

Comprehensive Artificial Infringement in China's Drug Regulatory Review

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ABSTRACT

The Hatch-Waxman Act struck a balance between branded drug manufacturers and generic drug manufacturers through an elaborate set of procedures, such as allowing generic drug companies to make or use the brand manufacturer's patented drugs for preparing to list generic drugs without permission of the patent holders, while treating the generic drug application for listing as an act of "artificial infringement" subject to court review.

Most Chinese scholars propose to directly transplant this approach into China, regardless of the different national systems between the two countries. In contrast, this article proposes the adoption of a comprehensive artificial infringement, which contains restrictions to drug innovators and precaution against pay-for-delay settlements. These restrictions are inspired by the Canadian system, including the requirements that drug innovators bring actions in due time and compensate generic drug manufacturers if they lose in a lawsuit. Pay-for-delay settlements, which are a challenge in the U.S., refer to the payments made by drug innovators to generic drug manufacturers in order to delay the listing of generic drugs. This article explains how Chinese administrative agencies can use the proposed comprehensive artificial infringement to prevent such unlawful settlement agreements in China.

As shown in this article, this proposal would be more applicable to China and hopefully implement well, since it takes into sufficient consideration the Chinese national system and empirical experiences of the U.S. and Canada.

INTRODUCTION

Most countries have strict administrative approval procedures for drug listing. Generally, the process of listing a branded drug¹ in China tends to exceed 10 years since the research and development ("R&D") and clinical trials involved take much time.² Generic drugs must be consistent with the

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1. In this article, "branded drug manufacturers", "drug innovator" and "innovator company" refer to the same and are used inter-exchangeably; "generic drug manufacturers" and "generic company" are used in the same way.

"Branded drug" or "brand name drug" means what is listed under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act. "Generic drug" means a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act is approved.

2. *Dudong Xinyao & Fangzhi Yaoyan Liucheng, Liaojie Xinyao Yanfa Xiangmu Guanli Shijianzhou (读懂新药 & 仿制药研流程, 了解新药研发项目管理时间轴)* [Understanding Research Process of New Drug & Generic Drug, Learning Timeline of R&D Project Management of New Drug], CANBIGOU (参比购) (Oct. 21, 2019),

listed branded drug in terms of safety, quality and efficacy.³ A generic drug does not need to go through the same clinical trials as the branded drug.⁴ Before 1984, however, generic drugs were required to apply for listing in the same way as branded drugs in the United States (“U.S.”), and a generic company could not perform experiments using patents of the branded drug until they expired.⁵ This amounted to prolonging the monopoly period of the branded drug.

Against this background, a lawsuit between two pharmaceutical companies⁶ gave birth to the Hatch-Waxman Act⁷ in 1984, which states: it is legal to make or use patented drugs for preparing to list generic drugs without permission of the patent holders; and it is an act of infringement to submit such an application for listing, i.e., artificial infringement.⁸ As such, drug innovators are entitled to sue generic drug manufacturers when the latter applies to list a drug, which in turn allows drug innovators to maintain their monopoly on the market for 30 months due to a stay of the generic drug application (i.e., “Stay-of-Effectiveness Period”).⁹ However, if the generic drug manufacturers win the lawsuit, they are awarded a 180-day exclusivity period in the market (i.e., “Administrative Exclusivity Period”).¹⁰ Drugs are a special kind of product, and their exclusivity in the market can bring about huge profits because drug companies can charge high prices without competition. Thus, generic drug manufacturers are incentivized to apply earlier for a listing to pursue the 180-day exclusivity, while drug innovators in turn actively sue to maintain their monopoly in the market.

The Hatch-Waxman Act of the U.S. has struck a great balance between branded drug manufacturers and generic drug manufacturers by designing a “Stay-of-Effectiveness Period” of 30 months and an “Administrative Exclusivity Period” of 180 days. The pragmatic effects of this innovative model are so appealing that many countries have introduced or plan to introduce it into their own pharmaceutical management system, including China, where it is termed the “Pharmaceutical Patent Link System” (“PPLS”). However, is the current legal soil in China really adequate to transplant the merit of this Act?

<https://www.canbigou.com/index.php?m=content&c=index&a=show&catid=63&id=466>
[<https://perma.cc/95KK-QR6Y>] (China).

3. *Id.*

4. *Id.*

5. See Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and its Impact on the Drug Development Process*, 54 FOOD DRUG LAW J. 187–94 (1999).

6. *Bolar Pharmaceutical Co., Inc. v. Roche Products, Inc.*, 469 U.S. 856 (1984).

7. 21 U.S.C. § 355(j)(l) (2013); 35 U.S.C. §§156, 271(e), 282 (2015).

8. 35 U.S.C. § 271(e)(2)(A) (2015) (“It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505 (b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent”) (also known as “Artificial Infringement or “Fictional Infringement”); see *infra* Part I.B.2.

9. 21 U.S.C. § 355(j)(5)(B)(iii) (2013); see *infra* Part I.B.1 (explaining that when a generic company makes Certification IV and the patentee files a lawsuit, the FDA will not approve the ANDA within 30 months, which is Stay-of-Effectiveness Period).

10. 21 U.S.C. § 355(j)(5)(B)(iv) (2013); see *infra* Part I.B.1 (explaining that a “180-day exclusivity period” means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective).

The Chinese government has taken several actions to reform the pharmaceutical system since 2017, including an attempt to establish PPSL. However, China's lack of a provision similar to the U.S.'s "artificial infringement" provision may be the fundamental hindrance to direct introduction of the Hatch-Waxman Act.

Despite this problem, many Chinese scholars suggest directly introducing the artificial infringement provision of the U.S. By contrast, the present article proposes a comprehensive version of "artificial infringement" for implementation in China, which would involve some restrictions on innovator companies, including a requirement that drug innovators bring actions in due time and compensate generic drug manufacturers if they lose the actions. This article also proposes plausible legal treatment of "pay-for-delay settlements"¹¹ in China, which have been a serious problem in the U.S. pharmaceutical system.

Part I identifies the problems of no artificial infringement in China and of pay-for-delay settlements in the U.S. by means of comparing relevant systems currently existing in China with the Hatch-Waxman Act of the U.S. This part focuses on core regulations in the Chinese and U.S. systems, as well as the Canadian system. Part II proposes China provide a comprehensive version of artificial infringement, which incorporates some stipulations in Canada and tries to treat potential pay-for-delay settlements based on the artificial infringement scheme in the U.S. This version will be more viable in China due to the power structure of China's administrative and national legal system. Part III addresses potential criticisms of the proposal and hence attempts to provide further support.

I. PHARMACEUTICAL PATENT LINK SYSTEM

Currently, China has no true pharmaceutical patent link system. In recent years, the Chinese government has actively advocated for the establishment of such a system. For example, the State Food and Drug Administration of China¹² expressly proposed to establish a PPLS,¹³ and the State

11. See, e.g., Alicia I. Hogges-Thomas, *An American Drug Problem: Reclaiming Consumers' Rights Under The Hatch-Waxman Act*, 37 Vt. L. REV. 737 (2013) (A pay-for-delay (or also called "reverse payment") settlement refers to a settlement entered into between an innovator company (patent holder) and a generic company (infringer) in a patent infringement lawsuit. Under the settlement, the innovator company agrees to pay a certain type of economic benefit to the generic company, and as a consideration, the generic company promises to delay entry of its generic drug into the market. Normally, it is infringers that pay patent holders for settlement, and that is why pay-for-delay settlements are also called "reverse payments").

