct investment and development and research of brand drugs. In recent years, South Korean authorities

have started to encourage domestic enterprises to develop export market for brand drugs as well as carried out reforms to encourage brand drug investment. The patent linkage system in South Korea has been built based on the *US-Korea Free Trade Agreement* signed on June 30, 2007 by taking reference of the patent linkage system in US. The FTA became effective on March 15, 2012. Based on requirements in the FTA, South Korea supplemented its *Pharmaceutical Affairs Act*, initially and comprehensively enforced it in 2012 and March 2015 respectively.

## **(II) Main content**

On the one hand, the patent linkage system in South Korea is similar to that of US, which primarily includes:

1. The brand drug manufacturer should inform the patents related to a brand drug application within 30 days after receiving a notice of approval for new drug application from Ministry of Food and Drug Safety (MFDS).

The patents are listed in the Green List. MFDS should evaluate validity of patents submitted by the brand drug applicant and delete those not complying with certain criteria. A Third person such as a generic drug manufacturer may also file an objection to the patents submitted by the brand drug applicant.

2. When applying for authorization for the sale of generic drug, the generic drug applicant shall make one of the following 6 declarations concerning each patent listed in the green list:

(1) The patent has expired;

(2) The authorization for sale is not sought for until the patent is expired;

(3) The patentee and entities listed acknowledge that generic drug applicant is exempted from obligation of notification;

(4) The Korean IP Court or other courts has ruled over the listed patents

(5) Listed patents are irrelevant to the generic drug in application;

(6) Listed patents are invalid or will not be infringed even though valid.

3. Generic drug applicant shall notify the patentee (notice of patent challenge)

within 20 days if it makes the 6<sup>th</sup> declaration. The patentee shall file a request for the containment of the sale of the generic drug to Minister of MFDS within 45 days after receiving the notice of patent challenge (patent holder is required to file a patent infringement case with the court before that). The containment will last for 9 months after the patentee receives the notice. However, the containment, rather than hold back the examination and approval, can simply hold back the sale of the generic drug.

Similar to that of US, the first generic drug applicant accomplishing the patent challenge shall be granted a 9-month market exclusivity. The first person accomplishing the patent challenge refers to the first person that receives a favorable judgment, a judgment ruling patent invalid or a judgment ruling not constituting infringement, and moreover, such judgment is made within 9 months since the patentee receives the notice of patent challenge.

On the other hand, South Korea also makes some changes towards the patent linkage system so as to reduce the impact thereof on its industry, The differences lie in:

#### 1. Objects for linkage

Different from the patent linkage system in US which deals with chemicals only, the patent linkage system in South Korea covers biological agents and chemicals. The United States provides an independent and effective patent protection system for biological products in the approval of biosimilars. The system has elements similar to that of patent linkage system applied to chemicals, including notification of a new drug manufacturer to submit copy of biosimilar application and information of manufacturing technology within 20 days after FDA accepts a biosimilar application, submission of announcement of approval of application to new drug manufacturer within 180 days before the biosimilar is put into commercial sales, and its subsequent opportunity of enforcing preliminary injunction, etc. However, such system fails to directly influence FDA's review progress and provide containment correspondingly, as is so in the patent linkage system for chemicals, which therefore is generally known "soft linkage" in the industry.

#### 2. Holdup period in procedure linkage: 9 months of non-automatic stop

While a court accepts a patent lawsuit, FDA will automatically stay the approval of

the generic drug for 30 months, which will influence the progress of generic drug application to some extent. Whereas, South Korea applies procedures of non-automatic examination, according to which, the patentee applies for initiating the marketing prevention system and requests the MFDS to examine. The non-automatic holdup period lasts for 9 months.

The 9 months demonstrates the longest average period patent infringement trial in South Korea from the acceptance of case to the issue of judgment as KIPO spent 7.9 months in average in a patent infringement case from the acceptance of case to issue of an effective first-instance judgment in 2014. A holdup period 9 months is complied with the domestic situation of judicial practice in South Korea.

### 3. 9 months of market exclusivity for first generic drug

In order to encourage generic drug manufacturers to challenge patents of brand drugs and accelerate access of generic drugs into market, FDA provides the first generic drug with 180-day exclusive marketing while South Korea awards the first generic drug with a market exclusivity of 9 months, specifying that the 9 months is primarily for the adaption to annual hospital drug bidding and procurement in South Korea, which will be beneficial for the market development of first generic drug manufacturer, and meanwhile, for the compensation of the funds spent by generic drug manufacturers in the patent litigation, which will better inspire generic drug manufacturers to challenge patents.

## **Section II Data Protection Model**

### **I Europe**

Brand drug manufacturers have attempted to convince the European Union to introduce patent linkage system but have encountered severe objection from various areas in EU. It is reported that European Generic Medicines Association insisted that patent linkage system was in contradictory to EU Regulatory Law in 2006 based on the

ground that it failed to be complied with the legislative mission of the Bolar provision. However, some EU states such as Hungary, Portugal, Czech and Italy are attempting to build linkage systems in different forms.

At the moment, in leading with patent issues in drug registration, the European Union primarily enforces the following systems.

## **1. Test data protection**

Drug test data protection system of “European Economic Community (EEC)” initiated from Article 4.8 in the Directive 65/65/EEC. In 1987, EEC passed Directive 87/21/EEC of Council of European Economic Community, providing that generic drug applications shall be approved so long as bioequivalence data are provided. The test data protection system was introduced in accompany with the said provision. Revised in 2001 and 2004, the test data protection system currently in force is formulated.

The term of drug test data protection is 10 years since the drug is approved, the former 8 years of which is a period of data exclusivity, meaning during the 8 years, no generic drug applications related to the new drug are will be accepted or approved. After data exclusivity expires, generic drug applications may be accepted, which, whereas, are not approved until expiration of data protection of the new drug. Besides, if new indications are added during the period of data exclusivity or the drug is transferred from prescription to OTC, the drug shall be granted with one extra year of data protection. Orphan drugs have a 12-year-period data protection, the former 10 years of which is period of data exclusivity.

## **2. Supplementary protection certificate**

In order to compensate loss of patent protection term resulting from procedures of approval of NDA, an extended patent protection term is provided for specific drugs via a supplementary protection certificate.

Drug-related patents entitled for an extended term of patent protection include patents of product, preparation method and usage.

Requirements for granting the extension of patent protection include: (1) patent concerned has not yet expired on the date when the applicant files a supplementary



protection certificate application; (2) the drug application has been approved by drug authority of member state and the new drug is a drug approved to be sold and used on market of the said member state for the first time (even though the new drug application is approved in other EU member states earlier), and (3) patent concerned is not granted a supplementary protection certificate in the said member state.

The supplementary protection certificate is effective for 5 years to the longest since the basic patent protection term expires, and remained basic protection term after the approval of the drug application plus the effective term of supplementary protection certificate shall not exceed 15 years.

Supplementary protection certificate extends market exclusivity rather than complete patent right. During its effective term, imitation of patented drug is allowed but the generic drug is not allowed to sell or use.

## **II Japan**

### **(I) Current situation of pharmaceutical industry**

In Japan, the generic drug is an emerging industry while brand drug takes an absolute leading position. Moreover, after the expiration of patent protection, the brand drug is still entitled to a relatively long period of market exclusivity. Taking consideration of control of domestic insurance system cost expenditure, Japanese authorities have started to take measures of encouraging development of generic drugs. Therefore, although the output value being still low, a steady trend of gradual growth is kept.

図 1. 国内ジェネリック医薬品市場規模推移・予測

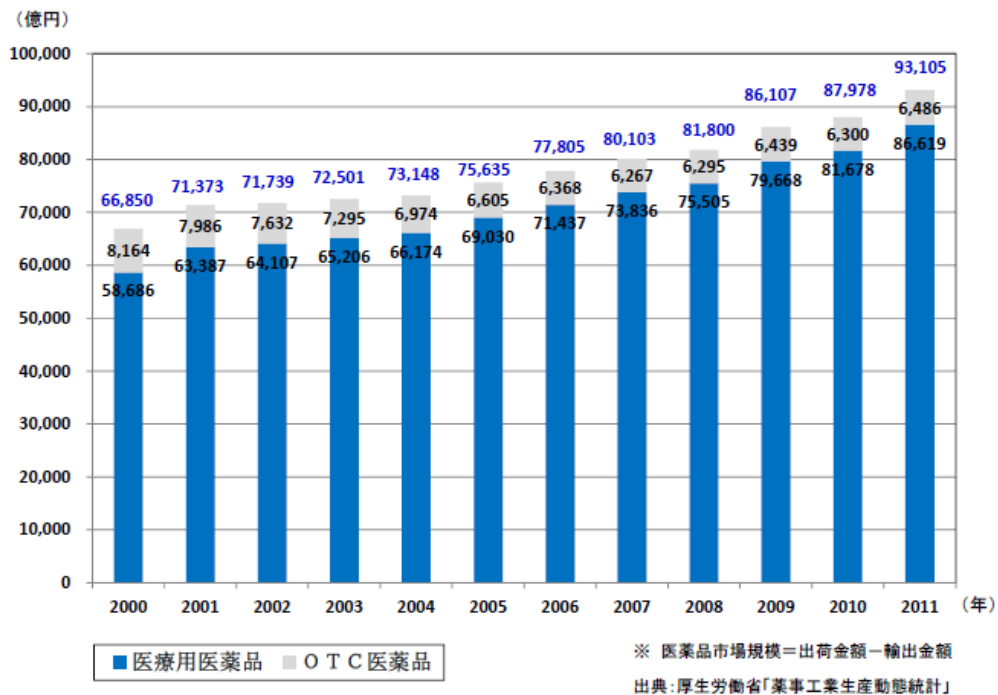
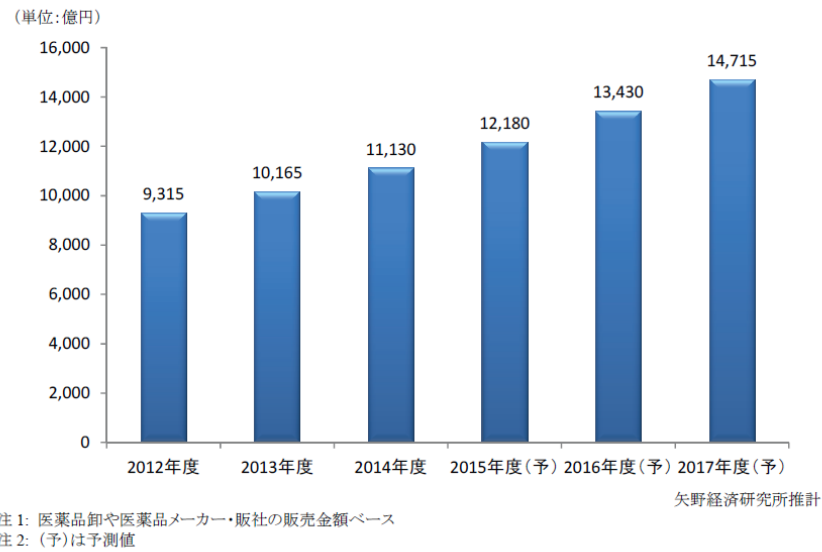


Fig. 2: Output of Generic Drug (former) and Brand Drug (latter) in Japan

## **(II) Relevant System**

Similar to the European Union, Japan does not have patent linkage system, either, and the protection provided for drug-related patent is primarily regulated in the *Pharmaceutical Affairs Act* and the *Patent Act*. Issues related to patent protection involved in approval for new drug application are dealt with mainly through the following three measures:

### **1. Banning generic drugs of certain patented drugs from sale**

According to relevant provisions in the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan's Ministry of Health, Labor and Welfare, if the active ingredient of certain drug cannot be manufactured since the active ingredient of brand product is patented, such generic drug application will not be approved. If some indication, function, dosage, route of medication, etc (hereinafter referred to as indications and functions) are patented, the generic drug application may be approved so long as it is marked with other indications and functions. Generally speaking, according to the policies, the application of other applicants will not be approved so long as indications and functions concerned are patented.

### **2. Extension of patent protection term**

Seeing that it generally takes 10-15 years from discovery of a new compound to approval of NDA, whereas the patent protection term is 20 years, and that therefore the pharmaceutical company is generally entitled with a market exclusivity for 5-10 years, Japan's *Patent Act* provides the extension of patent protection term in its Article 62 bis, which is similar to that of Europe and the United States. A patentee may be compensated for a period no longer than 5 years from the later date of date of patent application and the start date of clinical test to the date of approval of NDA.

### **3. New drug reexamination system**

Drug registration data protection specified in TRIPS has two layers of meanings:

one is to ensure that the drug data shall not be disclosed, while the other is to prevent such data from improper commercial use. However, TRIPS does not provide measures for data protection directly and explicitly; let alone mention the issues of market exclusivity. It is widely believed in developed countries in Europe that data protection and market exclusivity are entirely identical concept and both the United States and EU take a model of providing special protection for such data, namely, not only banning disclosure of drug test data submitted by a new drug applicant but also granting a certain period of marketing exclusivity for some term. As a WTO member state, Japan also grants market exclusivity to brand drugs. During the drug registration in Japan, unless a generic drug manufacturer is authorized by a brand drug manufacturer, it will not be allowed to cite data information of the brand drug manufacturer to certify efficacy and safety of its own product, so as to get approval from authority of drug registration.

