

# Patent Linkage System Centred on Information Disclosure

Liang Zhiwen

On 8 October 2017, the CPC Central Committee and the State Council jointly released the Opinions on Deepening the Reform of Review and Approval System and Encouraging Innovation of Drugs and Medical Devices (hereinafter referred to as “the Opinions”), wherein Article 16 proposes “making an attempt to establish a patent linkage system”. It arouses heated disputes over whether and how to transplant the patent linkage system in China. In this writer’s view, to resolve those disputes, three key issues need to be clarified: first, what is the patent linkage system? Second, whether current pharmaceutical innovative market needs new and stronger incentives. In other words, whether the investment on brand-name drugs in China is severely impacted in the absence of a patent linkage system similar to that in the U.S. Third, how to design the Chinese patent linkage system so as to comply with the pharmaceutical innovation development strategy in China? Among the pros and cons, this writer once wrote an article in favour of establishing a patent linkage system centred on information disclosure.<sup>1</sup> This article is in an attempt to further show the rationality of establishing the patent linkage system centred on information disclosure in China.

## I. Patent linkage is a highly abstract and inclusive academic term

Patent linkage is not a term used in any laws, but a recap of relevant systems and a series of legal rules set up in the Drug Price Competition and Patent Term Restoration Act (1984, U.S.) (hereinafter referred to as the Hatch-Waxman Act). Generally speaking, patent linkage means that, under the laws and regulations of some countries, a drug administrative authority shall link the approval conditions for marketing a drug with the patent protection of the drug. If a drug is suspected of patent infringement, its application for marketing should not be approved.<sup>2</sup> The core approach of

this system is to link the marketing approval of a drug with its patent status, which effectively stops the marketing process of a generic drug within the term of a patent, and further provides better protection for the drug patent.

When discussing the transplanting of the patent linkage system, people, regardless of whether they are for or against it, tend to give first consideration to the above core approach. However, the term “patent linkage” may lead to the neglect of supporting rules in the system. For instance, people may pay no attention to the rules in the Hatch-Waxman Act on the balance of interests, but emphasize one-sidedly the protection of drug patents. In fact, it is just the effect that the U.S. pursued by pushing the TRIPS-plus rules. Patent linkage regulations in the U.S. leded free trade agreements are usually aimed to strengthen the protection of drug patents, and the principled provisions thereof are least related to the balance of interests doctrine in the Hatch-Waxman Act.<sup>3</sup> Undoubtedly, the Opinions also construct the entire patent linkage system on the basis of the above core approach, wherein Article 16 reads:

“When applying for drug registration, an applicant shall specify the relevant patents and ownerships thereof, and shall notify relevant drug patentees within the prescribed time limit. In case of any dispute over a patent, the party concerned may file a lawsuit with the court, during which technical review of drugs shall not be suspended. With respect to the drug that has passed the technical review, the Food and Drug Administration shall determine whether to approve the marketing of such drugs, according to the court’s effective judgment, ruling or mediation document. If no effective judgment, ruling or mediation document is made within the prescribed time period, the Food and Drug Administration may approve the marketing.”

The patent linkage system described in the Opinions is not complete. First, if a new drug applied for marketing is claimed by a patent, unless the Patent Law is revised, it

would not be possible to judge whether patent infringement is established at this stage. According to Article 69.5 of the effective China's Patent Law, it shall not be deemed as patent infringement if "any person produces, uses, or imports patented drugs or patented medical apparatus and instruments, for the purpose of providing information required for administrative examination and approval, or produces or imports patented drugs or patented medical apparatus and instruments especially for that person". It means that clinical trials of generic drugs in preparation for marketing application do not constitute patent infringement. Meanwhile, submission of the application documents for marketing approval is not covered by the patent right defined in Article 11 of the China's Patent Law. As clarified in said article, patent right means the right to "for production or business purposes, manufacture, use, offer to sell, sell, or import the patented products, use the patented method, or use, offer to sell, sell or import the products that are developed directly through the use of the patented method". This provision is different from 35 U.S.C. § 271(e) (2) of the U.S. Patent Act, which sets forth that it shall be an act of infringement to submit an application under the Federal Food, Drug, and Cosmetic Act for a drug claimed in a patent or the use of which is claimed in a patent.