12. State Food and Drug Administration of China is abbreviated as "CFDA", or "NMPA" for CFDA's successor National Medical Products Administration, so as to distinguish it from the Food and Drug Administration ("FDA") in the United States.

13. Guanyu Guli Yaopin Yiliao Qixie Chuangxin Baohu Chuangxinzhe Quanyi de Xiangguan Zhengce (关于鼓励药品医疗器械创新保护创新者权益的相关政策) [Policies Relevant to Encouraging Innovation in Pharmaceutical and Medical Devices and Protecting the Rights of Innovators] (consultation draft, published May 12, 2017) ST. FOOD AND DRUG ADMIN., <http://samr.cfda.gov.cn/WS01/CL0778/172606.html> [<https://perma.cc/WM9C-W3RK>] (China).

Council also “actively explore[d] establishment of a patent link system.”¹⁴ In its Drug Registration Management Measures, however, the State Food and Drug Administration only provided that “the relevant regulations on pharmaceutical review and approval and pharmaceutical patent link are separately formulated” in Rule 98.¹⁵ This implies that construction of a PPLS in China is not as simple as directly introducing a “Stay-of-Effectiveness Period” and an “Administrative Exclusivity Period” like in the U.S. because lawmakers need to balance the interests of different groups to effectively implement PPLS in the current legal system. The most significant problem, however, is that China lacks other supportive legislation to practice PPLS in reality. Moreover, China has a significantly different legal system from the U.S. Below, Part I of this article details the lack of artificial infringement in China by describing the current legislation and practice of PPLS in both the U.S. and China.

A. WHAT IS THE PHARMACEUTICAL PATENT LINK SYSTEM?

The “pharmaceutical patent link system” has become prevalent in the medical and pharmaceutical field in China in recent years.¹⁶ In fact, this concept has also directly been used in official Chinese documents.¹⁷ However, it currently lacks an explicit definition from authorities. In fact, some foreign scholars might not understand what the concept specifically refers to. Therefore, this article first attempts to clarify this concept.

From a broad perspective, the “pharmaceutical patent link system” means linking the regulatory approval for the listing of generic drugs with the expiration of patents of corresponding innovative drugs.¹⁸ Put another way, in the registration of generic drugs, the status of patents of previously-listed branded drugs will be considered, thereby avoiding potential patent disputes. A country’s drug administration department links the conditions for approving the generic drug listing to the patent protection status of the

14. Guanyu Shenhua Shenping Shenpi Zhidu Gaige Guli Yaopin Yiliao Qixie Chuangxin de Yijian (关于深化审评审批制度改革鼓励药品医疗器械创新的意见) [Opinions on Deepening Reform of Review and Approval System and Encouraging Innovation in Pharmaceuticals and Medical Devices] (issued by the General Office of the CPC Central Committee and General Office of the State Council, Oct. 8, 2017) (China).

15. Yaopin Zhuze Guanli Banfa (药品注册管理办法) [Drug Registration Management Measures] (drafted by the St. Food & Drug Admin., Oct. 23, 2017, consultation draft) ST. FOOD AND DRUG ADMIN., <http://samr.cfda.gov.cn/WS01/CL0778/178900.html> [<https://perma.cc/3WL4-9F2Y>] (China).

16. The number of recent discussions in China on this topic—in publications and at conferences—support this statement. *E.g.*, ZHICHANLI, <http://news.zhichanli.com/search.html?key=%E8%8D%AF%E5%93%81%E4%B8%93%E5%88%A9%E9%93%BE%E6%8E%A5&p=2> [<https://perma.cc/L5CW-XYG4>] (more than 10 articles were published in the PPLS column of Zhichanli, a well-known online IP magazine, from the end of 2017 to the beginning of 2019); CHENG YONGSHUN & WU LIJUAN, EXPLORING THE PHARMACEUTICAL PATENT LINK SYSTEM (2019), <https://item.jd.com/12564226.html?cu=true> [<https://perma.cc/J3TQ-E2KT>] (a book on the topic was published in 2019); and the topic of PPLS was repeatedly discussed at the China Pharma IP Summit 2019 (Oct. 23-25, 2019).

17. See *supra* notes 13-15.

18. See Ding Jinxi (丁锦希) & Han Beibei (韩蓓蓓), *Zhongmei Yaopin Zhuanli Lianjie Zhidu Bijiao Yanjiu* (中美药品专利链接制度比较研究) [Comparative Study of Pharmaceutical Patent Link Systems in China and the U.S.], 39 ZHONGGUO YIYAO GONGYE ZAZHI (中国医药工业杂志) [China Pharmaceutical Industry Journal] 950-55 (2008).

corresponding listed drug (i.e., innovative drug), and if the generic drug is suspected of infringing the patent(s) of the innovative drug, the generic drug's listing application will not be approved.

This concept seems fairly simple, but it involves a variety of supportive policies or regulations to ensure implementation of the “link”. For example, first, a drug innovator must submit to a country's drug administration department the information on patents directed to a branded drug or its use when applying for the listing of the branded drug.¹⁹ The patent information constitutes a cornerstone of the PPLS, and it serves the basis for filing declarations by generic companies when they apply to list their generic drugs.²⁰ Second, generic companies must reveal information on patents of relevant innovative drugs which they know or should know.²¹ Third, the legal treatment of generic drugs' registration when patent disputes occur between generic companies and drug innovators must also be considered, which in turn involve the Stay-of-Effectiveness Period.²² Lastly, the national drug administration department must consider whether to stay generic drug applications if they fail to declare relevant patents when filing the applications.²³

The design of these supportive regulations is the connotation of the term “pharmaceutical patent link system.” It is the very reason why individual countries have different regulations, resulting in differences of PPLS between countries.

Tracing back to the source of the term, it is the U.S. that founded the “pharmaceutical patent link system.”²⁴

B. PHARMACEUTICAL PATENT LINK SYSTEM IN THE U.S.

The Drug Price Competition and Patent Term Restoration Act, known as the Hatch-Waxman Act, outlines the process for pharmaceutical manufacturers to file an Abbreviated New Drug Application (“ANDA”) for approval of a generic drug by the Food and Drug Administration (“FDA”).²⁵ While protecting drug innovators, the program also tries to facilitate and increase the incentives for generic companies to submit an ANDA.²⁶

19. 21 U.S.C. § 355(b)(1) (2013).

20. 21 U.S.C. § 355(j)(2)(A)(vii) (2013).

21. See, e.g., Tao Guandong (陶冠东), *Lundao Yiyao Zhuanli Minxing Eryuan Fenli Tizhi Yingxiangxia de Yaopin Zhuanli Lianjie Zhidu* (论道医药专利| 民行二元分立体制影响下的药品专利链接制度) [On Pharmaceutical Patent Link System under the Influence of the Binary Discrete Systems between Civil and Administrative Litigations of Medical or Pharmaceutical Patents], ZHICHANLI (Sept. 26, 2018, 9:30 AM), <http://news.zhichanli.cn/article/7075.html> [<https://perma.cc/9UFG-23U6>] (China).