However, Japanese authorities make some innovation in its system within the TRIPS framework based on its own specific national condition instead of blindly implanting European and American data protection system in total and uncritical acceptance. In other words, it sets up a new drug reexamination system after the drug is put into market. Such a system is believed to play a role similar to data protection de facto.

The “thalidomide incident” in 1962 and “SMON (subacute myelo-optico-neuropathy) incident” in 1970 incited more concern on drug safety. In view of restriction in “quality” and “quantity” of clinical research in drug registration, Japan introduced a new drug reexamination system in 1979, aiming at re-confirming safety and efficacy of a new drug after putting into market. Term of reexamination lasts from the date of approval to date of application for reexamination (required by law), which may differ among various drugs, such as a decade for orphan drugs, 8 years for drugs containing new active ingredients, 6 years for new combined medication prescriptions and new routes of medication; 4-6 years for new indications and dosages, with as long as a decade further extended depending upon actual circumstances for pharmacoepidemiological surveys or clinical studies concerning pediatric medication dosage. Such system, in fact, happens to share the same term of market exclusivity granted under data protection system. And the longer a term of reexamination is, the more highly protected a reexamination applicant will be.

According to relevant regulations, data submitted in application for approval of new

drug application (including domestic brand drugs and imported brand drugs) include: source or background of new drug discovery and conditions for drug usage in foreign countries; manufacturing technology, standard and test method; stability; pharmacologic action; drug absorption, distribution, metabolism and excretion; acute toxicology, sub-acute toxicology, long-term toxicity, teratogenicity and other toxicity tests; clinical test. The application of a generic drug upon expiration of reexamination of an brand drug, only three data are required: manufacturing standard and test method, acceleration test and bioequivalence. Where a drug is patented, the application of its generic drug will not be approved. And if a generic drug submits its application during the period of reexamination of the brand drug, all data required for NDA shall be submitted, which is actually rather difficult. Thus, such system plays a role similar to data protection system to an brand drug manufacturer, ensuring its market exclusivity during the period of reexamination. Only after the patent and its reexamination periods are expired will its generic drug be approved.

### **Section III India: A Third Way**

India, ultimately, holds a negative attitude towards patent linkage system after undergoing twists and turns in judicial judgment. On December 19, 2008, Squibb filed an ex-parte injunction to the Supreme Court in Delhi with an attempt to stop India's administration of drug from approving a generic drug of an anticancer drug "Dasatinib".

The Supreme Court in Delhi enacted an injunction to suspend the application of India's generic drug manufacturer Hetero Drugs Ltd. for generic Dasatinib. The court also curbed review of administration of drug registration on the drug. "DCGI (Drug Controller General of India) is expected to prevent any party from violating any law while exercising its function of administration. If a defendant's drug in application infringes the plaintiff's patent right, the defendant's application shall not be approved," ascertained by court in the judgment.

The judgment worried numerous generic drug manufacturers in India. According to some experts, it was not necessary to place DCGI in the position of "patent police" as only patent office and court were competent in evaluation on the very sophisticated issue of patent validity and it was not wise to endow DCGI with no experts of patent with such a responsibility. Other experts also indicated that DCGI was not a party

concerned in the case, thus the judgment was not legally binding to DCGI.

In order to patch up a debate concerning patent linkage, the Supreme Court in Delhi made a reverse judgment in a patent-related dispute between Bayer and Cipla on August 18, 2009. The judgment concluded that there was a basis for the establishment of patent linkage system under current Drug Law and Patent Law in India on the grounds as follows: first of all, it was not appropriate to entitle DCGI jurisdiction of patent; secondly, patent right was a private right, which should be by the right holder, and it was not appropriate to change a private right to a public right; thirdly, it was a violation of Bolar provision specified in 107A in India's Patent Law; and fourthly, provision of patent protection required in Article 27 in the TRIPS was not allowed to discriminate any technical area and the formulation of patent linkage was exactly deal with the drug area only. The judgment also demonstrated the functions of government sectors, holding that patent examination and trial of invalidation were rather complicated, which only patent office and court were competent in. The drug administration was lack of expert, time and manpower and does not have the jurisdiction. "It is still controversial on whether to set up a patent linkage system in international community. There is no unified policy among different states. Developing nations and Europe are increasingly bitterly against patent linkage," said Muralindhar, judge in this case.

Although the Supreme Court in Delhi clearly vetoed the attempt to set up a patent linkage system in India in its judgment, how to protect rights of patentee's rights and how to deal with a drug registration application submitted by a generic drug manufacturer in its term of patent protection remained unsolved.

In order to balance the competition between patented drug manufacturers and generic drug manufacturers in a fair way without the establishment of patent linkage system, it is suggested a notification system should be introduced, whose main content includes:

1. DCGI should list all the NDAs in its official website, by which, brand drug manufacturers may track information in the database. A patentee may file a lawsuit (interpleader cause) to court if affirming that a generic drug applied by anyone else may infringe his patent right.
2. A court may make a declaratory judgment if affirming the patent valid and may be infringed by the generic drug declared in judgment. Declaratory judgment is a way of judicial remedy invoked by the plaintiff in seeking a declaration of its rights, which,

rather than involve with economic compensation, confirms rights of one party concerned before actual impairment occurs. Lawsuit of declaratory judgment helps all the parties concerned as it is capable of preventing inevitable actual infringement and its resulting long-term proceedings.

3. An brand drug manufacturer is required to provide “notification” in its NDA, disclosing patents and patent applications of all the drug-related products and methods. The public shall be available to such information and confirm patents related to the drugs. Such a system not only increases transparency but also enables objection system to be implemented more effectively.

## Section IV Analysis and Comments on the Three Models

### I. Comments on patent linkage system

#### (I) Comparison of patent linkage systems in three states

The United States, Canada and South Korea set up their patent linkage systems but differ from one another in specific system design.

**Chart 1 Patent Linkage System of US, Canada and South Korea**

Link type Compared factors	US chemicals patent linkage	Canadian chemicals patent linkage	South Korean patent linkage
Legal ground	Hatch-Waxman Act	<i>Patented Medicines (NOC) Regulations</i>	US-Korea FTA, Pharmaceutical Affairs Act of South Korea
Object linked	Chemicals	Chemicals and biological agents	Chemicals and biological agents
Information announcement	Orange Book System	Patent Register	Patent List (Green List)
Patent declaration	Four declarations	The same as the United States	The same as the United States
Administration	FDA	Health Canada	KIPO
Procedure linkage	45-day query +30-month automatic stay	45-day query +24-month automatic stay	45-day query term+9-month non-automatic stop

First generic drug market exclusivity	180 days	N/A	9 months
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## (II) Patent challenge: with United States as an example

According to the Hatch-Waxman Act, only the first generic drug applicant that files for patent challenge (submission of ANDA with Paragraph IV Declaration) is granted with a 180-day period of market exclusivity under circumstances of either no infringement of patent or the patent being invalid ruled by the court. It means that during the 180 days, only the drugs of the generic drug applicant and brand drug applicant is available to the market. Its huge economic benefit contained (in other words, only the generic drug applicant and brand drug holder share the drug's market) is an important factor to inspire generic drug manufacturers to file patent challenge.

### 1. Number of patent challenges

The following chart shows number of new drug products which generic drug manufacturers filed for patent challenge against in previous periods.

**Chart 2 Number of New drugs in Patent Challenge in the United States**

Period	1984-1991	1992-2001	2001-October 2004	2010-January 2016
Number of new drugs	26	104	123	299

### 2. Challenges supported

From January 1, 2010 to January 28, 2016, FDA approved about 661 NDAs (including those for biological drugs) and 157 of which, generic drug manufacturers filed patent challenges against. In other words, they submitted ANDAs with Paragraph IV Declaration. Of all those patent challenges, 5 ANDAs received provisional permissions from FDA, accounting for 3.18% of the total; 15 got no provisional permission or final approval after the stay, accounting for 9.55% of the total; 38 received official approvals from FDA, accounting for 23.7% of the total; 99 were still in



stay.

### **(III) Effects patent linkage system**

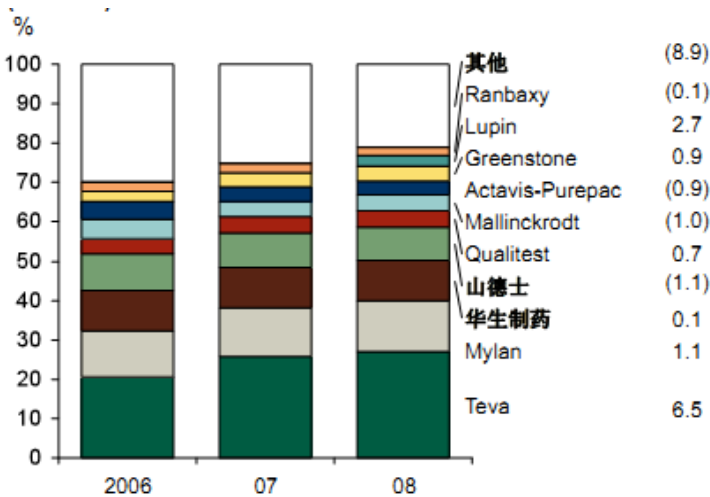
#### **1. Facilitating industrial development**

Practices show that patent linkage system facilitates both brand drug industry and generic drug industry.

With regard to facilitating development of brand drug industry, taking the United States as an example, before the Hatch-Waxman Act was enforced, activities of drug innovation were predominantly conducted in Europe, which, dominated in micro-molecular drug innovation; whereas, nowadays, the United States is the world's largest drug market. In 2013, its amount of sales was as high as USD 339.7 billion and its gross pharmaceutical industry occupied 2.1% of GDP, making pharmaceutical industry one of its pillar industries. Among 5,000 new drugs developed on a global scale, 3,400 were developed in the United States, increased by 40% since 2005. The US generic drug market accounted for 45% of global generic drug market, which was worth USD 43.5 billion in 2013, expected to reach a 2-digit annual growth in 2018. In South Korea, since South Korea enforced a patent linkage system in 2012, its pharmaceuticals have remarkably increased their investment in new drug development and research. Till 2015, South Korean companies made multiple significant breakthroughs in areas of new drug development and research such as tumor, diabetes and cardiovascular disease and large international pharmaceuticals and China's pharmaceuticals signed patent license agreements with South Korean pharmaceuticals in succession in gross turnover of over USD 7 billion.

Concerning development of generic drug industry, also taking the United States as an example, the system facilitated generic drug industry in the following aspects: Firstly, it increases the number of generic drugs. Prior to 1984, American generic drugs accounted for over 18.6% of prescription drugs; the ratio in 2013 rose to 86%, expected to rise to 90% in 2020. Secondly, it accelerates the marketing for generic drugs. Of a total of 17 essential drug patents from 1990 to 1993, 14 had their generic drugs being marketed within 1 month right after the patents expired. Thirdly, it promotes the centralization of generic drug market. Challenging pressure in patent declaration and incentive measures for first generic drug (according to the Hatch-Waxman Act, only the first ANDA applicant that submits Paragraph IV Declaration, being ruled non-

infringement or the patent being invalid by the court is granted with a 180-day market exclusivity) have intensified competitive advantages of generic drug manufacturers, promoted concentration of generic drug industry and created TEVA, RANBAXY and other generic drug giants. According to data shown in Fig. 3, nearly 80% of shares on US generic drug market were occupied by top ten generic drug manufacturers.



**Fig. 3: Market Shares Occupied by Top Ten American Generic Drug Manufacturers**<sup>17</sup>

其他: Others

山德士: Sandoz

华生制药: WATSON Pharmaceuticals

## 2. Objectively enhancing patent quality and reducing double, invalid and junk patents

Studies show that brand drugs may suffer from significant sales loss as soon as generic drugs are rolled out. Brand drugs may lose about 75% of amount of sales in three months after generic drugs are rolled out; and they lose nearly 80% in 6 months. From that perspective, once the patent challenge succeeds, the brand drug manufacturer will encounter significant loss, whereas, such loss, in turn, will stimulate the brand drug manufacturer to make innovation in real means or make more innovation in order to ensure market exclusivity. Hence, it will objectively enhance patent quality and reduce double, invalid and junk patents.

<sup>17</sup> Chen Wei. Generic drug market [J]. *Biotech World*. Issue 46, June 2011.