Second, the legal effect of the Opinions is to "determine whether to approve the marketing of such drug according to the court's effective judgment, ruling or mediation document". This seems to go far beyond the remedy provided in the U.S. Patent Act for an act that "shall be deemed to be an act of infringement". Under 35 U.S.C. § 271(e) (4), "the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed". In other words, marketing of the drug can be approved, but the effective date of the approval shall not be earlier than the date of the expiration of the patent which has been infringed.

Third, the Opinions do not include the Orange Book rule, Declaration rule, or the First Generic Drug exclusivity - all of which jointly constitute the patent linkage system in line with the balance of interests doctrine. For instance, the Orange Book rules play a crucial role in the American legal system, because generic drug manufacturers are only required to provide a certification with respect to the patents which claim the listed drug in the Orange Book. For in-

stance, 21 U.S.C. §355(j)(2)(A)(vii) (IV) only involves patents claiming for brand-name drugs which have been listed on the filing date of an application for drug marketing.<sup>4</sup>

Fourth, in the patent linkage system mentioned in the Opinions, there is no distinction between chemical medicines and biological medicines. In 2010, the U.S. enacted the Biologics Price Competition and Innovation Act (BPCIA), which provides for a fast review and approval system of follow-on biologics that are biosimilar or interchangeable with reference biologics. BPCIA set up a patent linkage system that is different from the Hatch-Waxman Act mainly on the grounds that the costs of generic biologics are greatly different from those of small molecular compounds.

Although the Opinions is only a principled framework of the patent linkage system, if Chinese lawmakers eventually determine to establish a patent linkage system, the balance of interests shall be embodied in specific laws and regulations. If the system is constructed merely in accordance with Article 16 of the Opinions, the patent linkage system to be established in China will provide a broader protection for brand-name drugs than the U.S., or possibly the broadest among all the countries. Thus, in addition to the rules established in the Hatch-Waxman Act, the Opinions shall also learn law-making experiences from other countries for "making an attempt to establish a patent linkage system".

From the perspective of comparative law, patent linkage system is rarely seen in countries other than the U.S. and countries that have concluded free trade agreements with the U.S. The European Union (EU) has insisted for many years that there should be no patent linkage system for approval of drugs for marketing under EU law.<sup>5</sup> Nor does India vote for the transplanting of the patent linkage system.<sup>6</sup> Among those countries where the patent linkage system has been established, the competent drug marketing authority deals with marketing applications of patents in the following two manners:<sup>7</sup> first, the application for marketing of a generic drug will be denied, if such a generic drug may infringe other's patent. This is the highest level of protection conferred by the patent linkage system. The second approach is that, the competent authority informs the patentee that its patent may be infringed by a third party's product that is applied for marketing. If the competent authority approves the marketing of a generic drug within the term of patent, it should notify the original patent owner of all the information on the marketing application. I believe that China should learn from the second approach and establish a pat-

ent linkage system centred on information disclosure.<sup>8</sup>

## II. Patent linkage system centred on information disclosure will not impact innovations in the pharmaceutical industry

Even if “making an attempt to establish a patent linkage system” has reached the point of no return, the discussion on what legislative mode should be adopted in China is still of great significance. It is because basic characteristics of the pharmaceutical innovation market shall be first taken into consideration, and then the legislators can decide what legislative mode should be adopted to give incentives to pharmaceutical innovations.

In a more general sense, the pharmaceutical innovation stimulating mechanism needs balance the interests between brand-name drug manufacturers, generic drug manufacturers, the supervisory authority and the general public. For brand-name drug manufacturers, if the innovation-stimulating legal mechanism cannot provide them with a certain monopoly position in the market place to shield their products from free competition, it will be hard for these manufacturers, which are mainly engaged in R&D, to afford the costly marketing approval trials. As to generic drug manufacturers, a majority of which are small- and medium-sized enterprises, they hardly can invest such a huge amount of money in acquiring various data necessary for marketing approval. Thus, whether similar products could be provided and how competitive those similar products are mainly depend on whether those generic drug manufacturers can enter into the market as early as possible, and to what extent they can make full use of the innovators’ achievements (such as trial data) to get the marketing approval. For the general public, their interests are not only in obtaining marketed products, but also in innovative products, and the safety of those products.<sup>9</sup>

Can the patent linkage system centred on information disclosure balance the interests in an abstract sense? It is out of question that as far as drug patentees are concerned, the patent linkage system in the U.S. has an overwhelming advantage over the traditional, infringement-oriented patent protection, because it is not necessary to file patent lawsuits against generic drug manufacturers. Generally speaking, patent litigation is costly and fraught with uncertainty. Obviously, in comparison with the rules in the

Hatch - Waxman Act and the Opinions, the patent linkage system centred on information disclosure provides weaker protection for brand - name drug patents. As a result, the first query would be whether it will reduce the investment willingness in developing brand-name drugs.