22. *Id.*

23. *Id.*

24. Qiu Fu'en (邱福恩), *Chuangxin Yaoqi, Fangzhi Yaoqi Nimen Zhunbei Haolema?* (创新药企、仿制药企你们准备好了吗?) [Are You Ready, Innovator Companies and Generic Companies?], IPRDAILY, http://www.iprdaily.cn/article_19350.html [<https://perma.cc/V598-G45B>] (last visited Jan. 20, 2020).

25. See Mossinghoff, *supra* note 5.

26. See Garth Boehm et al., *Development of the Generic Drug Industry in the US after the Hatch-Waxman Act of 1984*, 3 ACTA PHARMACEUTICA SINICA B 297, 297–311 (2013).

1. ANDA Process and “Bolar Exception”²⁷

The ANDA process is constructed on the basis of the branded new drug application (“NDA”).²⁸ Compared to the NDA, a new kind of market exclusivity is introduced under the ANDA by means of a five-year period of data exclusivity awarded when the FDA approves the listing of a drug that is a new chemical entity.²⁹ The term of patents covering the drug is allowed to be extended by a portion of the time the drug is under regulatory review by the FDA.³⁰ Moreover, the drug innovator is required to provide the FDA with the bibliographies of patents it believes cover its drug, and the FDA publicly lists those patents in the Orange Book,³¹ which builds the foundation of the ANDA process and pharmaceutical patent linkage.

Specifically, when a generic company is ready to file its ANDA, the Act requires it to declare how its activities, when it begins to market the drug, will relate to patents listed in the Orange Book. There are four options or “Certifications”: it can state (I) that there have never been patents listed, (II) that listed patents have Expired, (III) that it will not market the drug until all the patents listed in the Orange Book have expired, or (IV) that it believes the patents in the Orange Book are not relevant or are invalid.³² Generic companies are incentivized to file Certification IV because the first company to file an ANDA with such a certification obtains 180 days of administrative exclusivity if their ANDA is approved, during which period the FDA cannot approve another generic drug application.³³ If the generic company files under Certification IV, a statement must be filed within 20 days from the date of filing the ANDA to inform the patentee, which has 45 days to decide whether to file a lawsuit. If the patentee files a lawsuit, the FDA will not approve the ANDA within 30 months (i.e., Stay-of-Effectiveness Period) unless the generic drug applicant wins the case.³⁴

On the other hand, the Act provides a generic company with a safe harbor (i.e., “Bolar Exception”³⁵) from patent infringement lawsuits during the time when the generic company is preparing its ANDA.³⁶ In preparing

27. 35 U.S.C. § 271(e)(1) (2015) (“It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products”) (also known as the “Research Exemption” or “Bolar Exception”); see Part I.B.1.

28. See *Abbreviated New Drug Application (ANDA)*, FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda> [https://perma.cc/5UYW-N9TZ] (last visited Jan. 22, 2020).

29. Boehm, *supra* note 26.

30. See WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RESEARCH SERV., RL32377, THE HATCH-WAXMAN ACT: LEGISLATIVE CHANGES AFFECTING PHARMACEUTICAL PATENTS (2004).

31. *Id.* at 3 (stating that “each holder of an approved new drug application (NDA) is required to list patents it believes would be infringed if a generic drug were marketed before the expiration of these patents. The FDA maintains this list of patents in its publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the ‘Orange Book’”).

32. Mossinghoff, *supra* note 5.

33. SCHACHT & THOMAS, *supra* note 30, at 4.

34. 21 U.S.C. §§ 355(j)(2)(B); 355(j)(5)(B)(iii) (2013).

35. 35 U.S.C. § 271(e)(1) (2015); see Part I.B.1.

36. Boehm, *supra* note 26; SCHACHT & THOMAS, *supra* note 30, at 3.

materials for ANDA, the generic company needs to learn how to manufacture the drug, manufacture a test batch, and run bioequivalence studies; all of these are activities for which the generic company could be sued for patent infringement. To prevent liability for the conduct needed to prepare an ANDA, the Patent Act of the U.S. provides generic companies with the “Bolar Exception”, i.e., it cannot be construed as the act of infringement to make or use a patented invention solely for uses reasonably related to the development and submission of information under a law which regulates the manufacture, use, or sale of drugs.³⁷

2. ANDA Litigation and Artificial Infringement

Apart from the Bolar Exception, the Patent Act of the U.S. further provides for artificial infringement,³⁸ which serves as a legal basis on which the patentee can bring a lawsuit against a generic company that files an ANDA and informs the FDA under Certification IV. The act of submitting an ANDA is not the act of making, using, selling, importing or offering to sell patented products, (i.e., typical infringing acts), so it is called “artificial” or “fictional.”³⁹ Pursuant to the artificial infringement, the patentee is entitled to sue the generic company for patent infringement in the ANDA process, so as to at least gain the benefit of the Stay-of-Effectiveness Period.⁴⁰

This is a complete system that has been designed in the U.S. to ensure effective implementation of its PPLS. Pursuant to the Hatch-Waxman Act or the Patent Act, the act of filing an ANDA with Certification IV is an act of patent infringement. By means of this, PPLS actually promotes litigation between drug innovators and generic companies.⁴¹ Specifically, an innovator is prompted to commence patent enforcement litigation against the generic infringer, while the generic company is incentivized to file a countersuit to declare the patents listed in the Orange Book invalid.⁴²

3. “Pay-for-Delay” or “Reverse Payment” Settlements—A Byproduct of the United States’ PPLS

Many patent infringement lawsuits result in a reverse payment settlement where patentees, instead of being paid, pay alleged infringers for settlement.⁴³ These settlements occur because patents are, by nature, a kind of

37. 35 U.S.C. § 271(e)(1) (2015) (“It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products”) (also known as the “Research Exemption” or “Bolar Exception”); see Part I.B.1.

38. 35 U.S.C. § 271(e)(2)(A) (2015) (“It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505 (b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent”) (also known as “Artificial Infringement” or “Fictional Infringement”).

39. Mossinghoff, *supra* note 5.

40. Mossinghoff, *supra* note 5.

41. See Boehm, *supra* note 26; see SCHACHT & THOMAS, *supra* note 30.

42. See Boehm, *supra* note 26; see SCHACHT & THOMAS, *supra* note 30.

43. *FTC Staff Report Finds 60 Percent Increase in Pharmaceutical Industry Deals That Delay Consumers Access to Lower-Cost Generic Drugs*, FED. TRADE COMM’N (May 3, 2011), <https://www.ftc.gov/news-events/press->

exclusivity right that entitle patentees to monopoly within the patent term. As long as infringers promise to quit the market (in the lawsuits based on artificial infringement, generic companies agree to delay marketing their generic drugs) the patentees can continue to monopolize without any competition and earn back the money that was paid to the alleged infringers in the settlements.

PPLS substantively promotes litigation and, in turn, seems to promote pay-for-delay settlements between innovator companies and generic companies. According to a study by the Federal Trade Commission (“FTC”) in 2011, pay-for-delay agreements cost consumers and tax payers \$3.5 billion a year.⁴⁴ Since PPLS aims to encourage competition between generic and brand-name companies, the anticompetitive nature of reverse settlements presumably interfered with the goal of the Hatch-Waxman Act. Pay-for-delay settlements appear to be a byproduct of the Act, which allow the innovator company to maintain its patent and monopoly profits, while the generic company receives a pay-off, leaving consumers as the only loser in the game.