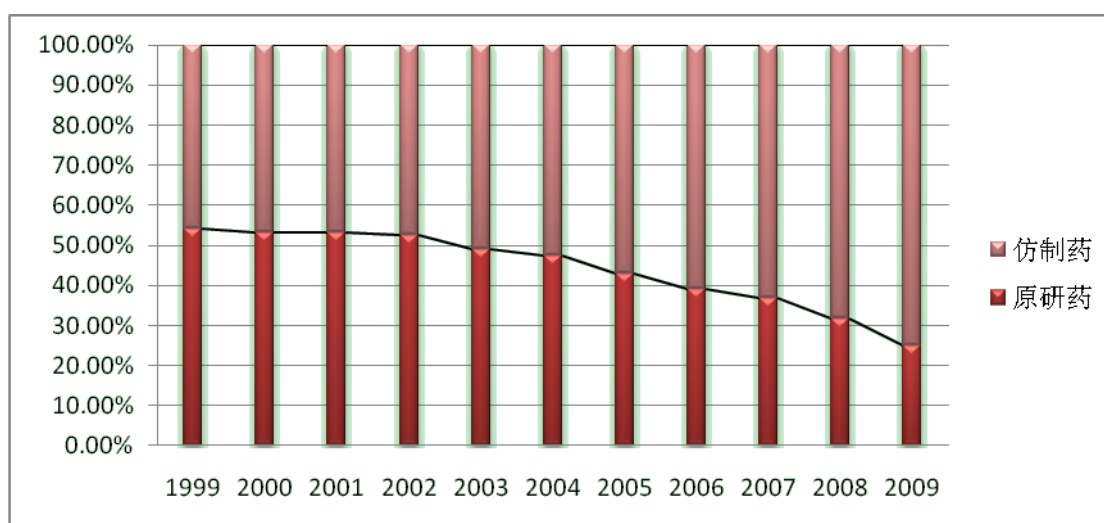
Taking Lilly's antidepressant Fluoxetine as an example, in December 1995, Barr Labs submitted both ANDA and Paragraph IV Certification to FDA. Lilly, as a result, filed a lawsuit, claiming that Barr Labs infringed Lilly's No. 626549 patent. Barr Labs argued that the patent was suspected of double patenting. The focus of argument lied in whether No. 4590213 patent expired in April 1994 and No. 626549 patent had the same claims. The court made double patenting analysis in which one of the claims in No. 626549 patent was holding back cerebral neuron from absorbing 5-hydroxytryptamine by taking Fluoxetine while one of the claims in No. 4590213 patent was a way of curing human anxiety provided for patients to cure their anxiety by taking Fluoxetine in effective concentration. It was approved by experts from Lilly and Barr Labs that neuron was held back from absorbing 5-hydroxytryptamine by control of 5-hydroxytryptamine. Based on such experimental results, the court believed that it was a natural physiological process that animals inhibited absorption of 5-hydroxytryptamine by taking Fluoxetine, which was accessible to human beings. It had a variety of purposes, including anxiety. Therefore, the court affirmed that the two patents had no outstanding difference, which constituted double patenting.

### **3. Decreasing patent disputes after the marketing of generic drugs**

Since the patent linkage system was introduced, accepted patent disputes resulting from approval of application of generic drugs accounted for only 6% from 1984 to 2004, effectively guaranteeing economic benefits of patentees and encouraging innovation. Their R&D strength was maintained as high as 20%.

### **4. Not outstanding adverse impact on marketing of generic drugs in the automatic stay**

Brand drug manufacturers generally postpone approval of application generic drugs by making use of the 30-month automatic stay in the patent linkage system, resulting in a delay the marketing of generic drugs. Overall, however, such an adverse impact is neutralized since two policies (180-day period of market exclusivity for first generic drug manufacturer and ANDA simplified application) motivate generic drug manufacturers. Occupancy on US drug market (as shown in Fig. 4 as follows) indicates no outstanding adverse impact on the marketing of generic drugs.



**Fig. 4 1999-2009 US Prescription Drug Distribution (Including Brand Drugs (latter) and Generic Drugs(Former))**<sup>18</sup>

## II. Comments on data protection system

Europe and Japan do not have patent linkage system. Europe enforces data protection system while Japan achieves the same results as providing a period of market exclusivity under data protection system via new drug reexamination system. Such a model is beyond doubt inclined to protection of brand drug industry.

Under circumstances of market-oriented economy, the motive of innovation originates from pursuit of profit. Enterprises gain surplus profit by technical innovation and further enhance their capacity of innovation, forming a virtuous cycle of “innovation-return-innovation”. Therefore, market realized and commercial benefit gained is fundamental criterion for judgment on whether technical innovation is successful. And enterprises, as subjects of investment, interest, technical innovation and risk taking in market-oriented economy, play an irreplaceable role in boosting independent innovation. Thus, economic benefit of data protection system is primarily reflected in innovation incentive effect. In other words, enterprises are motivated in their initiative to develop brand drugs, increase investment in development and production, and get returns in a huge amount so as to advance rapid growth of GDP in the pharmaceutical industry.

Taking Japan as an example, according to studies, in the 1980s, Japan’s innovation

<sup>18</sup> Yu Xuanqiang. Historical development of American generic drugs [J]. China Prescription Drug. No. 78, September 2008.

output and efficiency in the pharmaceutical industry were not that outstanding. From 1979 to 1986, four Japanese R&D pharmaceuticals (Takeda, Sankyo, Shionogi and Fujisawa) encountered a sustainable decline in their return on sales (ROS). Till earlier in the 1990s, their ROS was still lower than it was in 1979. However, it was found in observation of their R&D investment/amount of sales that ratio of their R&D investment in the corresponding period presented a momentum of steady growth. One cause for that was the establishment of the new drug reexamination system in Japan. In 1979, Japan set up a drug reexamination system, by which, awarded eligible drugs with data exclusivity and protection. Subsequently, as its reexamination system was constantly improved, some brand drugs were granted with an extended term of data protection. The above policies enforced significantly boosted innovation in Japan's pharmaceutical industry. However, one nonlinear characteristic of scientific and technological policies lies in common hysteresis in their formulation and enforcement, making their output performance hard to immediately show up; besides, the period of new product development in the pharmaceutical industry is so long that hysteresis of R&D fund investment in business performance is more remarkable in the bio-pharmaceutical industry. In the mid- and late 1990s, influenced by government's guide policies, pharmaceuticals kept annual increase in their R&D investment and ROS and as a result, Japan's pharmaceutical industry embarked on its brilliant period in rapid development.

### **III Comments on India's model**

India holds a passive and reactive attitude towards drug patent protection. It, so far, has been focused on consideration of drugs from the perspective of public interest, particularly the enforcement of compulsory drug license system, out of domestic situations and traditional causes, even though it has joined the WTO and lost in the WTO dispute with the United States. Moreover, as is set forth, it has vetoed the patent linkage system by judicial judgment. Therefore, in India, the relevance between drug application and patent protection is lack of foundation in regime.

The protection of drug patent in China has gone through a process in which it has started from scratch and constantly reinforced it, aiming at boosting innovation in drugs. It is worth discussion on whether it is necessary to refer to India Model and back to provisions in the Patent Law of 1985. In fact, as China has incorporated drugs in scope of patent protection since it made the first amendment to the Patent Law in

1993, China, which has taken a step of drug patent protection, will hardly “retrace its step” to reduce its protection for drug patent or even hardly retreat from originally rendering drug patent protection to no drug patent protection rendered after it joins the WTO; let alone TRIPs on transitional period no matter whether a transitional period to developing nations has expired.

In addition, noteworthy, India’s generic drug industry is developed in spite of its controversial drug patent protection. Many Indian generic drug manufacturers seek development in the United States and make full use of American patent linkage system to seek a way out for the sake of business development and benefit.

#### **IV System comparison and conclusion**

According to Kappos, ex-Commissioner of United States Patent and Trademark Office, Europe provides drug patent with sufficient protection by systems of data protection and supplementary protection certificate. Besides, Europe has a good lawsuit tradition. Thus, it is an effective system overall in spite of no patent linkage system. However, compared with the United States, Europe is lack of “early resolution system” in which court makes judgment on patent issues in the proceedings of generic drug approval and enables those innovators to ascertain their rights.

And both Europe and Japan are quite outstanding in R&D capacity of domestic brand drug manufacturers. In such a background, they have a foundation to continue to boost development of brand drug manufacturers by system design concerned. Even so, as set forth, their brand drug manufacturers make slower innovation than those in the United States and South Korea where patent linkage system is enforced. It can be concluded from the facts that innovation center has been transferred from Europe to the United States after a patent linkage system is enforced in the United States; domestic brand drug industry in South Korea has made considerable development and became to grant license to many large international manufacturers after the patent linkage system is enforced in South Korea. It seemingly indicates to some extent that the patent linkage system better facilitates development of brand drug industry than data protection system.

In comparison, the restriction of data protection system to development of generic drug development and research is as plain as the nose on the face, which deviates China’s current practice of dominating generic drug industry.



## **Chapter II Developing Situations of Domestic Pharmaceutical Industry**

Currently, most pharmaceutical enterprises in China mainly manufacture generic drugs, and some enterprises which not only manufacture generic drugs, but also research, develop and manufacture the brand drugs also exist, like Hengrui Pharmaceuticals, Tasly Pharma Luye Pharma and others. Meanwhile, such companies as Hua Medicine, which are only engaged in research and development of brand drugs, all exist. Therefore, simply viewing from the perspective of R&D of brand drugs, some pharmaceutical enterprises have certain ability of innovation and strength in research and development.

### **I. Advantages of the pharmaceutical industry in China**

#### **1. Market advantages**

China, with an enormous population, has the aging problems. The population aging in China is a new opportunity for our pharmaceutical market. The aging population with low immunity will result in higher prevalence. According to the statistics made by the Ministry of Health of China, the two-week prevalence for the aged above 65 is 466‰, far higher than that of other ages, e.g., 75‰ for population aged 25-34. In general, the medical consumption for aged population is generally more than 80% of that in total life period<sup>19</sup>, so the aged population contributes more to the pharmaceutical consumption market. Currently, 23%-40% of prescription drugs and 40%-50% of over-the-counter (OTC) drugs are taken by the aging population.<sup>20</sup> Meanwhile, since the implementation of “New Medical Reform”, we have been committed to improving medical insurance. Up to 2010, our medical insurance system had covered the population of over 1.28 billion, forming a medical insurance system with the urban workers, urban residents and “new rural cooperative medical system” being principal, and covering 90% of urban and rural areas of the whole country. Along

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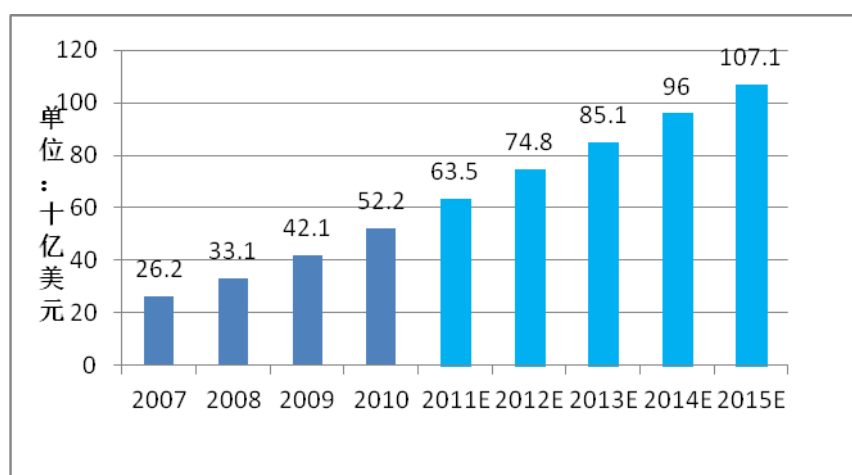
<sup>19</sup> Haitong Securities Company Limited: Strategic Report of 2011: Main Trend in Increase, Prosperous in a Long Run, [EB/OL].[http:// www.htsec.com](http://www.htsec.com).

<sup>20</sup> Deloitte. The next phase: Opportunities in China's pharmaceuticals market[EB/OL].



with the gradual improvement of medical insurance system and steady rise of medical reimbursement, the drugs consumption market is greatly stimulated and per capita medical expenditure rises gradually. The proportion of aging population increased by 21% from 2000 to 2009, while growth rate for per capita health expenses reached 256%. It is anticipated by WTO and BMI that in the future 5 years, the growth rate for per capita health expenses will be still higher than aging growth rate, about 5 times per year, but the two will be finally the same<sup>21</sup>. The aging and rise of people's living standard will drive China's medical consumption demands to a new round of rapid increase.

Based on large population and rapid growth of GDP, China's medical market has been rising in recent years. According to the data provided by Southern Medicine Economic Research Institute and Deloitte, the compound growth rate for sales volume of China's medical drug from 2007 to 2010 was 25.9%, that from 2011 to 2015 is anticipated to reach 15.5%, and the sales volume can reach USD 107.1 billion in 2015 (as shown in Fig. 5)<sup>22</sup>.