This query has its practical significance. Under the background of innovation - led development, to strengthen intellectual property protection tends to become an invincible rhetoric. In fact, however, the driver of innovation may not necessarily come from strong economic incentives through intellectual property protection. Conversely, sharing or imitation in some industries does no harm to innovations, but even turns into a primary impetus for innovations. Meanwhile, the legislative goal of intellectual property protection is not for the sake of protection of rights, but for achieving the goal of innovation stimulation. But, innovation stimulation is only one of the goals pursued by the intellectual property system. For instance, compulsory licensing may be granted to a pharmaceutical patent for the sake of public health. Impacts on different interested parties need to be taken into consideration when the patent linkage system is established. Of course, to guarantee reasonable rewards of drug innovators is also an important factor that should be taken into account. In view of the role of the U.S. in the promotion of its patent linkage system, I am going to take a look at the costs and rewards of brand-name drug development in American laws.

As we all know, the development of brand-name drugs is a very lengthy and costly process. When it is mentioned, it only refers to the development of brand-name drugs containing new chemical elements (NCEs) or new active ingredients. A study shows there are more than 4,300 companies that are engaged in drug innovation, yet only 261 organizations (6% ) have registered at least one NCE since 1950. Of these, only 32 (12% ) have been in existence for the entire 59-year period. The remaining 229 (88% ) organizations have failed, merged, been acquired, or were created by such merger and acquisition (M & A) deals, wherein 137 have disappeared through M & A and 19 were liquidated.<sup>10</sup> It can be seen that drug innovations are at a high risk. Developing a new drug needs a long period of time, which can be generally divided into the following phases: discovery of candidate chemical compounds, clinical trials, marketing approval and post - marketing supervision. Since 1980, the average number of clinical trials conducted prior to filing for approval from the FDA has more than doubled,

and the number of patients in clinical trials has tripled.<sup>11</sup> Unlike the initial screening process, clinical testing costs have risen sharply because now more drugs are being studied to treat chronic diseases, which greatly multiplies the complexity of the trials and the difficulty of recruiting subjects. All told, due to the long-lasting concerns about drug safety by the general public, the average time needed for the development of a new drug has increased over the years, rising from 8.1 years in 1960s, to 11.6 years in the 1970s, to 14.2 years in the 1980s and 1990s.<sup>12</sup>

As a result, development of brand-name drugs requires huge investment. A widely-cited study demonstrates that R&D of small molecule drugs cost about US\$ 802 million on average in 2000, whereas those of biopharmaceuticals cost about US\$ 1,318 million on average in 2005.<sup>13</sup> The R&D costs of 106 randomly selected new drugs were obtained from a survey of 10 pharmaceutical firms. These data were used to estimate the average pre-tax cost of new drug and biologics development. The costs of compounds abandoned during testing were linked to the costs of compounds that obtained marketing approval. The estimated average out-of-pocket cost per approved new compound is US\$1,395 million. Capitalizing out-of-pocket costs to the point of marketing approval at a real discount rate of 10.5% yields a total pre-approval cost estimate of US\$ 2,588 million. Total capitalized costs were shown to have increased at an annual rate of 8.5% above general price inflation. Adding an estimate of post-approval R&D costs increases the cost estimate to US\$ 2,870 million.<sup>14</sup>

Due to the high costs of brand-name drug development, brand-name companies declared that they expect a dismal profit-making prospect. Many brand-name companies reported that they are currently undergoing a phase of transition. According to the respondent companies, the following trends are particularly noteworthy: difficulties in refilling the pipeline with new products, and decrease in the number of new drug applications on a year-by-year basis; increasing requirements in terms of safety and efficacy for new medicines, resulting in higher R&D costs; increasing control over prices and reimbursement levels, as well as on the prescribing practices of doctors by national health authorities; a significant number of patent expiries for important blockbuster medicines; and new advances in genomics, proteomics and personalised medicines.<sup>15</sup> A similar idea is also flooding the U.S. pharmaceutical industry. For instance, Eli Lilly has slashed thousands of jobs, and con-

solidations and mergers among industry players are an increasingly common occurrence.<sup>16</sup>

However, does it mean the pharmaceutical industry goes downhill?