C. PHARMACEUTICAL PATENT LINK SYSTEM IN CANADA

To comply with the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the North American Free Trade Agreement (NAFTA) obligations, Canada created a system of linking generic approval to patent status in 1993.⁴⁵ After two amendments in 2006 and 2017,⁴⁶ Patented Medicines (Notice of Compliance) Regulations (i.e., Canadian PPLS) have developed some unique provisions besides those similar to the U.S.⁴⁷ Two provisions directed to the first person (i.e., innovator company) are related to this article and will be introduced below.

Canada provides that if the patentee loses the case, the second person (i.e., generic company) is entitled to apply for an order requiring all plaintiffs to compensate its loss.⁴⁸ In the 2017 amendments, the loss expands from only direct loss to further include indirect loss.⁴⁹ On the other hand, if the first person does not bring an action without a reasonable basis within 45-days after receiving notification of filing an ANDA from the second person, no action can be brought against the second person for infringement.⁵⁰ In this way, subsequent filers of generic drugs can decide whether to file an ANDA

releases/2011/05/ftc-staff-report-finds-60-percent-increase-pharmaceutical [https://perma.cc/M7LX-UX8B].

44. *Id.*

45. See, e.g., Thomas A Faunce & Joel Lexchin2, ‘Linkage’ Pharmaceutical Evergreening in Canada and Australia, AUSTRALIA AND NEW ZEALAND HEALTH POLICY 4 (2007).

46. See, e.g., *id.*; Bradley White et al., *Canada’s Patent Linkage Regulations Get Long-Awaited Makeover*, OSLER (July 18, 2017), <https://www.osler.com/en/resources/regulations/2017/canada-s-patent-linkage-regulations-get-long-await> [https://perma.cc/5RUQ-CN9M].

47. Qiu, *supra* note 24.

48. Patented Medicines (Notice of Compliance) Regulations, SOR/93-133 (last amended on Sept. 21, 2017), Section 8 (Can.).

49. Qiu, *supra* note 24.

50. Patented Medicines (Notice of Compliance) Regulations, SOR/93-133 (last amended on Sept. 21, 2017), Section 6.01 (Can.).

with reference to the ruling of cases between the first and the second persons. This provision was also introduced in the 2017 amendments.⁵¹ In contrast to Canada, patentees in the U.S. carry no liability in the artificial infringement lawsuit, even if their patents are found to be invalid or generic drugs do not infringe their patents.

D. PHARMACEUTICAL PATENT LINK SYSTEM IN CHINA

In the background of encouraging innovation and medical reform at the national level in China, the PPLS has become one of the most prevalent legal issues in recent years. Innovative drugs are depleted in China in the long term, and domestic pharmaceutical manufacturers mainly produce generic drugs due to the lack of intellectual property protection as a driving force and incentive mechanism. It is necessary for China to learn from and absorb successful experiences of other countries, so as to drive innovation while maintaining the prosperity of generic drugs in the market, and thereby ensuring that the public can afford medicine when they are sick.

1. The Process for Approval of Generic Drugs and “Bolar Exception”

a. Currently Effective Pharmaceutical Patent Link System

Many people assume that China already has PPLS, and currently effective Drug Registration Management Measures indeed appear to cover all elements of PPLS according to Rules 18-19.⁵² Specifically, Rule 18 provides “an applicant shall provide information on patent and its ownership of the applicant or other parties in China, in respect of the drug applied for registration, its formula, manufacturing processes or uses, etc.”⁵³ This means that when a drug innovator files a branded drug application, information of patents covering the drug is required to be submitted. Also pursuant to Rule 18, “Where another party owns the patent in China, the applicant shall provide a statement of non-infringement”,⁵⁴ which means that the generic company shall submit a certification. “The drug regulatory department shall publish the information or the statement submitted by the applicant on its official website”⁵⁵, which means that the generic company can find some information shown in the U.S.’s Orange Book. According to Rule 19, “For a drug patented in China, applicants other than the patentee may submit the application for registration two years prior to the expiry date of the patent.”⁵⁶ Not

51. *Id.*

52. Yaopin Zhuce Guanli Banfa (药品注册管理办法) [Drug Registration Management Measures] (promulgated by the St. Food & Drug Admin., June 18, 2007, effective Oct. 1, 2007) NAT’L MED. PROD. ADMIN., <http://www.nmpa.gov.cn/WS04/CL2174/300629.html> [<https://perma.cc/UCU7-VGDM>] (China).

53. *Id.*

54. *Id.*

55. *Id.*

56. *Id.*

only this provision, but the Chinese Patent Law, further stipulates a Bolar Exception.⁵⁷

Despite all the above, these provisions are so overbroad that applicants can submit information without substance to easily meet the formal requirements.⁵⁸ The statements submitted by generic companies are often incomplete and even inaccurate, and there is also no further procedure to supervise them.⁵⁹ Moreover, even though the involved patent is likely to be invalidated, a specific generic company has no incentive to actively institute invalidation, since its competitors also can benefit from the invalidation result without any expense. On the side of the patentee, even if it knows that the generic company probably infringes its patent, it cannot bring an action until the generic drug is marketed due to the Bolar Exception.⁶⁰ In one word, these current overbroad regulations seem to be in vain, and demonstrate that China has not established a pharmaceutical patent link system.

b. Pharmaceutical Patent Link System in Plan

The Chinese government seems to have proactively called for and promoted the establishment of PPLS in recent years, and one of these typical measures is drafting the “Policy on Encouraging the Protection of Innovative Innovators in Pharmaceutical Medical Devices” on May 12, 2017, which specifies the details of this system.⁶¹ The following table compares its relevant contents with the PPLS of the U.S.

57. Zhuanli Fa (专利法) [Patent Law] (promulgated by Standing Comm., Nat'l People's Cong., Dec. 27, 2008, effective Oct. 1, 2009) Art. 69(5), THE CENTRAL PEOPLE'S GOVERNMENT OF THE PEOPLE'S REPUBLIC OF CHINA, http://www.gov.cn/flfg/2008-12/28/content_1189755.htm, [https://perma.cc/286W-PJQ5] (China) (Article 69: “The following shall not be deemed to be patent right infringement: (5) 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 any other person imports patented drugs or patented medical apparatus and instruments especially for that person”).

58. Chen Yongshun (程永顺) & Wu Lijuan (吴莉娟), *Lundao Yiyao Zhuanli | Chuxian Duanni: Sishi Erfei de Zhongguo Zhuanli Lianjie Zhidu* (论道医药专利 | 初现端倪: 似是而非的中国专利链接制度) [*On the Pharmaceutical Patent | The Plausible Chinese Patent Linkage System*], ZHICHANLI (Jan. 23, 2018, 7:27PM), <http://news.zhichanli.cn/article/5737.html> [https://perma.cc/2ZJ5-GYSR] (China).