**Note: USD 1 = RMB 6.79**

**Unit: USD 1 billion**

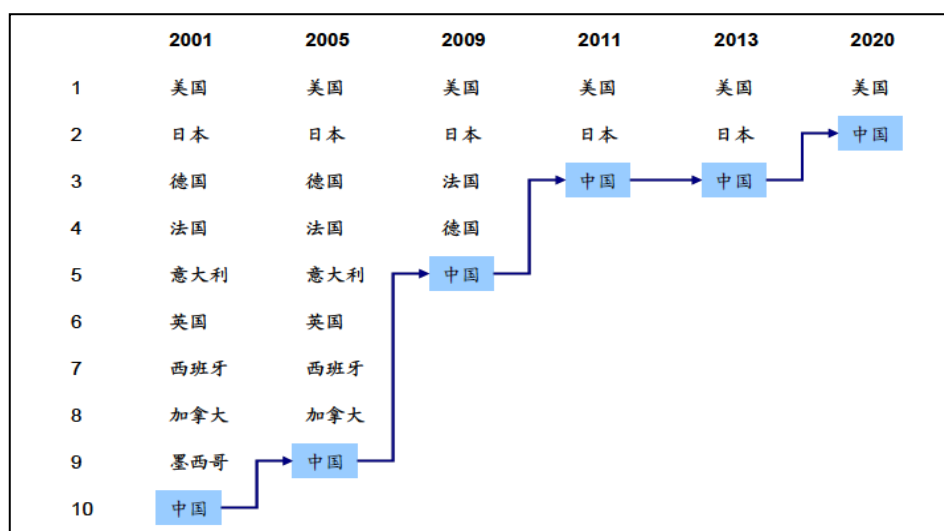
**Fig. 5 Sales Volume of China's Medical Market**

<sup>21</sup> Deloitte. The next phase: Opportunities in China's pharmaceuticals market[EB/OL]. [http://www.deloitte.com/view/en\\_CN/cn/ind/lshc/723313bbb0943310VgnVCM3000001c56f00aRCRD.htm](http://www.deloitte.com/view/en_CN/cn/ind/lshc/723313bbb0943310VgnVCM3000001c56f00aRCRD.htm).

<sup>22</sup> Deloitte. The next phase: Opportunities in China's pharmaceuticals market[EB/OL]. [http://www.deloitte.com/view/en\\_CN/cn/ind/lshc/723313bbb0943310VgnVCM3000001c56f00aRCRD.htm](http://www.deloitte.com/view/en_CN/cn/ind/lshc/723313bbb0943310VgnVCM3000001c56f00aRCRD.htm).

**Data: Southern Medicine Economic Institute (SMEI), Association of the European Self-Medication Society (AESGP), BMI**

Since China's entry into WTO, China has been actively undertaking and playing its role in international market and catching up with the developed countries. Till 2010, it had become the third biggest medical market in the world, and will be anticipated to surpass Japan in 2020, becoming the second biggest medical market in the world (as shown in Fig. 6). Due to the huge market potential, China is deemed as a rising emerging market in global pharmaceutical industry and has become a "big cake" plundered by the big pharmaceutical companies in the world. China is not only an origin of raw material or research, but also can edge itself into the international medical market with its excellent market potential.



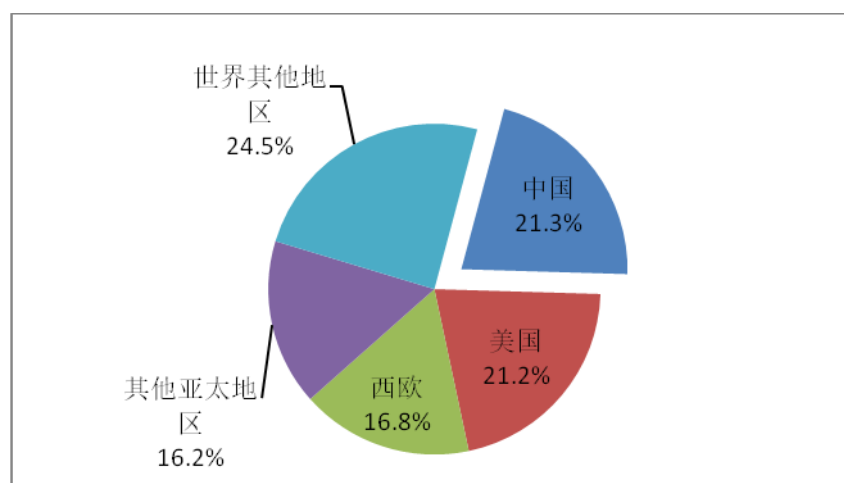
**Fig. 6 Ranking of Top 10 Pharmaceutical Markets in the World**

**Data: IMS Institute for Healthcare Informatics**

## 2. Product advantages

The pharmaceutical industry in China develops rapidly. National gross value of pharmaceutical industry increased from RMB 436.4 billion in 2003 to RMB 1004.8

billion in 2009<sup>23</sup>. The annual value of the chemical API, as an important industry representing international competitiveness of our pharmaceutical industry, accounts for nearly one half of national gross value of medicines, and the exported ones are above 60%<sup>24</sup>. In China, totaling 1016 enterprises manufacturing chemical API can manufacture nearly 1500 kinds of chemical API. Currently, our country has become the biggest producer and exporter for chemical API in the world. According to report made by Italian Chemical Pharmaceutical Generic Association (CPA), China surpassed the United States to become the biggest mono-market of generic APIs in the world with USD 4.05 billion in 2010, accounting for 21.3% of global market share (as shown in Fig. 7), and it is deemed to be one of the globally fastest growing market of generic APIs in the future five years, with an anticipated annual growth rate of 12.6%<sup>25</sup>.



**Fig. 7 Market Shares of Global Generic APIs**

**Data: CPA**

### **3. Cost advantages**

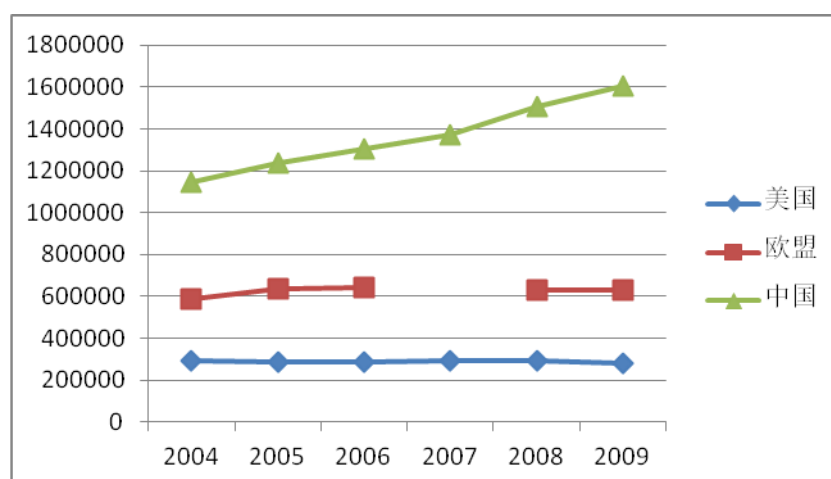
China is a populous country so that the human resources are rich and cheap. As is

<sup>23</sup> CFDA: To solve the new difficulties under the new circumstances with scientific supervision conception. The National Working seminar on Administration of Food and Drug was Held. [EB/OL]. <http://www.sda.gov.cn/WS01/CL0050/51994.html>

<sup>24</sup> Shanghai Biopharmaceutics Industry Association: China has become the largest manufacturer and exporter of chemical API in the world. [EB/OL]. <http://www.sbia.org.cn/plus/view.php?aid=6572>

<sup>25</sup> Patricia Van Arnum.API Market Outlook[EB/OL]. <http://www.pharmtech.com/pharmtech/article/articleDetail.jsp?id=755428>

shown in Fig. 8, the number of employees in our pharmaceutical industry continuously increased in recent years, accounting for nearly 1.4 times that of Europe and the United States, while the average hourly reward for employees in the manufacturing industry is low in China, only accounting for 4% of the United States and 3% or so of European countries, even lower than Philippines with cheap labor forces. Due to the rich labor forces and cheap labor cost, a lot of international pharmaceutical enterprises have set up factories in China and make China its major manufacture region. In recent years, as per capita cost of Chinese subjects is lower, the clinical test cost is only about one third of that in America<sup>26</sup>. Therefore, the international pharmaceutical enterprises began to pilot the research and development after transferring their production, and they successively established their R&D centers in China to transfer their R&D businesses, or outsource the R&D businesses to China's R&D outsourcing enterprises.



**Fig. 8 Comparison of Employees in Pharmaceutical Industry among the United States, Europe and China**

**Data: EU data from The Pharmaceutical Industry in figures - Edition 2005~2011<sup>27</sup>;**  
**American data from Bureau of Labor Statistics, Occupational Employment Statistics<sup>28</sup>;** (2005, 2009, 2010)<sup>29</sup> **Chinese data from *China Statistics Yearbook on High Technology Industry* (2005,**

<sup>26</sup> IMS-Pharma VOICE. China: A Booming Market Takes its Place on the World Stage[EB/OL]. <http://www.imshealth.com/portal/site/ims/menuitem.856807fe5773bfb9ec895c973208c22a/?vgnextoid=796555d0e3070310VgnVCM1000007f8c2ca2RCRD&vgnnextfmt=default>

<sup>27</sup> EFPIA. The Pharmaceutical Industry in figures - Edition 2005~2011[EB/OL]. <http://www.efpia.org/Content/Default.asp?PageID=608>

<sup>28</sup> Bureau of Labor Statistics. Occupational Employment Statistics[EB/OL]. [http://www.bls.gov/oes/2008/may/naics4\\_325400.htm](http://www.bls.gov/oes/2008/may/naics4_325400.htm)

<sup>29</sup> NBS, NDRC, Ministry of Science and Technology of PRC, China Statistics Yearbook on High Technology Industry [M]. China Statistics Press.

## II. Problems existing in Pharmaceutical Industry

### 1. Small number of marketed brand drugs

Since 2003, the brand drugs were continuously put into market, but the number is rather small. In recent years, the total number of marketed brand drugs was less than one fourth of that of the United States in 2006, far lagged behind that of European and American countries. Currently, the internationally admitted innovated drugs are artemisinin and sodium dimeraptosuccinate.

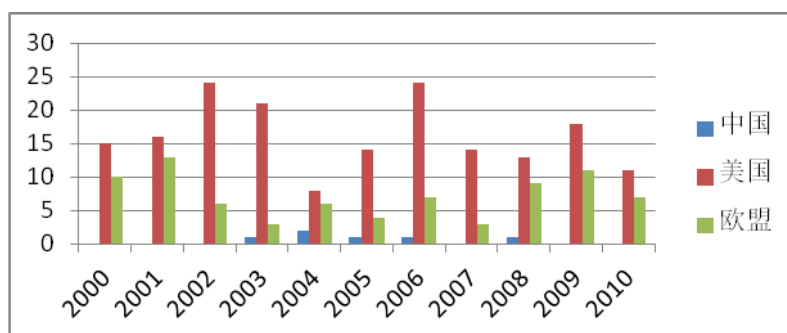


Fig. 9 Annual Number of Marketed New Drugs of Each Country (Organization)

Data: Marketed New Drugs from 2000 to 2010<sup>3031323334353637383940</sup>

<sup>30</sup> 2001,10(3) Zhang Li, Liao Bin, Liao Qingjiang. New marketing drugs abroad in 2000 ( I ) [J]. Chinese Journal of New Drugs, 2001, 10 (3)

<sup>31</sup> 2002,11(4). Liao Bin, Zhang Li, Liao Qingjiang. New marketing drugs abroad in 2001 [J].Chinese Journal of New Drugs, 2002, 11 (4).

<sup>32</sup> Liao Bin, Liao Qingjiang. New marketing drugs abroad in 2002 [J].Chinese Journal of New Drugs, 2003, 12 (5).

<sup>33</sup> Liao Bin, Cong Xin, Liao Qingjiang. New marketing drugs abroad in 2003 [J].Chinese Journal of New Drugs, 2004, 13 (5).

<sup>34</sup> Liao Bin, Cong Xin, Liao Qingjiang. New marketing drugs abroad in 2004 [J].Chinese Journal of New Drugs, 2004, 14 (4).

<sup>35</sup> 2006,15(10). Liao Bin, Liao Qingjiang. New marketing drugs abroad in 2005 [J].Chinese Journal of New Drugs, 2006, 15 (10).

<sup>36</sup> 2007,16(8). Liao Bin, Liao Qingjiang. New marketing drugs abroad in 2006 [J].Chinese Journal of New Drugs, 2007, 16 (8).

<sup>37</sup> 2008,17(9). Liao Bin, Liao Qingjiang. New marketing drugs abroad in 2007 [J].Chinese Journal of New Drugs, 2008, 17 (9).

<sup>38</sup> 2009,33(5).Liao Bin, Cong Xin, Liao Qingjiang. New marketing drugs abroad in 2008 [J].Progress in Pharmaceutical Sciences, 2009, 33 (5).