The answer is no, because drugs have a long life cycle and bring huge returns. Different from other products, the life cycle of drugs is obviously longer. At a social level, a longer life cycle of drugs brings about higher social benefits. First, patients can directly benefit from the R&D of drugs. The R&D of new drugs have overcome human diseases that were once incurable, and effectively improved the life quality of patients. Second, the extension of human life expectancy and the improvement of the life quality are conducive to an increase in social welfare. One study shows that "increases in longevity have been as valuable as all other sources of economic growth combined".<sup>17</sup>

At the same time, brand-name drugs also provide their manufacturers with abundant revenues in return, which can be seen from the increasingly growing net profit margin and return on equity on a year-over-year basis made by pharmaceutical companies. According to Fellmeth, a comparison was made between the top 300 of the Fortune 500 in 2003 and the nine large pharmaceutical companies in terms of net profit margin, concluding that the median return on equity (net of research expenses) of the nine pharmaceutical companies listed in the top 300 of the Fortune 500 was over four times that of the remaining 277 companies (58.5% versus 13.4%). Average return on equity for the drug developers was even greater in proportion to that of other companies of comparable size (52.1% versus 11.4%).<sup>18</sup> The writer compared 12 pharmaceutical companies listed in the Fortune 500 in 2016 with all the pharmaceutical companies listed in the Fortune 500 in terms of average net profit margin and average return on equity, the results of which are shown in Table 1 (shown in the following page). It can be seen that the profits made by the 12 pharmaceutical companies are much higher than those of all the companies.

### III. The patent linkage system centred on information disclosure will not influence brand-name drug manufacturers to achieve their commercial goals

As stated above, the pharmaceutical industry has obtained tremendous profits in return. Under the current legal framework, what strategies are adopted by the brand-name drug manufacturers to achieve their profit-making commercial goal? To sum up, there are primarily the following strategies:

First, the return on investment of brand-name drugs comes from leading market shares thanks to first-mover advantage. Brand-name drug manufacturers, as new drug developers, have much pricing power that derives from their monopoly position by taking advantage of being first into the market; and meanwhile, brand-name drugs are so attractive to consumers (patients) and doctors for the good quality and reliable efficacy that it is hard for them to shift to generic drug consumption.<sup>20</sup>

Second, patent plays a crucial role in the return on investment in pharmaceutical innovation. Patents granted for brand-name drugs can cover the production, sales, offering to sale, use and import of new drugs, so as to prevent generic drugs from entering into the competitive market, and in such a way to set a monopoly price. To guarantee sufficient returns on pharmaceutical innovation, drug developers usually start filing patents in the very preliminary new drug R&D phase. Moreover, to maintain sustainable competitiveness, drug developers keep on applying for patents in the whole life cycle of new drugs. Although the patentability, such as novelty and non-obviousness, of those supplementary patents, which are filed during the subsequent R&D phase of brand-name drugs, are questionable, brand-name drug manufacturers can also stay in a *de facto* monopoly position due to the high litigation costs for patent invalidation disputes. Generally speaking, the patents filed in the subsequent phases are not intended to provide protection for active ingredients, but mostly for auxiliary elements of the drug. The expiration date of the later-filed patent will be extended, such that the brand-name drugs could enjoy longer monopoly position in the market than the basic invention. In the case of the blockbuster antidepressant Paxil

Table 1 Return on Investment of Pharmaceutical Companies listed in the Fortune 500 in 2016<sup>19</sup>

	Net profit margin%	Return on equity %	average net profit margin% of 12 pharmaceutical companies	Average return on equity % of 12 pharmaceutical companies	average net profit margin% of companies listed in the Fortune 500	average return on equity % of the companies listed in Fortune 500
Pfizer	14.2	4.2	23.58	11.20	5.46	3.03
Johnson & Johnson	22	11.6				
Novartis	34.8	13.5				
Roche	17.6	12.2				
Sanofi	11.5	4.3				
Merck Sharp & Dohme	11.2	4.4				
GlaxoSmithKline	35.2	16.3				
Abbott	15	8.9				
AstraZeneca	11.4	4.7				
Gilead Sciences	55.5	34.9				
AbbVie	22.5	9.7				
Amgen	32	9.7				

Note: Pharmaceutical companies listed in the Fortune 500 in 2016 include China National Pharmaceutical Group Corporation.