59. *Id.*

60. *Id.*

61. Guanyu Guli Yaopin Yiliao Qixie Chuangxin Baohu Chuangxinzhe Quanyi de Xiangguan Zhengce (关于鼓励药品医疗器械创新保护创新者权益的相关政策) [Policies Relevant to Encouraging Innovation in Pharmaceutical and Medical Devices and Protecting the Rights of Innovators] (consultation draft, published May 12, 2017) ST. FOOD AND DRUG ADMINISTRATION, <http://samr.cfda.gov.cn/WS01/CL0778/172606.html> [https://perma.cc/WM9C-W3RK] (China).

Table 1: Comparison of PPLS in China with that of the U.S.

	China ⁶²	The U.S.
Drug Innovator	6 years of data exclusivity ⁶³	5 years of data exclusivity for NCE ⁶⁴
	Patent term extension of 5 years at most for innovative drugs ⁶⁵	Patent term extension of a portion of the time the drug is under regulatory review by the FDA ⁶⁶
	Chinese Marketed Drug Catalogue	Orange Book
Generic company	at most 24 month Stay-of-Effectiveness Period when patentee brings an action ⁶⁷	30 month Stay-of-Effectiveness Period ⁶⁸
	1.5 year of data exclusivity ⁶⁹	180 days of Administrative Exclusivity Period ⁷⁰

As shown in Table 1, the PPLS planned by China has encompassed almost all the basic elements of those in the U.S., except that there are some data differences between the corresponding parameters. As such, can the planned system be implemented in China as it has been in the U.S.? The answer is still no. The reason is because the problem existed in the PPLS of China, as identified by this article.

62. *Id.*63. *Id.*64. Boehm, *supra* note 26.

65. *Li Keqiang Zhuchi Zhaokai Guowuyuan Changwu Huiyi Queding Fazhan “Hulianwang+Yiliao Jiankang” Cuoshi deng* (李克强主持召开国务院常务会议 确定发展“互联网+医疗健康”措施等) [Li Keqiang Presided over the State Council Executive Meeting to Determine the Development of “Internet + Medical Health” Measures, etc.], ZHONGGUO ZHENGFUWANG (中国政府网) [CHINESE GOVERNMENT WEBSITE] (Apr. 12, 2018, 7:40 PM), http://www.gov.cn/premier/2018-04/12/content_5282000.htm [https://perma.cc/VF4T-UNPX] (China).

66. See SCHACHT & THOMAS, *supra* note 30.

67. Guanyu Guli Yaopin Yiliao Qixie Chuangxin Baohu Chuangxinzhe Quanyi de Xiangguan Zhengce (关于鼓励药品医疗器械创新保护创新者权益的相关政策) [Policies Relevant to Encouraging Innovation in Pharmaceutical and Medical Devices and Protecting the Rights of Innovators] (consultation draft, published May 12, 2017) ST. FOOD AND DRUG ADMINISTRATION, <http://samr.cfda.gov.cn/WS01/CL0778/172606.html> [https://perma.cc/WM9C-W3RK] (China).

68. 21 U.S.C. § 355(j)(5)(B)(iii) (2013); see *infra* Part I.B.1 (explaining that when a generic company makes Certification IV and the patentee files a lawsuit, the FDA will not approve the ANDA within 30 months, which is Stay-of-Effectiveness Period).

69. Guanyu Guli Yaopin Yiliao Qixie Chuangxin Baohu Chuangxinzhe Quanyi de Xiangguan Zhengce (关于鼓励药品医疗器械创新保护创新者权益的相关政策) [Policies Relevant to Encouraging Innovation in Pharmaceutical and Medical Devices and Protecting the Rights of Innovators] (consultation draft, published May 12, 2017) ST. FOOD AND DRUG ADMINISTRATION, <http://samr.cfda.gov.cn/WS01/CL0778/172606.html> [https://perma.cc/WM9C-W3RK] (China).

70. 21 U.S.C. § 355(j)(5)(B)(iv) (2013); see *supra* Part I.B.1 (explaining that a “180-day exclusivity period” means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective).

E. FUNDAMENTAL PROBLEM TO CHINESE PHARMACEUTICAL PATENT LINK SYSTEM

1. Having Bolar Exception, but No Artificial Infringement

As seen from the above comparison between the U.S. and China, one problem with China's PPLS is that there is no provision similar to the U.S.'s "artificial infringement" provision. Pursuant to §271(e)(2)(A) of the Patent Act of the U.S., if a drug or its use is patented, the act of filing an ANDA for the drug under regulatory review is deemed patent infringement.⁷¹ This infringement stipulation is intended to provide a legal basis for jurisdiction of federal courts.⁷² Otherwise, the act of filing an ANDA can be absorbed by the Research Exemption (or Bolar Exception) and hence considered as non-infringement.⁷³

In China, the Bolar Exception was introduced into the current Patent Law as Article 69(5) in 2008.⁷⁴ This law required that even if a patent holder for a drug knew that a generic company submitted an ANDA for the drug, the patent holder could not do anything but wait to market the drug after approval. As such, the design of a "Stay-of-Effectiveness Period" would not make any sense. Also, the generic company would be forced into a dilemma and sustain greater economic loss in the future if it was ultimately found to infringe the drug patent after the generic drug has been marketing.⁷⁵ Therefore, there is Bolar Exception, but no artificial infringement, which constitutes one impediment to a pharmaceutical patent link system in China.

Of course, in a lawsuit over artificial infringement, the patent holder cannot claim damages, but only request an injunction for the generic company's ANDA to be denied before the expiration of the drug patent.⁷⁶

2. Precaution against Pay-for-Delay Settlements

As stated above, pay-for-delay settlements are a flaw in the U.S.'s PPLS. From 2011 to 2016, several congressional bills were proposed, titled "Fair and Immediate Release of Generic Drugs Act," which mainly focused on changing the definition of the first-to-file generic company and removing

71. Zhang Weijun (张伟君) & Chen Ying (陈滢), *Niyizhong de Woguo Yaopin Zhuanli Lianjie Keneng Weifan Xianxing Zhuanli Fa* (拟议中的我国药品专利链接制度可能违反现行专利法) [Proposed Pharmaceutical Patent link System in China probably Violating the Current Patent Law], ZHICHANLI (Jan. 3, 2018, 8:00 AM), <http://news.zhichanli.cn/article/5572.html> [https://perma.cc/T5TG-ZQ7G] (China).

72. *Id.*

73. Yongshun & Lijuan, *supra* note 58.

74. Zhuanli Fa (专利法) [Patent Law] (promulgated by Standing Comm., Nat'l People's Cong., Dec. 27, 2008, effective Oct. 1, 2009) Art. 69(5), THE CENTRAL PEOPLE'S GOVERNMENT OF THE PEOPLE'S REPUBLIC OF CHINA, http://www.gov.cn/flfg/2008-12/28/content_1189755.htm, [https://perma.cc/286W-PJQ5] (China) (Article 69: "The following shall not be deemed to be patent right infringement: (5) 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 any other person imports patented drugs or patented medical apparatus and instruments especially for that person").

75. Yongshun & Lijuan, *supra* note 58.

76. Chen Yongshun (程永顺) & Wu Lijuan (吴莉娟), *Lundao Yiyao Zhuanli | Yaopin Zhuanli Lianjie Zhidu zai Zhongguo Zhenyang Luodi?* (论道医药专利 | "药品专利链接制度"在中国怎样落地?) [On the Pharmaceutical Patent | How does Pharmaceutical Patent Linkage System Land in China?], ZHICHANLI (Feb. 5, 2018, 9:16 AM), <http://news.zhichanli.cn/article/5827.html> [https://perma.cc/9XMA-UXHU] (China).