## 2. Generic drugs are at seriously low and repeated level

A vast number of enterprises in China, especially the small- and medium-sized enterprises mainly manufacture the generic drugs, 60% of which are OTC drugs, demonstrating a serious problem of repeat manufacturing. As for the 205 chemical drugs and biological products in *National Essential Medicines List (for Primary Healthcare Facilities)* (version 2009), each, in average, has 108 manufactures, with nearly 30% of varieties having more than 100 manufacturers. Among 102 Chinese patent medicines, each, in average, has 56 manufactures, with nearly 20% of varieties having more than 100 manufacturers.<sup>41</sup> In fact, although OTC drugs take up about 70% market share, the profits simply take up 30%; while the new drugs with 30% market share take up 70% profit.<sup>42</sup> With low profit, enterprises naturally fail to invest more on research and development of new drugs, but can only repeatedly manufacture the generic drugs, which is a vicious circle hard to break.

## 3. Small-sized enterprises take the lead

Research and development of brand drugs are featured as vast investment, high risk and long cycle. As per pharmaceutical industry report made by the United States in 2011, when a brand drug is researched and developed, 5000~10000 compounds should be screened, with only 250 left at pre-clinical study phase, about 5 being put into clinical study, and eventually, only one sixth can pass examination and get approval from FDA. It will take 10-15 years to finish the whole R&D process, and many alternative compounds are screened and abandoned in clinical Phase III.<sup>43</sup> According to statistics made by American Tuftson center on research and development cost of American drugs, the average cost for research and development of brand drugs in 2001

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<sup>39</sup> 2009,100. Ma Peiqi. New drugs globally and firstly approved in first half of 2009 [J]. Shanghai Food and Drug Information Research, 2009, 100.

<sup>40</sup> 2010,102. Ma Peiqi. New drugs globally and firstly approved in the second half of 2009 [J]. Shanghai Food and Drug Information Research, 2010, 102.

<sup>41</sup> Lin Jianning, Analysis on Comparison of Domestic and Foreign Developing Situations of Pharmaceutical Industry, China Pharmacy, 2011,22(24):2218-2221

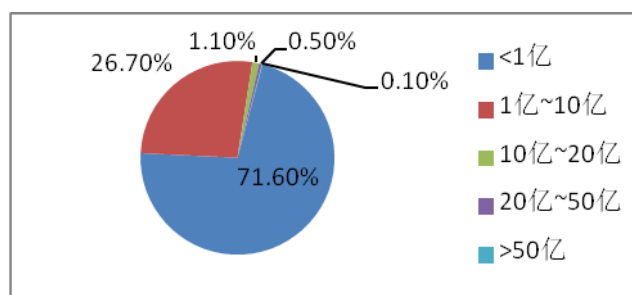
<sup>42</sup> Li Xiping, Liu Weiwei, Yang Jiao, Analysis on GMP Syndrome of small- and medium-sized pharmaceutical enterprises and the Countermeasures, Market Modernization, 2006,(487):152.

<sup>43</sup> PhRMA. Pharmaceutical Industry Profile 2011[EB/OL].

[http://www.phrma.org/sites/default/files/159/phrma\\_profile\\_2011\\_final.pdf](http://www.phrma.org/sites/default/files/159/phrma_profile_2011_final.pdf)

was USD 0.802 billion, 6 times as that in 1975, while that in 2005 was USD 1.3 billion.<sup>44</sup> So, considering the characteristics of drugs research and development, the enterprises engaged in drugs research and development should for the first place, be capable of providing long-term and huge investment, and only the large-size enterprises can meet such conditions.

But according to the statistics, till the end of 2009, among 6806 pharmaceutical enterprises (including those for medicines and medical devices) included in statistics made by the National Bureau of Statistic (NBS), 71.6% of them had a sales volume of less than RMB 100 million while only 1.7% had the sales volume of above RMB 1000 million (as shown in Fig. 10)<sup>45</sup>. It can be concluded that the small-sized pharmaceutical enterprises take the lead of our pharmaceutical industry.



**Fig. 10 Proportion of Different-scale Pharmaceutical Enterprises in 2009**

**Data: Southern Medicine Economic Research Institute**

#### **4. Insufficient investment of drugs research and development**

Due to the industrial features of pharmaceutical research and development, more investment should be provided for research and development. Only by investing more on R&D and providing more funds for hardware and software, can the enterprises obtain better achievements. Currently, the more popular international index for assessing R&D input capacity is R&D strength, namely R&D expenditures of an

<sup>44</sup> PhRMA. Pharmaceutical industry profile.2007[EB/OL].

<http://www.phrma.org/sites/default/files/539/profile2007.pdf>,2011/7/10.

<sup>45</sup> Lin Jianning, Analysis on Comparison of Domestic and Foreign Developing Situations of Pharmaceutical Industry, China Pharmacy, 2011,22(24):2218-2221

enterprise in that year/sales revenue of an enterprise in that year<sup>46</sup>. As shown in the following figure, R&D investment of pharmaceutical manufacturing industry in European and American countries is above 15%, while the number remains at about 1% in China. Experiences of developed countries show that enterprises with R&D investment above 5% may have relatively strong competitiveness, that 2% can only sustain basic survival of an enterprise, and that less than 1% results in extremely difficult survival of an enterprise<sup>47</sup>. So most pharmaceutical enterprises in China face survival problems.

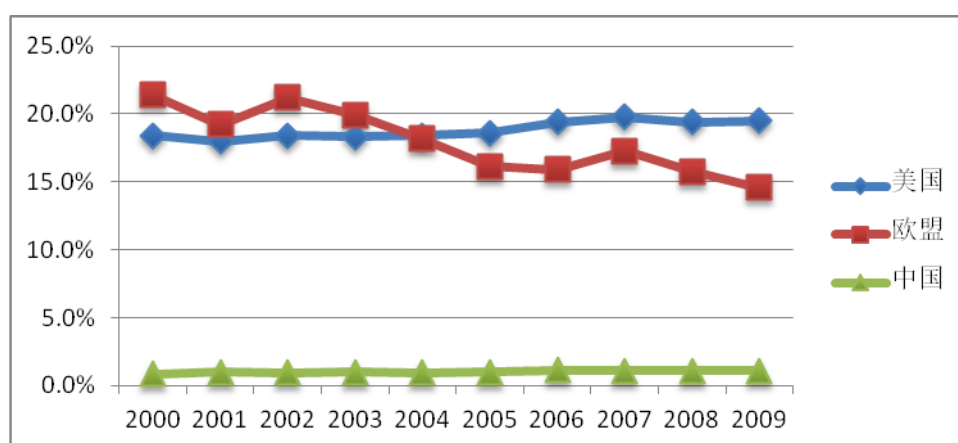


Fig. 11 Investment on R&D of Pharmaceutical Industry

Pharmaceutical Industry Profile 2011<sup>48</sup>; Total Global Medicines Market<sup>49</sup>; IMS Health<sup>50</sup>; 《China Statistics Yearbook on High Technology Industry》 (2005、2009)<sup>51</sup>

Different from the United States, Canada's generic drugs developed quickly before establishing patent linkage system. The Aim of Canada's establishment of patent linkage system is to balance the competition of benefits between brand drugs and

<sup>46</sup> Fu Jiaji, Quan Yunhuan, Gaojian, etc, Technical Innovation Science, Tsinghus University Press, 1998.

<sup>47</sup> Pan Chenglie, Why the enterprises shall be taken as subjects in Independent Innovation, China Enterprise News, 2006-1-10(6).

<sup>48</sup> PhRMA. Pharmaceutical Industry Profile 2011[EB/OL]  
[http://www.phrma.org/sites/default/files/159/phrma\\_profile\\_2011\\_final.pdf](http://www.phrma.org/sites/default/files/159/phrma_profile_2011_final.pdf)

<sup>49</sup> EGA. Total Global Medicines Market [EB/OL]  
[http://www.egagenics.com/doc/pharma\\_figures\\_2008-11-28.pdf](http://www.egagenics.com/doc/pharma_figures_2008-11-28.pdf)

<sup>50</sup> IMS Health. Top-line Market Data  
[EB/OL].<http://www.imshealth.com/portal/site/ims/menuitem.5ad1c081663fdf9b41d84b903208c22a/?vgnextoid=fbc65890d33ee210VgnVCM10000071812ca2RCRD&vgnextfmt=default>

<sup>51</sup> NBS, NDRC, Ministry of Science and Technology of PRC, China Statistics Yearbook on High Technology Industry [M].China Statistics Press.



generic drugs and effectively reduce the patients' medical expenses. In the United States, objective of Hatch-Waxman Act has been realized, and the generic drugs industry and brand drugs industry have been development prosperously. On the contrary, Canada was dominated by the generic drugs before establishment of patent linkage system, while the scale of generic drugs industry reduced after establishment, and price of generic drugs increased. The global competitiveness of biomedical companies remained unchanged. In the *AstraZeneca v. Canada*, the Supreme Court of Canada ruled that "the patent linkage system makes two administrative systems interlaced, whose administrative objects have some conflicts". The Food and Drug Act can guarantee safety and efficacy of the marketed new drugs, while the patent law can provide monopoly rights for inventors for some time.

## Chapter III Establishing System of Linking New Drug Application and Patent Protection

### Section I Current Regime

The System of Linking New Drug Application and Patent Protection mainly concerns two branches of laws, the patent law and the drugs administrative law.

#### I. The Patent Law

The patent law in China also experienced the process from none to existence regarding drugs patent protection.

On Mar. 12, 1984, our first integral *Patent Law of the People's Republic of China* was adopted at the 4<sup>th</sup> meeting of the Standing Committee of the Sixth National People's Congress, and took into effect on Apr. 1, 1985. Article 25 of the *Patent Law of the People's Republic of China* effective in 1985 indicated that “drugs and substances produced by chemical methods” were excluded from objects under patent protection. In 1992 and 2000, under the international pressure and demand of entry into WTO, the Standing Committee of NPC successively made important amendments to the patent law twice for the purpose of ensuring the level of patent protection to be in conformity with international standards. The amended Patent Law expanded the patent protection scope and started to provide patent protection for drugs and chemical substances, making the protection scope of drug patent reach a new level.

It should be specially noted that prior to 2008, our patent law did not clearly specify whether using drug-related patent of other parties for application of drug registration constitute patent infringement or not. Article 69 dealing with infringement exception in Patent Law stipulates that “using relevant patents especially for scientific research and test” is not deemed as infringement. But whether the foresaid acts fall within Article 69 remains controversial.

In 2002, several judgments have been made by court concerning such issue, the

most famous of which were patent infringement disputes between Sankyo Pharmaceuticals Co., Ltd. and Beijing Winsunny Pharmaceutical Co., Ltd. and between Eli Lilly and Company and Gan & Lee Pharmaceuticals. In the former case, Beijing No.2 Intermediate People's Court ruled that the involved drug, Olmesartan Medoxomil Tablet, which the plaintiff accused the defendant of infringement, was still under examination and approval phase of drugs registration. although the defendant used the involved patent to manufacture the involved drugs for the purpose of making clinical trial and applying for production license, its manufacturing act was to meet the demand of national administration for administrative approval of drugs registration aiming at verifying the safety and efficacy of the involved drugs it produced. Considering the manufacturing of involved drugs by defendant was not directly for sale, and thus did not belong to the act of implementing patent of others for the business purpose under the *Patent Law of the People's Republic of China*, the court therefore concluded that the act of the defendant did not constitute infringement of the involved patent. In the latter case, the same court ruled that in view of the current evidences of the said case, the involved drugs for application "recombinant Lispro Insulin" and "dual-phase recombinant Lispro Insulin injection 75/25", are under examination and approval phase of drugs registration and cannot be marketed. Although the defendant has made clinical trial and applied for production license, its objective was to meet the demand of national administration for administrative approval of drugs registration, aiming at verifying the safety and efficacy of involved drugs produced. Although the "recombinant Lispro Insulin injection" applied by defendant had been approved for drugs registration and can be marketed, the plaintiff failed to prove the defendant had produced and thus marketed the involved drug. Based on such grounds, the court ruled that the manufacturing act of the defendant was not directly for sale, which did not constitute act of implementing patent of others for business purpose.

Certainly, other courts have made some opposite judgments. In the patent infringement case of Ji Ling and Chengdu Kanghong Pharmaceutical v. Jilin Liyuan Pharmaceutical Co., Ltd., in 2006, Jilin High People's Court sustained the judgment made by Changchun Intermediate People's Court, holding that Article 95 of General Principles of the Civil Law of the People's Republic of China indicates that the patent rights lawfully obtained shall be protected by law. The defendant's application for drugs registration has a unique objective. Once being approved, the Songling Xuemaikang tablets will be produced, namely, the defendant's act of application is for the preparation of patent infringement, which is illegal in nature and has risk of

infringement. The claim of the two plaintiffs requesting defendant to cease application and production of Songling Xuemaikang tablets should be supported. The judgment made by Jilin High People's Court emphasizes that the application for drugs registration is for the preparation of patent infringement, which is illegal in nature and has risk of infringement. Such conclusion is difficult to understand as Article 11 of the Patent Law does not involve those contents.