(paroxetine), for example, the brand-name drug manufacturer secured 10 such patents. The last expiring patent would, unless challenged, have blocked generic competition until 2019, compared to a successful challenge that secured generic approval and entry in 2003.<sup>21</sup> Sometimes, in subsequent phases, brand-name drug manufacturers may also file patents covering new formulations relating to the basic invention or the product line. Such a patent strategy is often called “evergreening patent”, which strengthens the competitive advantage of brand-name drug manufacturers and delays the competition with generic drugs, and thereby, provides brand-name drug manufacturers with high profits.

Third, data protection for drugs will also prolong the period of exclusivity of brand-name drugs. Drug data protection is required in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) would appear to require that steps be taken to ensure that the data are protected. Except for shorter than patents in terms of protection period, data protection for drugs is better in line with the life cycle of drugs on the grounds that the protection of data begins from the date of the first marketing approval, while the term of a patent usually begins with the filing date, and drugs generally enter into the market long after the expiration of the patent. The regime in the U.S. for granting authorizations for medicinal products provides that, when a patent protects a product, in most cases the term of regulatory data protection is extended for 30 months or longer.<sup>22</sup> This is because the primary competitiveness of generic drugs comes from cost saving in clinical trials. Joseph Stiglitz, the American economist and Nobel Prize winner, indicated that the most significant factor affecting pharmaceutical innovation is the sharp growing cost of clinical trials. In the costs of US\$800 million for NCEs development, the average costs of trials are on the order of US\$400 million per NCE.<sup>23</sup> Since the costs of pre-clinical trials and clinical trials account for one half or even two thirds of the development costs for brand-name drugs, generic drug manufacturers generally tend to apply for marketing approval according to the Abbreviate New Drug Application (ANDA) procedures after the expiry of the data protection period so as to save huge costs spent on clinical trials, in spite of the fact that generic drug manufacturers can independently obtain experimental data in exchange for the marketing approval for generic drugs.

Fourth, brand-name drug manufacturers can make

profits not only from patent protection, but also from public funds for drug R&D. Profits of brand-name drug manufacturers also include government investments in basic R&D, and pricing protection for brand-name drugs under the medical insurance system. Government investment on the fundamental R&D of drug covers a great portion of the R&D cost invested by the brand-name drug manufacturers. The U.S. funds (publicly and privately) more than US\$ 60 billion per year in medical research. The annual appropriations of the National Institutes of Health (NIH) rose from US\$ 700,000 going into World War II to US\$ 30 billion in 2010.<sup>24</sup> In China, there is also a huge amount of public funding devoted to the R&D of new drugs. Nevertheless, the Medical insurance system has three common objectives concerning drug pricing and compensation mechanism: (1) to ensure that patients in need have access to the necessary medicines; (2) to ensure that health budgets remain under control to ensure sustainability of the health system; and (3) to create/maintain incentives for further innovation.<sup>25</sup> Inclusion of brand-name drugs into the list of drugs under the medical insurance system broadens the scope of protection of brand-name drugs. For products that still benefit from market exclusivity, German law provides for direct negotiations between the sickness funds and the brand-name companies. The duration of those contracts concluded before loss of exclusivity (LoE) can be extended beyond LoE without the need for a tender procedure. The law obliges pharmacists to dispense the product subject to the rebate contract if the patient is insured with the sickness fund that is the other party to the contract.<sup>26</sup>

Fifth, before expiration of the patent covering the brand-name drug, brand-name drug manufacturers sometimes pre-emptively launch generic drugs, which is often known as “authorized generic drugs”. Generally speaking, the manufacturing cost only accounts for a small portion of the overall cost of a drug, which results in that generic drugs cost much less than the brand-name drugs. Generic drug manufacturers provide drugs of same efficacy at a lower price. The price competition between generic drugs and brand-name drugs reduces the overall medical expenses of the society. Nevertheless, generic drugs on the market do not seriously impact the profits on brand-name drugs. On the one hand, the competition with generic drug pushes brand-name drug manufacturers to develop new drugs. Price competition prevents brand-name drug manufacturers from setting a monopoly price for drugs. In order to gain