180-day exclusivity from the generic company that is a party of a pay-for-delay settlement.⁷⁷ However, the Generic Pharmaceutical Association (GPhA) argued that patent settlements save consumers and taxpayers billions of dollars and that many generics have entered the market before the patents expired, thanks to patent litigation settlements between generics and brand-name companies.⁷⁸ Recently, a new bill titled “Preserve Access to Affordable Generics and Biosimilars Act” was introduced to Congress, suggesting that as long as an ANDA filer (generally, a generic company) receives anything of value and agrees to limit or forego its ANDA product, the settlement agreement shall be presumed to have anticompetitive effects.⁷⁹

U.S. consumers and the FTC have historically challenged pay-for-delay settlements under the antitrust laws in cases such as *Andrx Pharmaceuticals, Inc. v. Biovail Corp. Intern.*,⁸⁰ *In re Cardizem CD Antitrust Litig.*,⁸¹ *Schering-Plough Corp. v. FTC*,⁸² *In re K-Dur Antitrust Litig.*,⁸³ and *FTC v. Actavis Inc.*⁸⁴ However, different courts adopted different tests to determine whether the settlements were anticompetitive in these cases, thus resulting in a variety of different rulings. In fact, the Third Circuit’s decision in *In re K-Dur Antitrust Litigation* (“*K-Dur*”), decided in July 2012, is arguably the first pro-consumer circuit court decision in pay-for-delay cases since 2002.⁸⁵

Since pay-for-delay settlements are destructive to the public interest in the U.S.,⁸⁶ but quite difficult to eliminate, this article attempts to precaution against them at the outset of the pharmaceutical patent link system in China.

II. A COMPREHENSIVE ARTIFICIAL INFRINGEMENT TO MAKE CHINESE PPLS OPERATE WELL

The proposal of this article is to add the “artificial infringement” provision into the PPLS of China and, at the same time, take account of how to avoid “pay-for-delay settlements” between innovator companies and generic companies. Since the PPLS has historically only resided in discussion and never entered into force in China until now, there is just now a realization of the lack of an “artificial infringement” provision in the Chinese legal system, and an even more limited awareness of the “pay-for-delay” settlement. Scholars have suggested introducing into the Chinese Patent Law a provision similar to the U.S.’s 35 U.S.C. § 271(e)(2)(A) or interpreting the generic

77. See S. 1882, 112th Congress (2011-2012); S. 504, 113th Congress (2013-2014); S. 131, 114th Congress (2015-2016).

78. *FAIR Generics Act could remove 180-day exclusivity*, GABIONLINE (Nov. 25, 2011), <http://www.gabionline.net/Policies-Legislation/FAIR-Generics-Act-could-remove-180-day-exclusivity> [https://perma.cc/DE6Q-5RGK].

79. See S. 3792, 115th Congress (2017-2018).

80. *Andrx Pharmaceuticals, Inc. v. Biovail Corp. Intern.*, 256 F.3d 799, 803 (D.C. Cir. 2001).

81. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 899-900 (6th Cir. 2003).

82. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1058 (11th Cir. 2005).

83. *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012).

84. *FTC v. Actavis Inc.*, 570 U.S. 136 (2013).

85. See *Hogges-Thomas*, *supra* note 11.

86. See *FED. TRADE COMM’N*, *supra* note 43.

company's application for the listing into a "making" under Art. 11 of the Chinese Patent Law.⁸⁷

A. PROPOSAL OF A CHINESE STATUTORY SOLUTION: ARTIFICIAL INFRINGEMENT + RESTRICTIONS ON INNOVATOR COMPANIES + STRINGENT EXAMINATION OF PAY-FOR- DELAY SETTLEMENTS

The proposed statute introduces the artificial infringement clause from the U.S. Additionally, it proposes a restriction on innovator companies and stringent examination of pay-for-delay settlements. The innovation capability of Chinese enterprises has significantly developed in the past decades, but compared to developed countries such as the U.S. and European Union ("EU"), the innovation still falls short, including in the pharmaceutical industry. Apart from balancing interests between innovator companies and generic companies, it may be more crucial at the current stage in China to place a slight bias on generic companies. By doing so, the ultimate beneficiary will actually be patients who can buy drugs at lower prices.

1. Draft of a Chinese "Artificial Infringement" Provision

Considering that regulations for the PPLS will be separately formulated in China,⁸⁸ this provision can be drafted into the future regulations for PPLS. As a matter of fact, the Amendment of the Patent Law (drafted version), which was reviewed in the 7th Session of the Standing Committee of the 13th National People's Congress in December 2018 and on which comments from the public were collected until February 3, 2019, includes no relevant clauses to a pharmaceutical patent link.⁸⁹

This article proposes that China should adopt the following amendment:

Comprehensive Artificial Infringement for Public Benefit

- (a) *It shall be an act of infringement to submit a Generic Drug Application (GDA) under Rule 13 of the Drug Registration Management Measures⁹⁰ for a drug claimed in a patent or the preparation of which is claimed in a patent.*
- (b) *If the patent holder does not sue within the prescribed time limit of 20 days⁹¹ after receiving a notification of submitting a GDA from the applicant, the patent*

87. See, e.g., Tang Xihe (汤溪贺), *Queshao Nizhi Qinquan Cheng Jianli Yaopin Zhuanli Lianjie Zhidu Zuida Zhang'ai—Jiantan Wanshan Zhuanli Lianjie Zhidu de Tidaixing Fang'an* (缺少拟制侵权成建立药品专利链接制度最大障碍——兼谈完善专利链接制度的替代性方案) [Lacking Artificial Infringement being the Biggest Barrier to Establish Pharmaceutical Patent Link System—Also on Alternative Approaches to Improve Patent Linkage System], 136 ZHONGGUO ZHISHI CHANQUAN (中国知识产权) [CHINA INTELLECTUAL PROPERTY] (2018).

88. See ST. FOOD AND DRUG ADMIN., *supra* note 15.

89. See, e.g., *Zhuanlifa Yinglai Disici Xingai* (专利法迎来第四次修改) [the Fourth Amendment of the Patent Law], Baidu (百度) (Dec. 25, 2018, 4:32 PM), <https://baijiahao.baidu.com/s?id=1620811959970035231&wfr=spider&for=pc> [https://perma.cc/A3GM-75VJ] (China).

90. See ST. FOOD AND DRUG ADMIN., *supra* note 15; Yaopin Zhuze Guanli Banfa (药品注册管理办法) [Drug Registration Management Measures] (drafted by the St. Food & Drug Admin., Oct. 23, 2017, consultation draft) ST. FOOD AND DRUG ADMIN., <http://samr.cfda.gov.cn/WS01/CL0778/178900.html> [https://perma.cc/3WL4-9F2Y] (China) ("Rule 13: The application for registration of generic drugs refers to the one for production of drugs that are consistent with the listed original drug or reference drug in respect of safety, quality and efficacy.").

91. ST. FOOD AND DRUG ADMIN., *supra* note 13.

holder shall bring no action against the applicant of this GDA based on the same patent.