In the Patent Law implemented on Oct. 1, 2009, Bolar exception was introduced, while extension of patent protection term was not. Article 69.5 of the Patent Law stipulates that to get information for the government approval requirement, any person manufactures, uses, imports patent drugs or the patent medical devices, and specially for whom manufactures, imports patent drugs or patent medical devices, shall not be deemed as infringement. Such a provision aims at taking the interests of the patentees and the utilization of patent by social public into account, so as to better realize the legislation mission stipulated in Article 1 of the Patent Law. On the one hand, the patent system should protect the legal rights of patentees, encourage the invention and creation, while on the other hand, the patent system should boost advancement of science and technology and development of social economy. The patent system shall be beneficial for earlier marketing of generic drugs in China so as to solve the issue of high price of drugs. However, the provision simply takes reference of Article 271(e)(1) of the Patent Act of US, leaving Article 271(e)(2), namely, the provision of artificial act of infringement, out.<sup>52</sup> The artificial act of infringement refers to any person making application of registration for new drugs in literature (Paper DNA) or application of generic drugs registration to drugs administrative regulatory department is deemed as infringement.

Using patents of others for pre-clinical trial, clinical trial and research on production technology parameters during application of drugs registration is excluded from patent infringement. Yet, it is not explicitly provided in the *Patent Law* whether the drugs registration application made by an applicant with drugs administrative of the State Council constitutes patent infringement if other party owns valid patent right with respect to the said drug. According to the constitutive factors stipulated in Article 11 of the *Patent Law*, the drugs registration application (including application of clinical trial and production) is not deemed as infringement. It appears to be favorable to generic drug enterprises, but may be unfavorable for the generic drug enterprises to

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<sup>52</sup> Jerome Rosenstock, *The Law of Chemical and Pharmaceutical Invention*, Second edition, Aspen Law & Business, P15-69.

file a non-infringement litigation, in order to pursue for a confirmation of non-infringement prior to the expiration of patent. Rather, the dispute can only be solved after the marketing of generic drugs.

## **II Laws and Regulations concerning Drug Administration**

Prior to 2002, the issue of drug patent protection was not stipulated in laws and regulations concerning drug administration. *Measures for Administration of Drug Registration (Trial)* (DRR) promulgated in October 2002 stipulated the patent issues in examination and approval of drugs registration for the first time, which involves three aspects, namely, (i) specification of the state of drug patent and non-infringement guarantee, (ii) CFDA's attitude in dealing with patent-related issues in drug registration, and (iii) research and development of generic drugs prior to the expiration of brand drug-related patent. DRR formally put into effect on May 1, 2005, and firstly amended in 2007, and in February 2014, the Draft of DRR for public comment was released, with amendment towards the aforesaid three aspects. The evolution processes are as follows:

The patent linkage system also includes the aforesaid three aspects, but more detailed and operable than current regulations in China.

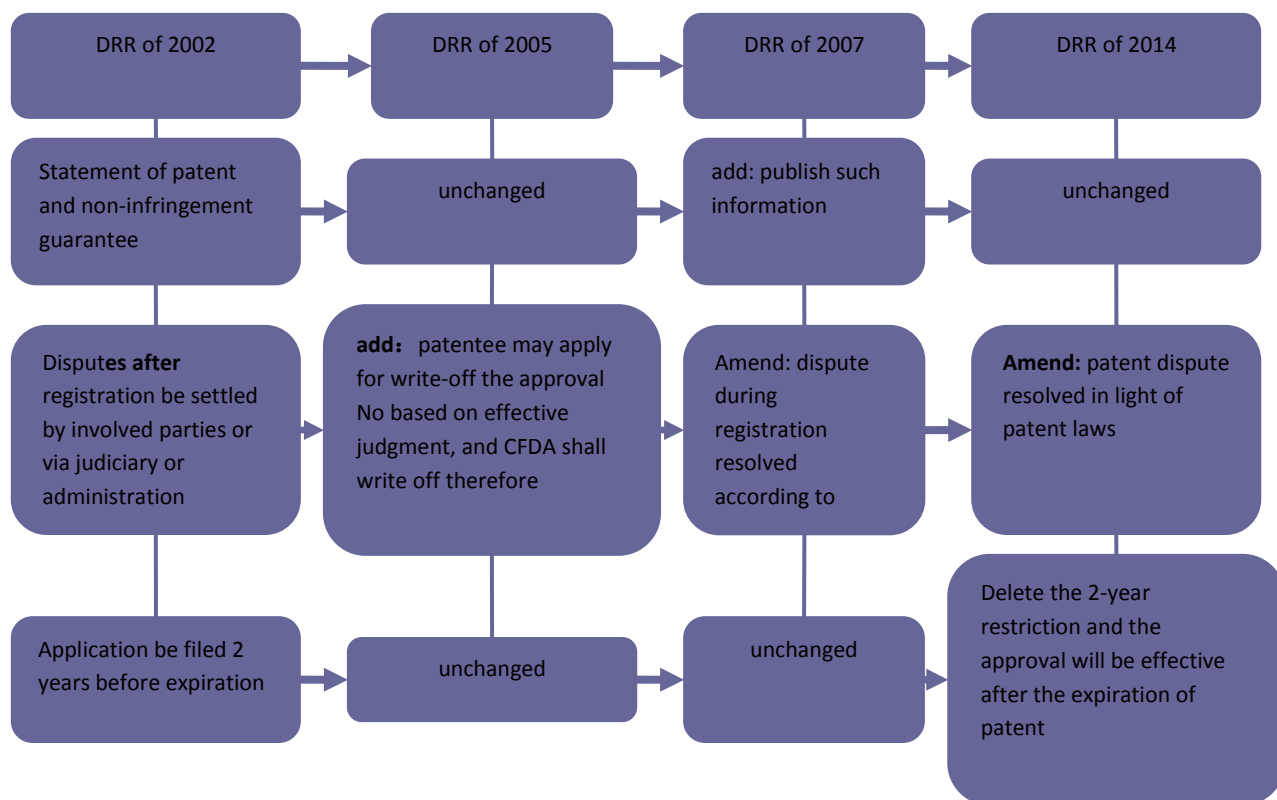


Fig. 12 Changes to provisions concerning drugs application and patent protection of DRR and its former three drafts of amendments

On Jul. 25, 2016, the General Office of China Food and Drug Administration again publicly solicited opinions on *DRR (Revised Draft)*, the project group submitted opinions concerning two issues in this revised draft to the General Office of China Food and Drug Administration, indicating:

First, the Drug Administration Law, the higher-level law of DRR, was amended in December, 2013 and April, 2015, respectively. However, the amendment in December, 2013 involved only one provision while the amendment in April, 2015 involved only five provisions, both of which did not make substantial amendment to the Drug Administration Law. The main provisions in the current Drug Administration Law remain unchanged as were set forth in 2001. With more than a decade of development in Chinese pharmaceutical industry, the actual situation has been changed significantly. It is imperative to amend the Drug Administration Law based on the actual situation

and the future development trend. From the aspect of legislative techniques, it is problematic to amend DRR before amending the Drug Administration Law. It will definitely cause a new round of amendment if the amended DRR is inconsistent with the amended Drug Administration Law. This is extremely unfavorable for the stability of the law.

Second, innovation is the core and power to achieve sustainable development of the pharmaceutical industry as well as enhance international competitiveness of Chinese drugs. However, the amendment in Article 18 and 19 in DRR was obviously unfavorable for the innovation in the pharmaceutical industry.

On the one hand, according to Article 129 of the revised draft (corresponding to Article 20 of the original DRR), “For others’ drugs having obtained Chinese patent rights, the applicant may file an application for marketing. CFDA will conduct investigation and examination according to these measures. If related requirements are met, CFDA will approve and issue documents for marketing.” The original provision, “for patented drugs, the applicant may file an application two years before the expiration of the patent. CFDA may not approve and issue documents until the expiration of the patent.” Taken literally, the applicant of generic drugs may file an application at any time, and CFDA does not have to approve and issue documents based on the drugs’ status of patent. That will be a great threaten to the market of brand drugs.

On the other hand, according to Article 130 of the revised draft (corresponding to Article 19 of the original DRR), “As for the drugs applying for marketing or the prescription, technologies or purpose being used, the applicant shall provide a description of patent owned by the applicant or others in China as well as its status. Where others hold a patent in China, the applicant shall provide a declaration claiming not constituting infringement of others’ patent. The food and drug administration shall publish the description or declaration provided by the applicant on the website of administrative organs. Where disputes of patent rights occur, the laws and regulations related to patent shall be applied.” Therefore, the original provision “...the drugs applied for registration..., the applicant shall provide a description of patent and patent ownership...” was amended as “...the drugs applied for marketing...” Furthermore, according to Article 3 of the revised draft, “drug registration” means a process in which the food and drug administration carries out comprehensive evaluation on the safety, effectiveness and quality controllability of the drugs applied for marketing and make an

administrative decision after the applicant of drug registration files an application for drug registration according to legal procedures and related requirements. The application for drug registration includes the application for clinical trial of drugs, the application for marketing of drugs, the supplemental application for changes in registration items after drugs' marketing, and the application for renewal. In other words, the circumstances for the requirement of providing a description of patent ownership have been reduced from all types of applications for drug registration to one type, the application for marketing. There is no such requirement for other types of application of drug registration.

According to the current Patent Law, the patentee of brand drugs is not entitled to institute infringement proceedings based on the patent law if the generic drugs are not marketed. Meanwhile, the patent status of the drugs applying for marketing is not the statutory factor for CFDA during its approval and documents issuing. Therefore, after generic drugs are marketed, it may constitute infringement and the documents approving the marketing of drugs will be contradicted with the liability of cessation of patent infringement, which means both the generic company and the innovation company will suffer huge losses. Innovation is vitally interrelated with the sustainable development of the pharmaceutical industry. And the patent system is the most important guarantee for innovation and technical progress. However, the revised draft cuts off the relationship between the drug registration and patent protection. It is retrogression in terms of innovation protection. Therefore, it is suggested that patent issues should be taken into consideration in administration of drug registration on the basis of the current system so as to eliminate some patent infringement disputes before the marketing of generic drugs or even before their application for registration. It will be favorable for enterprises, industries, and the whole social resources.

### **III Problems Existing in Current Drug Policy of China**

#### **( I ) Poor Protection on Drugs Patent is unfavorable for Innovation and Development of Drugs**

Research and development of drugs are featured as long cycle, huge funds and high risk. The potential huge profits of brand drugs can directly drive the enterprises to fund research and development of new drugs, while restoring the research and development cost of brand drugs and obtaining subsequent research and development funds should be sufficiently protected by the patent. However, the brand drugs have



been basically controlled by foreign firms for a long time, while the pharmaceutical enterprises in China, with limited innovation level, mainly manufacture the generic drugs. Viewing from the perspective of protecting domestic pharmaceutical industry, it is said that strengthening drug patent protection will protect foreign companies while do harm to the interests of domestic pharmaceutical enterprises, especially generic drug enterprises. That is why protection of drug patent has been insufficient ever since the implementation of patent system.

Yet, the drug patent protection practices for more than 30 years since 1985 show that strengthening drug patent protection has played an important role in promoting innovation and development of our pharmaceutical enterprises.

Between 1985 and 1993, considering such factors as the population is large, demand for drug is huge, and the developing level of the domestic pharmaceutical industry is low, in order to resolve the issue of medicine consumption of China and provide domestic pharmaceutical industry with more space for development, the patent law then did not protect drugs. But in fact, such policy did not bring benefits to our country.

Under the pressure of foreign countries, the Patent Law amended in 1993 start to protect drug patent. During the more than 20 years of drug patent protection, foreign brand drugs enter China continuously while the issue of drug accessibility that used to worry us a lot did not occur. Furthermore, the domestic pharmaceutical industry developed more quickly compared to that prior to 1993.

Meanwhile, the development and growth of domestic software industry are closely related to continuously reinforcing of software patent protection in China, which reflects that the patent protection plays an important role in industry innovation and development.

## **( II ) Regulations lacking of operability and systematicness harms various parties**

To boost development of domestic generic drugs and accelerate the marketing of generic drugs as soon as possible, China introduced Bolar exceptions in the amendment of the Patent Law in 2008, by taking reference of US. Meanwhile, provisions similar to patent linkage system in US were formulated in *DRR* promulgated in 2002. However, the Bolar exceptions in US, while providing support for early research and development

of generic drugs so as to accelerate the marketing as soon as possible, forms a institutional regime together with artificial infringement provisions and other provisions concerning examination and approval of drugs application, aiming at balancing the interests between the generic drug companies and brand drug applicants. In China, lacking of artificial infringement provision and imperfect laws and regulations of drugs administration will bring about hidden troubles for the development of domestic pharmaceutical industry.

1. Lacking of artificial infringement provisions results in lacking of legal grounds for the brand drug company to safeguard their legal rights

Where an brand drug enterprise finds that the generic drugs infringing its patent right has been applied for registration with CFDA, according to the current *DRR*, the patent disputes should be settled in the light of the Patent Law. Yet, the Patent Law fails to specify whether such action constitutes an infringement or no. Under such condition, how the brand drug applicant can organize the secondary infringement to safeguard its benefits?