higher profits, brand-name drug manufacturers will invest more in developing new drugs that can bring high returns. On the other hand, the appearance of generic drugs on the market means that the related market is attractive for investors. Otherwise, no investments will be made on generic drugs. Compared with generic drug manufacturers, brand-name drug manufacturers enjoy considerable cost advantage. It also costs to apply for marketing approval of generic drugs. Especially in the field of bio-products, the marketing of generic drugs needs to be applied for, and reviewed and approved under the procedures as a new drug. For brand-name drug manufacturers, the cost for marketing approval is a sunk cost. If brand-name drug manufacturers have recovered the costs of new drug R&D before the entry of generic drugs by virtue of their monopoly position and exclusive rights, brand-name drug manufacturers can even lower their production costs. Hence, brand-name drug manufacturers enjoy cost advantage in terms of generic drug production. Besides, brand-name drug manufacturers also enjoy other competitive advantages in providing “authorized generic drugs”: they can pre-emptively launch generic drugs by taking advantage of its exclusive protection to gain their leading position in the market; and, among consumers, brand-name drug manufacturers are renowned for high quality and reliable efficacy, which helps the sales of their own generic drugs.

#### IV. Patent linkage system centred on information disclosure complies with China’s national conditions

A patent linkage system similar to that in the U.S. may impact the duties and responsibilities of a conventional drug administrative authority, conflict with the legislative purpose of “Bolar” exemption under the patent law, and affect the accessibility of drugs and thus cause a certain impact on public health.<sup>27</sup> In regard to whether to introduce the patent linkage system in China, many factors shall be taken into careful consideration, such as international trade, and the investment on brand-name drugs and generic drugs at home and abroad. Further, special attention shall also be given to the degree of protection of public health by a country’s social health insurance system. Henry Waxman, congressman and the main drafter of the U.S. Hatch-Waxman Act, casted doubt on promoting the Hatch-Wax-

man model by signing Free Trade Agreements (FTAs) with developing countries:

“Many of our trading partners face vastly different challenges and circumstances than we do here in the U.S. .... (Hatch-Waxman), which delays market entry of low-cost generic drugs for years after a life-saving drug becomes available. That system works in this country because most people in the U.S. have health insurance that pays for essential drugs and because we have a health care safety net to assure that the poorest in our society are not left without medical care and treatment. But to impose such a system on a country without a safety net, depriving millions of people of life-saving drugs, is irresponsible and even unethical.”<sup>28</sup>

China has achieved remarkable achievements in improving the healthcare system, but there is no denying that the healthcare system is still at a rather low level. Price, in most cases, becomes an important factor affecting the accessibility of drugs. In regard to brand-name drugs under patent protection, there may be no substantial price difference for the same drug in developing countries and developed countries. But still, in developing countries, only a very small percentage of patients can afford those expensive drugs.<sup>29</sup> At an international level, because of the profit-seeking nature of brand-name drug manufacturers, brand-name drugs are primarily targeted to common ailments in those countries and regions that contribute to the majority of corporate profit. Brand-name drugs place emphasis on the development of chronic disease medications. A chronic condition may be a severe one that may never be cured, such as HIV or multiple sclerosis. However, it could also be one that is not life-threatening, but for which there is a perceived consumer demand and interest (such as depression, asthma, or even male pattern baldness).<sup>30</sup> Of course, these diseases also include heart disease, hypertension, and cancer that all countries need drugs to treat.<sup>31</sup> But brand-name drug manufacturers generally do not have enough motive to invest in the R&D of new drugs which could treat typical diseases in developed countries. The shortness of such kinds of drugs clearly shows the lack of investment willingness in these field. In addition, brand-name drug manufacturers have motive to develop new drugs for pediatric and rare diseases because of the limited number of patients and low profits.

The patent linkage system centred on information disclosure is also of great significance to China’s “One Belt, One Road” Initiative. Countries joining the “One Belt, One

Road” Initiative are mostly developing countries in which mainly generic drugs are produced, and may have drug accessibility and public health issues. After the exit of the U.S. from the Trans-Pacific Partnership (TPP) Agreement, a new agreement, “the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP)”, that is renamed from TPP, suspended more than 20 provisions concerning, among other things, data protection, patent linkage and compensation for the term of a patent.<sup>32</sup> It means that three developed countries, Japan, Canada and Australia, do not insist on TRIPS-plus rules, and recognize the basic interest of other developing countries. Under this background, for the purpose of pharmaceutical innovation protection, it is not necessary for China to set up a patent linkage system in the American way, which goes beyond the TRIPS agreement.