- (c) *If the patent holder sues within the prescribed time limit, the duties of the parties will be as follows:*
1. *Where the patent is announced invalid or judged to not be infringed, the patent holder shall bear any loss incurred to the applicant of this GDA during the Stay-of-Effectiveness Period; or*
 2. *Where the suit is resolved by a settlement between the parties, the two parties shall file the authentic settlement agreements, together with relevant materials formed in the lawsuit, with the State Anti-monopoly Administration Department⁹² for substantive examination.*

The PPLS is not yet established in China and the relatively detailed contents are just those mentioned in Part I.D.1.b of this article.⁹³ Also, Drug Registration Management Measures is in amendment, and the amended draft⁹⁴ gives a different GDA definition from that in the currently-effective version⁹⁵ but ignores the clauses about application and approval. It is possible that all relevant regulations to GDA will be planned to be covered by a specific set of regulations on the pharmaceutical patent link in the future. Thus, the proposed clause of this article temporarily adopts the definition of the GDA in the Drug Registration Management Measures's amended draft.

2. Elements of the Chinese Artificial Infringement

In order to better adapt to the current innovation level in China's pharmaceutical industry, the draft of the Chinese provision contains the U.S. approach to artificial infringement, the Canadian restrictions to innovator companies, and an improvement to the U.S.'s reporting requirement for settlement agreements. The following part of the article will therefore discuss and explain the sources of these elements and why some elements have been adjusted.

a. Section(a)---Element Based on the Approach of the U.S.

The first section of the proposed clause is the basic artificial infringement, which acts as a trigger for implementation of PPLS. Only after the trigger is pulled can the innovator companies acquire a "Stay-of-Effectiveness Period," and the generic companies have a chance of obtaining an

92. Note: Before the State Administration for Market Regulation was established in Mar. 17, 2018, anti-monopoly cases were presided over by the Commerce Ministry, State Administration for Industry and Commerce, and National Development and Reform Commission, according to case types. For example, the Commerce Ministry was in charge of cases involving concentration of business operators, and the National Development and Reform Commission was responsible for cases involving prices. Now, all anti-monopoly cases are presided over by the Anti-monopoly Bureau of State Administration for Market Regulation. Pay-for-delay settlements are likely of monopoly nature and thus would most likely be reviewed by this government entity.

93. ST. FOOD AND DRUG ADMIN., *supra* note 13.

94. See ST. FOOD AND DRUG ADMIN., *supra* note 15.

95. See NAT'L MED. PROD. ADMIN, *supra* note 52 (Rules 12 and 73-83; according to Rule 12, "A generic drug application refers to one for registering to produce a drug of an existing national standard and already approved by the State Food and Drug Administration.").

“Administrative Exclusivity Period,” thereby truly benefiting from this link system. Since the Chinese legal system has already encompassed the “Bolar Exception” in its Patent Law,⁹⁶ further introduction of the artificial infringement with reference to the PPLS of the U.S. cannot upend the systematic integrity of the Chinese legal system. Of course, it may be more proper to also introduce artificial infringement into the Chinese Patent Law like in the U.S.⁹⁷ since it is directed at patent infringement. As stated above, however, it is also viable for it to act as one new clause in the specifically-formulated pharmaceutical patent link regulations in the future, especially where the proposed statute contains other elements than pure artificial infringement.

b. Sections (b) and (c1)---Element Based on the Approach of Canada

The next sections, (b) and (c1), of the proposed clause are some restrictions to innovator companies with reference to the Canadian PPLS, so as to force innovator companies to prudently bring actions at a due time.

The proposed statute provides in section (b), that if the patent holder does not sue within 45 days, it shall not sue the applicant of the GDA based on the same patent. The model for this can be found in the PPLS of Canada. There, no action may be brought unless the patent holder sued within 45 days without a reasonable basis. This intends to give subsequent filers of generic drugs a definite ruling to decide whether to file an ANDA. In China, this provision has more than this significance. Specifically, there is no conspicuous “patent cliff” phenomenon in China, and the listing of generic drugs cannot dramatically decrease the sales volumes of innovator companies for their patented drugs.⁹⁸ For example, when patents of Glivec of Novartis and Invanz of MSD expired in 2013, their RMB sales almost remained constant in the subsequent 4 years, while after patents of Velcade of J&J expired in 2015 and Iressa of Az in 2016, their sales contrarily increased.⁹⁹ Innovator companies are thus likely to just wait and not sue until generic companies earn money. In this way, innovator companies can manage to claim considerable damages. But this act violates one of the goals of enacting PPLS, which is to allow generic companies to know whether their drugs infringe before listing, and may cause some generic companies to end up in bankruptcy.

96. Zhuanli Fa (专利法) [Patent Law] (promulgated by Standing Comm., Nat'l People's Cong., Dec. 27, 2008, effective Oct. 1, 2009) Art. 65(5), THE CENTRAL PEOPLE'S GOVERNMENT OF THE PEOPLE'S REPUBLIC OF CHINA, http://www.gov.cn/flfg/2008-12/28/content_1189755.htm, [https://perma.cc/286W-PJQ5] (China) (Article 65: “The following shall not be deemed to be patent right infringement: (5) 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 any other person imports patented drugs or patented medical apparatus and instruments especially for that person”).

97. See, e.g., Yongshun & Lijuan, *supra* note 76 (suggesting the addition of “except the act of submitting a Generic Drug Application (GDA)” to the Bolar Exception clause).

98. See, e.g., Zhuanjia Fenxi: Zhongguo Wu “Zhuanli Xuanya” Lianjia Weige Nan Luodi (专家分析: 中国无“专利悬崖”廉价伟哥难落地) [No Patent Cliff in China, Cheaper Viagra Hard to Market], CHINANEWS (中国新闻网) (Jan. 12, 2016, 11:01 AM), <http://www.chinanews.com/cj/2016/01-12/7712539.shtml> [https://perma.cc/G3RS-QVHG] (China).

99. Tony Chen & Matthew Chervenak, Jones Day, Valuating HK IPO Companies with Pharmaceutical IP Index (π Value), Presentation at the China Pharma IP Summit 2018 (Oct. 24, 2018).

On the other hand, the proposed statute provides that if the lawsuit results in the patent being announced invalid or not being infringed, its holder shall bear any loss incurred to the applicant of the GDA during the Stay-of-Effectiveness Period, thereby imparting on generic companies an explicit legal basis for seeking redress. In the history of PPLS implementation in the U.S., innovator companies repeatedly sued generic companies so as to actually prolong the “Stay-of-Effectiveness Period”.¹⁰⁰ Although the “Medicare Prescription Drug and Modernization Act” enacted in 2003 in the U.S. provides that innovator companies can enjoy only one 30-month stay per drug product per ANDA,¹⁰¹ the implementation of the 30-month stay delays the listing of generic drugs whose applicants finally succeed in challenging patents for generic drugs. The ANDA applicants of this type have sustained losses caused by the “Stay-of-Effectiveness Period” but have had no chance to seek redress.¹⁰² Put another way, the “Stay-of-Effectiveness Period” is similar to a preliminary injunction in its legal effect, since it already deters generic drugs from listing before courts have decided whether the generic drugs infringe or not, whereas the patent holders are not required to provide any form of guarantee and have no liability for compensation even if they lose cases.¹⁰³

Both of the provisions are restrictions to innovator companies. They have implemented well in Canada and would better adapt to the current status of the Chinese pharmaceutical industry.