2. *DRR* simply stipulates that the patent disputes should be handled in the light of patent law, which makes CFDA facing huge pressure

Seemingly, *DRR* simply specifies that the patent disputes should be handled in the light of patent law, which makes CFDA sharply demarcated from the drug patent-related issues. However, in fact, owing to the special position CFDA is in, namely, it is responsible for determining whether a drug can be marketed or not, it still faces huge pressures from various sides. Once the generic drugs suspected of infringement are applied for registration, the brand drug applicant will generally request CFDA not to approve such application, while the generic drugs applicant will request for approval. Furthermore, after the generic drug is marketed and there is a judicial judgment made concerning the disputes, CFDA will face pressure of whether to revoke the approval number.

3. Current regulations are not favorable for the healthy development of domestic generic drugs industry

Although the brand drugs enterprises cannot stop the marketing of generic drugs according to the current provisions, the marketed generic drugs enterprises will be sued infringement and resulted in patent disputes. The generic drugs enterprises will face such risks as litigation, ceasing production and compensation. Once the court

orders the generic drugs enterprises to cease infringement, the enterprise will fail to take back investment on equipment and the like, or even go bankrupted.

Meanwhile, under such conditions, some generic drug enterprises, for investment safety, will manufacture the low-level drugs without risk of infringement which have been imitated a lot, resulting in low profits. Hence, the enterprise cannot accumulate funds to perform research and development of high-level generic drugs. Such vicious cycle will hinder the healthy and strong generic drugs industry in China.

#### 4. Possibly affecting our drug accessibility

Currently, innovation capacity of drugs is weak in China. Very few new drugs can be independently researched and developed while a large number of rare drugs are researched and developed by foreign-owned enterprises. Under such circumstance, once the foreign-owned enterprises are unwilling to enter China or put off entering due to poor patent protection, it will add to difficulty for obtaining better-effect drugs. Additionally, the generic drugs enterprises in China, with poor imitating ability, are incapable of imitating such rare drugs or high-level brand drugs, or the imitated drugs are of poor quality. The demands for drugs of Chinese people will be affected.

## **Section II Opportunity of Establishment of System Linking Drug Application to Patent Protection**

The practice of patent law and drug law has been developed for a while, which has laid a foundation for implementation of patent linkage system. Seeing that both *DRR* and the *Patent Law of the People's Republic of China* are undergoing amendment, such opportunity should be taken to establish system linking drug application and patent protection.

In fact, with the development of practice, it is quite possible to establish the linkage system of drugs social insurance and patent protection by perfecting the current system.

### **I. Reform on Drugs Registration**

#### **1. Reform currently under implementation**

Currently, a series of reforms are implemented for drugs supervision in China, CFDA promulgated *Reform Work Plan of Chemical Drugs Registration and Classification*, and General Office of the State Council issued *A Suggestion for Quality of Generic Drugs and Therapeutic Equivalence Assessment*. To standardize the quality of generic drugs and therapeutic equivalence assessment, CFDA formulated *Guiding Principles about Selection and Determination of Reference Preparations for Ordinarily Oral-taking Solid Preparations*, *Guiding Principles about Measurement and Comparison of Dissolution Curve for Ordinarily Oral-taking Solid Preparations*, *Guiding Principles about Human Bioequivalence Study of Chemical Generic Drugs With Pharmacokinetic Parameters being as Final Evaluation Index*, etc.

### (1) Adjustment on drugs classification

On Mar. 4, 2016, CFDA formally promulgated *Reform Work Plan of Chemical Drugs Registration and Classification* (hereinafter referred to as “Plan”) to adjust the registration classification categories of chemical drugs into five categories. Based on this Plan, the meaning of brand drugs and generic drugs of China are the same as those of the United States, namely, the brand drugs refer to those contain new compounds with clear structures and pharmacological effects and have clinical values, while the generic drugs refer to those that imitate marketed brand drugs, including those that imitate the brand drugs that have been marketed abroad but not domestically and those that imitate the domestically marketed brand drugs. The new chemical drugs classification is as shown in the following table.

**Chart 3 Classification of New Chemical Drugs**

Registration classification	Classification Descriptions	Contents
1	Brand drugs that are not marketed both domestically and abroad	Drugs that contain new compounds with clear structures and pharmacological effects and have clinical values
2	Modified new drugs that are not marketed both domestically and abroad	2.1 API and its preparations that contain optical isomers with active components made by splitting or synthesis method, or forming known active components into ester, or forming known active components into salt (including salt with hydrogen bonds or coordination bonds), for

		changing acid radical, basic group or metal elements of active components of known salt, or forming the non-covalent bond derivatives (such as complex, chelate or clathrate compound), and have apparently clinical advantages
		2.2 Preparations that contain new dosage form (including new delivery system) with known active components, new prescription manufacturing process and new administration route, and have apparent clinical advantages
		2.3New compound preparations with known active components that have apparent clinical advantages
		2.4Preparations used for new indications and that have known active components
3	Drugs that are imitated by domestic applicants on brand drugs that have been marketed abroad but not domestically	API and preparations with the same active components, dosage form, specification, indications, administration route, usage and dosage as brand drugs
4	Drugs that imitate the marketed brand drugs domestically	API and its preparations with the same active components, dosage form, specification, indications, administration route, usage and dosage as brand drugs
5	Drugs that have been marketed abroad are applied to be marketed domestically	5.1Brand drugs marketed abroad (API and its preparations) that are applied to be marketed domestically
		5.2Non-brand drugs marketed abroad(API and its preparations) that are applied to be marketed domestically

## (2) Promotion of generic drugs equivalence assessment

Before a series of documents like *Reform Work Plan of Chemical Drugs Registration and Classification* were promulgated by CFDA, the examination and approval for marketing application of generic drugs in China were the same as brand drugs, namely, the data verifying safety and efficacy of drugs should be submitted. Since the brand drugs was not used as RLD for the marketing of generic drugs in the past, the aforesaid data submitted by generic drug applicants were seriously false, and meanwhile, the generic drugs are of variable qualities. According to the recently promulgated documents of CFDA, brand drugs shall be used as RLD for generic drugs,

and the bioequivalent data shall be submitted to verify that generic drugs are consistent with the reference listed drugs.

## 2. Relationship between drugs registration reform and establishment of system linking drugs application and patent protection

According to above reform contents, the generic drugs in China should take the brand drugs as RLD, namely, the generic drugs should use the quality and treatment standards of brand drugs, so as to be the same as brand drugs in active components, dosage form, administration route and curative effect and become substitutive with the brand drugs in clinic. When taking brand drugs as reference, the brand drugs and patent information covered thereof will be significantly important to generic drugs enterprises. The “Orange Book system” is to disclose such information. Thus, under the current reform, the conditions of establishing a system similar to the “Orange Book system” are required as well as met. If such a system is established in China, its combination with above current laws, regulations and judicial practices can basically meet the requirements of establishment of system linking drugs application and patent protection, the essential content of which are as follows:

**Chart 4 Comparison of Linkage Systems of China and United States**

	the United States	China	Comparative Results
Substance	Orange Book disclosing patent information covered by new drugs		None
	Bolar exceptions	Bolar exceptions (Article 69.5 of the Patent Law)	Same
	ANDA of generic drugs	<i>Reform Work Plan of Chemical Drugs Registration and Classification</i>	Basically the same in substantial contents
	Paragraphs I-IV declaration	Article 18.1 of current <i>DRR</i>	similar provisions lacking of operability and procedures guarantee
	271 (e) (2) artificial infringement		No similar provisions

	Automatic stay for 30 months	“Where a patent dispute occurs in the process of drug registration, it shall be settled in accordance with relevant laws and regulations on patent” (Article 18.2 of <i>DDR</i> )	1.No artificial infringement provisions in China  2. Effect of disputes handling results on marketing examination and approval of drugs suspected of infringement is not specified.
	180-day market Exclusivity		No similar provisions
Procedure	The patent descriptions submitted by generic drugs applicants are filed by FDA to USPTO, who examines patent-related issues and transfer the information to FDA	No similar procedures	
	After the generic drugs applicants submit the Paragraph I-IV declaration, they should inform each patent holder or new drugs approval holder	No similar procedures	
	The patent holders can raise a proceeding for patent infringement to the court within 45 days since receiving the notice	No similar procedures	
	After 30-month hold term expires, FDA can decide whether to approve marketing according to judicial judgment and technology of generic drugs.	No similar procedures	

## II Juridical Practices

### 1. Suit regarding ascertainment of non-infringement

After many years of juridical practices, *Provisions on the Cause of Action of Civil Cases* promulgated on April 1, 2008 included the “disputes of ascertainment of non-infringement” into cause of civil cases. Meanwhile, Article 18 of *Judicial Interpretation of the Supreme People's Court Concerning the Application of the Laws in Patent Infringement Cases* effective on Jan. 1, 2010 made further clarifications on the

qualifications for acceptance of a case to ascertain non-infringement. Under the interpretations, a people's court shall accept a case raised by the relevant person or other interested persons requesting the court to ascertain its act being non-infringement if (i) the patentee sends a warning notice on patent infringement to the relevant person; (ii) the relevant person or interested person has requested the patentee in writing to commence a proceeding; and (iii) the patentee neither withdraws the warning notice nor raises a proceeding within one month upon receipt of the written request or two months upon issuance of written request."

## **2. Intellectual property court**

Currently, Beijing Intellectual Property Court, Shanghai Intellectual Property Court and Guangzhou Intellectual Property Court have been founded in China, Beijing Intellectual Property Court has jurisdiction over both patent administrative cases (invalidation of patent) and patent infringement cases. Thus, it is considerable that the patent-related disputes arising during drug registration can be handled by Beijing Intellectual Property Court.

## **III Policy Encouragement**

In recent ten years, the pharmaceutical industry innovation has been the focus and objective of national policy.

The pharmaceutical industry innovation is an important part of the national intellectual property strategy. Early in 2006, the State Council promulgated the *National Medium- and Long-term Development Program on Science and Technology (2006 ~2020)*, in which, the "National Major New Drug Development Program" was determined as one of the 16 Science and Technology Major Programs.

In June 2008, the State Council promulgated *Outline of the National Intellectual Property Strategy*, in which, the first one for five specific tasks of patents is "guided by state strategic requirements, make arrangements in technical areas such as biology and medication, information, new materials, advanced manufacturing, advanced energy, ocean, resource environment, modern agriculture, modern transportation, aviation and spaceflight and the like in advance, and hold a batch of patents on core technologies to support the development of high-tech and emerging industries."



*Decision of the State Council on Accelerating the Fostering and Development of Strategic Emerging Industries* issued in 2010 indicates that the biology industry will be one of the seven major emerging industries in China.

In January 2011, Chen Zhu, Minister of Health, People's Republic of China indicated in overall objective of "12<sup>th</sup> Five-year" planning of health development that "till 2015, the basic medical health care system covering urban and rural residents will be set up, a basic medical insurance system will be more sound, public health service system and medical service system will be more improved, and drugs supply guarantee system will be more standardized.....people's health will take the lead of developing countries".

On Feb. 14, 2016, considering that the pharmaceutical industry concerns national health and owns a huge market, the executive meetings of the State Council was held to deploy the promotion of pharmaceutical industry innovation and upgrade, and clearly indicate four aspects: one is: "aiming at aspects for people in urgent need, to strengthen the research, development and innovation of brand drugs, first generic drugs, traditional Chinese medicines, new-type preparations and high-end medical devices, and to accelerate the industrialization of key drugs for frequently-occurring diseases like tumors, diabetes, cardiovascular and cerebrovascular diseases and rare diseases. For the domestic brand drugs and branded generic drugs issued with patents, international registration and certification should be performed.

The former vice chairman of National People's Congress, chairman of Chinese Pharmaceutical Association and president of Chinese Academy of Engineering Sang Guowei repeatedly emphasized in several meetings and surveys that we should vigorously promote the innovation and development of pharmaceutical industry, increase the investment of pharmaceutical research and development, and strive hard to make the pharmaceutical industry larger and stronger. He made a speech of *Policy and Environment of Research and Development for Brand drugs* on the "Second-session Pharmacy Summit" held on Jun. 19, 2016, on which, he specially indicated that it should improve the patent linkage system and set up the patent compensation system.

On Oct. 30, 2016, director of CFDA Bi Jingquan held a forum to listen to suggestions and opinions of drugs research, development and production enterprises on examination and approval reform of drugs, he emphasized that: "CFDA should strive to establish a drugs evaluation and approval system for encouraging innovation, perfect legal system, policy measures and technical guide. It should reconstruct the

examination and evaluation procedures based on clinic and integrate supervision resources with examination and evaluation being the center, to improve the examination and evaluation ability and supervision efficiency, research a series of policies for clinical trial management, data protection and patent linkage that are closely related to the innovation, so as to promote transformation and upgrading and supply-side structural reform of pharmaceutical industry. It should transform regulation concept (regulation combined into the service), strengthen communication and exchanges with industry, guide enterprises to carry out quality safety management standards and improve product quality and international competition. It should seize the time to promote quality and therapeutic equivalence assessment of generic drugs, to make the generic drugs and brand drugs substituted each other in clinic. It should carry out marketing authorization holder (MAH) system pilot and technology check, summarize experiences and perfect policy.”