In China, the development of brand-name drugs in relation to NCEs and new biological agents has just begun. A strategy of pharmaceutical innovation and development, namely, co-developing brand-name drugs and generic drugs, is reasonable and scientific. To be specific, the strategy includes the following four aspects: development of brand-new drugs, development of new dosage forms, development of “me-too” drugs, and further development of known drugs. The latter two aspects may also involve the research of new usages of drugs.<sup>33</sup> Therefore, it is necessary to provide certain protection for the achievements of simulating innovation under the strategy of co-developing brand-name drugs and generic drugs. The achievements of simulating innovation certainly can be protected under the existing intellectual property system, but they may be more suitable for data protection under the TRIPS agreement, with the help of the patent linkage system centred on information disclosure. This approach complies with China’s national conditions on pharmaceutical innovation.

The Measures for the Administration of Drug Registration (MADR) promulgated in 2005 in China actually established a patent linkage system, although it is only at a rather low level. Maybe for the sake of interests of Chinese generic drug manufacturers or practical demands of China pharmaceutical industry, the system was not enforced and implemented strictly. The U.S. once criticized China in the Special 301 Report for granting generic drug manufactures marketing approvals even before the brand-name pharmaceutical product has been approved.<sup>34</sup> In 2017, the U.S. initiated an investigation of China under Section 301, but it only

criticized China in the Special 301 Report issued in 2017 that “the lack of an effective mechanism for notifying interested parties of marketing requests or approvals for follow-on pharmaceuticals in a manner that would allow for the early resolution of potential patent disputes”.<sup>35</sup> In this regard, the U.S. never officially requires that China needs to set up a patent linkage system and a patent term restoration system similar to the Hatch-Waxman Act. A patent linkage system centred on information disclosure can be established under the Drug Administration Law. If so, it would be at a higher legal level and be more powerful than the current one established under the MADR, and thus it can be considered as “an effective mechanism for notifying interested parties of marketing requests or approvals for follow-on pharmaceuticals”.

Hence, we believe that there is no need to amend the Patent Law to establish a patent linkage system in line with China’s national conditions. That is to say, it is unnecessary to include the act of applying for marketing approval as an infringement of a patent. The patent linkage system targeted for “information disclosure” can be established merely under the provisions of the Drug Administration Law and the Implementing Regulations thereof. Specifically, the state drug administration authority shall disclose relevant information, such as the type of patent, its filing date, expiration date and patentee, comprehensively, and ensure that those information are open and accessible by the general public timely. It should be stipulated that an applicant must disclose whether the drug applied for marketing approval is claimed by any patents; the patentee of a drug patent may record information of its patent into the patent linkage system within a stipulated time period; and the registered information on drug patents shall be updated periodically. ■

The author: Professor of Law School of Nanjing Normal University, and researcher of Jiangsu Intellectual Property Protection and Development Institute

<sup>1</sup> Jiang Zhiwen (2017). Transplant and creation of patent linkage system. *Journal of Politics and Law*, 8.

<sup>2</sup> See supra note 1.

<sup>3</sup> Jiang Zhiwen (2014). Drug TRIPS-plus protection in U.S. Free Trade Agreement. *Journal of Comparative Law*, 1.

<sup>4</sup> A certification with respect to each patent which claims a use for such listed drug for which the applicant is seeking approval under this subsection: (I) that such patent information has not been filed, (II) that



such patent has expired, (III) of the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted. See 21 U.S.C. §355(j)(2)(A)(vii) (2006).

<sup>5</sup> See European Commission. Pharmaceutical Sector Inquiry: Preliminary Report, 378.

<sup>6</sup> See Sandeep K Rathod (2001). Patent linkage and data exclusivity: a look at some developments in India. *Journal of Generic Medicines*, 8 (3), 140, 143.

<sup>7</sup> See supra note 3.

<sup>8</sup> See supra note 1.

<sup>9</sup> Jiang Zhiwen (2016). Regulatory exclusive right: New development beyond patent law. *Studies in Law and Business*, 2.

<sup>10</sup> See Bernard Munos (2009). Lessons from 60 Years of Pharmaceutical Innovation. *Nature Reviews of Drug Discovery*, 8, 959-961.