A series of policies promulgated by our government are aimed to support the development of pharmaceutical industry, especially in recent years, by tracing the international trend, the development of bioengineering and pharmaceutical industry has been listed as the top priority. It encourages and directs the research and development of brand drugs, accelerates industrial transformation and strides forward to an brand drug country from a generic drugs country. Under the overall planning of pharmaceutical industry, the implementation of various concrete measures is a main driving force for considerable development of the pharmaceutical industry.

Although the current generic drugs enterprises take the lead of the pharmaceutical industry, seen from the long-term situations, innovation is the prime power in boosting sustained development of pharmaceutical industry in China. 17th Meeting of the 12<sup>th</sup> National People's Congress Standing Committee deliberated the *Decision about Authorizing the State Council to Carry Out Marketing Authorization Holder (MAH) System Pilot and Reform Pilot of Drugs Registration and Classification (Draft)*, indicating that the drug innovations should be encouraged and the drugs quality should be upgraded. The innovation and upgrade of pharmaceutical industry have become a national strategy, in which, innovation has become a keyword in the “13th Five-year Plan” of pharmaceutical industry. It is crucial for the pharmaceutical industry to transform from big to strong. Therefore, a lot of generic drugs enterprises will exist for a long time for the purpose of resolving the drugs accessibility, but more and more generic drugs enterprises will aim at research and development of new drugs, which will be continuously supported and encouraged by the nation. Eventually the

innovation will become the development trend for pharmaceutical industry.

## **Section III Suggestions on Establishing a System Linking Drug Application and Patent Protection**

### **I. The legislative proposals**

The establishment of a system linking drug application and the patent protection requires the mutual connection and cooperation between the patent department and the pharmaceutical department. Hence, legislatively speaking, it is necessary to make amendment to the relevant provisions of both the Patent Law and the Drug Act.

#### **( 1) The Patent Law**

In terms of the Patent Law, coordination can take place from two perspectives:

##### **1. Adding a provision of "artificial act of infringement"**

In Article 11 of the Patent Law, an act of infringing a patent right shall be added, that is, in an act of filing a drug register application with the CFDA, the application contains a valid drug patent or the drug involved in a patent of method of manufacturing. Meanwhile, the special method to undertake liability should be stipulated, which means, when the "artificial act of infringement" is constituted based on Article 11, the infringer shall withdraw the drug register application; if not, the infringer shall be disposed in accordance with the provisions of the Drug Administrative Law.

##### **2. Defining the act of drug application as act of patent infringement**

In Article 72.5 of the existing draft, the proviso shall be added, i.e. "except for the act of drug application ", to provide the legal basis for the prosecution. In other words, in the light of the Patent Law, for the purpose of providing administrative information for examination and approval, the manufacture, use or import of the patented drugs or

patented medical devices, as well as the specialized manufacture and import of the patented drugs or patented medical devices used for drug application shall not be deemed as patent infringement. But the act of file application for drugs or medical devices with CFDA shall be excluded from the foregoing act not being deemed infringement. The patentees of the patented drugs or devices, thinking the drugs or device under application having infringed their rights, may institute a prosecution of patent infringement.

### 3. Clarification of jurisdiction with respect to drug application-related cases

On the premise that the act of drug application is an act of patent infringement, in order to ensure the uniformity of the trial, it is suggested that the competent court of those cases should be the one located in the seat of CFDA with the jurisdiction of the patent cases, which refers to the Beijing Intellectual Property Court. Since the Beijing Intellectual Property Court is the only court of first instance having jurisdiction over patent invalidation administrative cases as well as patent infringement cases, the exclusive jurisdiction of the Beijing Intellectual Property Court over disputes involving invalidation and infringement of drug-related patent will be beneficial for the unification of the criteria of the trial of such case and improve the predictability of the operation of such a system.

## **( II ) To methodize the existing drug administration laws and regulations**

### 1. To improve the basic policy reserves: the information publicity system

As a convergence policy closely related to the registration of generic drugs, the establishment of mechanism linking drug application and the patent protection requires certain policy basis, namely the policy of disclosing RLD and patent information. The patent information of RLD is the object of patent linkage in the generic drugs application. Moreover, the establishment of RLD system also takes some time. Hence it is a necessary policy basis of implementing the patent linkage system at the approach of drug registration.

In recent years, with the development of the consistency evaluation of generic drugs in China, the selection and determination of RLD have achieved rather great progress in a certain extent. For example, in 2016, the General Office of the State

Council issued the *Opinions on Evaluating the Consistency of Quality and Efficacy of Generic Drugs*. It is clarified that “the RLD should be firstly chosen from the brand drugs, or the same kind of internationally recognized drugs.” “Where there is controversy in RLD, CFDA may determine after public demonstration among experts. And CFDA is responsible for the timely publication of RLD information.” It can be seen that the formulation of China's RLD system is relatively clear, but it has not yet been established.

Therefore, it is suggested that during the development of the consistency evaluation in China, the definition, selection and determination of RLD should be defined. The establishment of the RLD lists should be accelerated while the mechanism of patent information disclosure should be established simultaneously. By those means, a good policy reserve shall be made for the patent linkage system.

2. To synchronize the establishment and improvement of the other four core mechanisms

In accordance with the following table, in contrast to the United States and South Korea, despite there is an existence of the patent declaration system in China at present, its real significance is weak. There is also blank in the linking of procedures and organs, exclusivity of first generic drugs and the reverse reconciliation, although those four core mechanisms per se are essential contents of establishing the patent linkage system. Therefore, it is suggested that such four core mechanisms should be set up and improved simultaneously when establishing the mechanism I drug listing application and patent protection.

**Table 5 Comparison of core mechanisms of patent linkage systems in China, US and South Korea**

Operational links	NDA stages	Submission of ANDA	examination of ANDA		Approval of ANDA	
Essential	Publicity system	Patent	Procedure linkage	Linkage	Marketing	

mechanism	of information		declaration system (inform whether constituting infringement)	mechanism		system of administration	monopoly of the first generic drugs	Disposal of reverse reconciliation
	RLD	Disclosure of Patent		Query period	Suspension period			
US	Yes		Yes	45 days	30 months	Yes	180 days	Yes
South Korea	Yes		Yes	45 days	9 months	Yes	9 months	Yes
China	Under developing		Yes	No	No	No	No	No

3. To provide a term for containment and market exclusivity for first generics based on domestic situation

The provision of containment and market exclusivity for first generics will directly affect the interests of the generic drug manufacturer in the linkage system. Hence, it is suggested that when establishing containment, the period should be reasonably formulated by taking both the current situation concerning trial of patent infringement as well as the future developing trends into account. When considering the establishment of market exclusivity for first generics, the cost for patent challenge, as well as the possibly listing interregnum in the procurement and bids inviting of China should be considered, based on which the degree of award for first generics shall be comprehended rationally.

## II The anticipated effects

Article 18 of the current DRR sets the initial provisions of the patent declaration, that is, "in case that others have a patent in China, the applicant shall submit a declaration that it does not constitute any patent infringement". Article 130 of the *DRR (Revised Draft)* of 2016 remains the aforesaid provisions unchanged. However, the linkage system between drugs application patent protection in China has not really been introduced into the process of drugs registration and approval, that is to say, there is no substantive linkage system between drugs application patent protection.

Different from the drugs data protection system, there is no commitment for China on an international law ground for such system. Therefore, whether to establish and implement such a system shall be determined by taking consideration of the the institutional requirements and the future development of our country.

The implementation of linkage system involves interests of various parties, and the pros and cons of the relevant parties in the implementation will be the key to whether the implementation of the system can be effective or not. The research group explored the feasibility of implementing the patent linkage system in China through research on four parties of interests including brand drug manufactures, generics manufactures, social public welfare and administrations.

Based on the analysis, the linkage system can provide the brand drugs developers with sufficient warnings as well as the prevention and control mechanisms of generics before marketing so as to clarify the market prospect of patent drugs. As to the generics manufacturers, the system can also reduce the resources waste of generics industry, promote the supply-side reform of the industry, and optimize the industrial structure. For the public, it can also protect public welfare in the advent of new drugs and the introduction of generic drugs. As for administration and enforcement, although it will bring some complicated procedures and increase administrative costs, the system can effectively control the risk of administrative illegalities and solve the dilemma faced by the present regulators.

In other words, the well-designed linkage system is a non zero-sum game. During its implementation, all the aforesaid four stakeholders are able to attain to certain benefits. And advantages outweigh disadvantages overall. Therefore, it is suggested that China should consider introducing the linkage system when the relevant policies are allowed, aiming st promote the healthy development of pharmaceutical industry.

Specifically, establishing the relevant linkage system is beneficial for the protection of drug patents and pharmaceutical industry.

Firstly, clarification of the linkage system can help to reduce the drug administration's risk of being defendant in patent infringement cases. In the process of drugs application, if the patentee thinks that the drugs for application may infringe the patent right, the drug administration can suspend the examination and approval based on the system, and make the determination after litigation; otherwise, the drug

administration may, together with generics manufacturers, become the defendant in drug patent infringement cases.

Secondly, the mechanism can help to reduce the number of drug litigation cases after the approval and marketing. The resolution of dispute before the marketing of drugs will relieve the pressure of trial and avoid waste of litigation and social resources. The drug patent cases are generally complex and difficult cases. Once the drug is marketed, the drug patent cases will have wide influence with high amount of damages and complex technologies involved. The court will be under great pressure when facing such cases. As a result, settling the disputes before the involved drugs are marketed can help to reduce the impact of the case and business losses.

Thirdly, the generics manufacturers also need a relatively large investment in the generic drugs, and once the marketed drugs are ruled infringement, the company will face with heavy losses. Practice shows that the involved amount of drug patent cases is often large. Once the company lost the lawsuit, it not only cannot recover the initial investment, but will face with huge litigation damages. It is quite probable that the company cannot continue its operation.

Fourthly, settling the disputes before the involved drugs are marketed often involves in the validity of the involved patent. At present, the cases of patent validity are exclusively tried by the Beijing Intellectual Property Court, which is helpful to unify the relevant standards of drug patent cases.

As for the industry, practice shows that the currently widespread domestic generics companies are incapable of imitating the brand drugs, but can only make an imitation of generics. However, after the "second imitation" and "third imitation", the components and effects of generic drugs may be totally different from the brand drugs. Therefore, the establishment of the linkage system will not lead a large number of generics companies to become the defendants. Seeing from the relevant practice, the generics companies capable of imitating brand drugs can, by making use of the system, compete with the brand drugs companies through its own R&D. It will not only stimulate the brand drugs companies to improve their innovations levels, but also encourage the following generics companies to keep promoting their abilities of R&D and imitation through the integration of technologies and capital, so as to make the generics companies larger and stronger instead of resting on the current low-level imitation and surviving from the several low-end generics.



In terms of the system per se, on the one hand, the linkage system requires the brand drug company submit patent-related information, including the patent number, patent protection term and the information of patent right holders, covering the said new drug to CFDA during NDA. In this case, before the R&D and application for registration of the generics, the generic drug companies can have a general comprehension of the patent situations of its target brand drugs and reduce the risks of infringement thereafter. On the other hand, when filing ANDA, the generics applicants is required to submit the patent number and expiration time for all the patent covering the said brand drugs and the method for manufacturing thereof<sup>53</sup>, and make a declaration with respect to the involved patents covering the generics in accordance with the listed patents in the Orange Book. If a generic drug applicant submits a Paragraph IV declaration, which means the applicant considers that the patents of the related brand drugs are invalid, or the manufacture, use or sale of the generics does not infringe the patent right of others, the generics applicant shall notify the holders of patents or the holders of brand drugs' approval documents of his/her declaration. The generics companies shall notify the patentee of the patent challenges, so that the patentee can stop the infringement as early as possible as well as prevent the expansion of losses.

### **III Study formulation and improvement of other supporting systems**

As is mentioned above, the issue of drug patents involves not only the linkage system between drug application and patent protection, but also the systems of compensation for patent protection term and data protection. There are relevant provisions dealing with data protection in the current *Pharmaceutical Administration Law of the People's Republic of China*, but such provisions is lacking of specific operational implementing regulations in practice. On the other hand, system of compensation for patent protection term is still blank in China. These two systems are of great importance in promoting pharmaceutical innovation, which has been proven in practice in the United States, Europe and Japan. Considering that the core and focus of the development of pharmaceutical industry is to promote pharmaceutical innovations, when improving the linkage system between drug application and patent protection, the other two systems also require studying and establishing, the most important of which lies in the actual implementation and practice. Under the common and

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<sup>53</sup> Ding Jinxi and Han Beibei: Comparative Study on the Patent Linkage System in China and US, *Chinese Journal of Pharmaceuticals*, Issue 38 of 2008.

harmonious function of the three systems, can the drug patents in China be protected more sufficiently, so as to provide a solid institutional basis for the healthy, orderly and sustainable development of the pharmaceutical industry.



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