<sup>11</sup> See Emily Mchiko Morris (2012). The myth of generic pharmaceutical competition under the Hatch-Waxman Act. *FORDHAM INTELL. PROP. MEDIA & ENT.L.J.*, 22, 245, 253.

<sup>12</sup> See Emily Mchiko Morris (2012). The myth of generic pharmaceutical competition under the Hatch-Waxman Act. *FORDHAM INTELL. PROP. MEDIA & ENT.L.J.*, 22, 245, 254.

<sup>13</sup> See J. A. DiMAS, R. W. Hansen & H. G. Grabowski (2003). The Price of Innovation: New Estimates of Drug Development Costs. *J. HEALTH ECON.*, 22, 151; also see J. A. DiMAS & H. G. Grabowski, The Cost of Biopharmaceutical R&D (2007). *MAMANGE DECIS. ECON.*, 28, 469.

<sup>14</sup> See Joseph A. DiMasias, Henry G. Grabowskib & Ronald W. HansencTufts (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. *Journal of Health Economics*, 47, 20 – 33.

<sup>15</sup> See European Commission. Pharmaceutical Sector Inquiry: Preliminary Report (Final Report), at 33, 8 July 2009.

<sup>16</sup> See Emily Mchiko Morris (2012). The myth of generic pharmaceutical competition under the Hatch-Waxman Act. *FORDHAM INTELL. PROP. MEDIA & ENT.L.J.*, 22, 245, 215-246.

<sup>17</sup> See Kenneth J. Arrow et.al. (2011). Valuing Health Care: Improving Productivity and Quality, 12.

<sup>18</sup> See Aaron Xavier Fellmeth (2004). Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data Under the TRIPs Agreement. *HARV. INTE'L L.J.*, 45, 453, 470.

<sup>19</sup> Statistical data comes from the website of Fortune.

<sup>20</sup> See John Hudson (2000). Generic Take-Up in the Pharmaceutical Market Following Patent Expiry: A Multi-Country Study. *INT'L REV. L.&ECON.*, 20, 205, 207.

<sup>21</sup> See C. Scott Hemphill & Bhaven N. Sampat (2012). Evergreening,

Patent Challenges, and Effective Market Life in Pharmaceuticals. *J. HEALTH ECON.*, 31, 327, 327.

<sup>22</sup> See Trevor Cook (2007). Regulatory Data Protection in Pharmaceuticals and Other Sectors, in *PHARMACEUTICALS AND AGRO-CHEMICALS AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES* (Anatole Krattiger et.al .eds.) 438, 439.

<sup>23</sup> See Arjun Jayadev & Joseph Stiglitz (2009). Two Ideas to Increase Innovation and Reduce Pharmaceutical Costs and Prices. *Health Affairs*, 28 (1), W165-168.

<sup>24</sup> See Kenneth J. Arrow et.al. (2001). Valuing Health Care: Improving Productivity and Quality, 15.

<sup>25</sup> See supra note 15, at 131.

<sup>26</sup> See supra note 15, at 146-147.

<sup>27</sup> See supra note 1.

<sup>28</sup> See Henry Waxman, Statement of the Honorable Henry A. Waxman, a Representative in Congress from the State of California, at 149. Retrieved from <https://www.gpo.gov/fdsys/pkg/CHRG-108hhr91677/pdf/CHRG-108hhr91677.pdf>.

<sup>29</sup> See Cynthia M. Ho. Access to medicine in the global economy: International agreements on patents and related rights, at 27-28.

<sup>30</sup> See supra note 29, at 29.

<sup>31</sup> See supra note 29, at 28.

<sup>32</sup> Retrieved from <http://mai.vmghealthcare.com/article.asp?articleid=23537>. Last visited on 26 November 2017.

<sup>33</sup> Pharmaceutical Intellectual Property Research Committee of Chinese Pharmaceutical Association. Comparative Study on Drug Testing Regulatory Exclusive Right System. China Medical Science and Technology Press (2013 edition), pp.23-24.

<sup>34</sup> See 2012 Special 301 Report, at 34-35.

<sup>35</sup> See the United States Trade Representative (USTR), Special 301 Report, p33. Retrieved from <https://ustr.gov/sites/default/files/301/2017%20Special%20301%20Report%20FINAL.PDF>.