c. Section (c2)---Element Based on Chinese Administration Agencies

The last section of the proposed clause addresses how to cope with pay-for-delay settlements. As summarized in Part I, since 2011, different bills have been introduced in the U.S. Congress every year with the intent of making pay-for-delay settlements illegal. More scholars’ comments or suggestions focus on how to more accurately determine the antitrust characteristics of pay-for-delay settlements.¹⁰⁴ Some proposed that validity of the patent in-suit should be weighed in the determination.¹⁰⁵ The fact is, however, that the number of potential pay-for-delay settlements has significantly decreased

100. See, e.g., Chen Yongshun (程永顺) & Wu Lijuan (吴莉娟), *Lundao Yiyao Zhuanli | Weipian: Qu Taren zhi Chang, Jianli Fuhe Zhongguo Guoqing de Zhuanli Lianjie Zhidu* (论道医药专利 | 尾篇: 取他人之长, 建立符合中国国情的专利链接制度) [On the Pharmaceutical Patent | End: Taking the Advantage of Others and Establishing Patent Linkage System in line with the National Conditions of China], ZHICHANLI (Feb. 7, 2018, 2:31 PM), <http://news.zhichanli.cn/article/5837.html> [<https://perma.cc/DY4H-S5FA>] (China) (stating that Glaxo Smith Kline brought five actions for patent infringement against Apotex after Apotex first submitted an ANDA, and the “Stay of Approval” lasted for a total of 65 months).

101. Pub. L. No. 108-173 § 1101, 117 Stat. 2066 (2003); 21 USCA 355(j).

102. Qiu, *supra* note 24.

103. Qiu, *supra* note 24.

104. Tania Khatibifar, *The Need for a Patent-Centric Standard of Antitrust Review to Evaluate Reverse Payment Settlements*, 23 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1351 (2013).

105. See, e.g., Hogges-Thomas, *supra* note 11.

since *FTC v. Actavis*.¹⁰⁶ This demonstrates that the pay-for-delay settlement phenomenon may be more derived from the uncertainty of legal characterization, especially where some federal courts decided that the settlements are within the scope of patent monopoly and have no anticompetitive effects.¹⁰⁷

This is a large and complex topic, and this article does not intend to specifically resolve it. In fact, the EU has no PPLS, but patent settlements in the pharmaceutical sector in the EU still involve anti-monopoly issues, which shows to some extent that PPLS is not the fundamental source of patent settlements in the pharmaceutical sector.¹⁰⁸ Of course, PPLS actually encourages the formation of pay-for-delay settlements, or alternatively, pay-for-delay settlements are the “natural by-product” of the 180-day exclusive marketing provision of the Hatch-Waxman Act.¹⁰⁹

Therefore, section (c2) of the proposed clause leaves to the Anti-Monopoly Bureau the problems of how to assess whether patent settlements between innovator companies and generic companies are anti-competitive and how to punish the parties if the settlements are so. The Anti-Monopoly Bureau can enact an internal guideline on how to examine patent settlements, how to determine whether the settlements are anti-competitive based on Chinese Anti-monopoly Law, and specific punishment. This approach is in essence different from the mechanism of reporting the settlements to the FTC and Department of Justice in the U.S.¹¹⁰ In China, Administrative Agencies also function as enforcement agencies and have great power to directly enforce law. Once the Anti-Monopoly Bureau finds some settlements are anti-competitive through examination, it can directly punish the parties through a fine and injunction. This would be quite efficient.

B. ADVANTAGES OF THE PROPOSED ARTIFICIAL INFRINGEMENT PROVISION

This proposed provision offers such advantages as better serving the pharmaceutical industry of China based on its status quo and better exerting the Chinese Administrative Agency’s power to handle potential pay-for-delay settlements efficiently, so as to ultimately make cheaper but high-quality drugs accessible to the public. Of course, the elements of this provision—i.e., artificial infringement of the U.S. and some restrictions to innovator companies (“examination on pay-for-delay settlements” is in essence a restriction to innovator companies, since these companies tend to be promoters in artificial infringement actions)—are not necessarily bound together; instead, they can

106. See, e.g., Michael Carrier, *FTC v. Actavis: Where We Stand After 5 Years*, IPWATCHDOG (June 18, 2018), <https://www.ipwatchdog.com/2018/06/18/ftc-v-actavis-stand-5-years/id=98536/> [https://perma.cc/3KUB-QMC6].

107. See, e.g., Khatibifar, *supra* note 104.

108. *Problematic Patent Settlements in EU on the Decrease*, GABIONLINE (Aug. 19, 2011), <http://www.gabionline.net/Reports/Problematic-patent-settlements-in-EU-on-the-decrease> [https://perma.cc/KY2X-Q5MQ].

109. *Schering-Plough v. FTC*, 402 F.3d 1056, 1074 (11th Cir. 2005) (quoting *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 251 (E.D.N.Y. 2003)).

110. Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, 2242 (2003).

also be split into independent clauses in future regulations of the pharmaceutical patent link system.

1. Harmonization with the Status Quo of China's Pharmaceutical Industry and Better Serving It

China has become the second largest pharmaceutical consumer market in the world, but the total output value of all Chinese pharmaceutical companies is still less than that of one of the top ten pharmaceutical companies.¹¹¹ Pharmaceutical companies that are able to market branded drugs in China are mostly foreign-owned.¹¹² Also, patent cliff seldom emerges in China,¹¹³ one reason for which may be that the corresponding generic drugs are inferior in quality.¹¹⁴ According to the currently-effective Drug Registration Management Measures¹¹⁵, generic drugs are not required to provide bioequivalence data,¹¹⁶ which is inconsistent with the standard of generic drugs in the U.S.¹¹⁷

Against this background, China actually demand PPLS, which can not only urge development of branded drugs by according data exclusivity of several years to innovator companies, but also expedite the listing of generic drugs by providing artificial infringement and granting the first applicant of GDA administrative exclusivity of a period of time (otherwise, generic drugs have to wait to be listed until patents relating to them expire in China).¹¹⁸ However, innovator companies have no motivation to sue generic companies during the GDA, since listing of the generic drugs has not much impact on their sale and they cannot claim damages in GDA lawsuits.¹¹⁹ Innovator companies do not bring action against generic companies, the direct result of which is that the main function of the patent link system, i.e., to provide a way to resolve patent disputes before approval of generic drugs,¹²⁰ cannot be

111. *Zuowei Quanqiu Dierda Yiyao Xiaofei Shichang Zhongguo Yuanhe Meiyou Dansheng Kuaguo Da Gongsi?* (作为全球第二大医药消费市场 中国缘何没有诞生跨国大公司?) [Why Do Big Transnational Corporations Not Formed in China, as the Second Largest Drug Consuming Market in the World?], SINA (Oct. 12, 2018), http://med.sina.com/article_detail_103_2_53994.html [https://perma.cc/DA2E-LK3A] (China).

112. See, e.g., *Xiaochu Huanzhe Yongyao "Dongdian"* (消除患者用药“痛点”) [Eliminating Patients' "Painful Point" When Using Drugs], CHINESE GOV'T (Apr. 13, 2018, 7:32 AM), http://www.gov.cn/zhengce/2018-04/13/content_5282106.htm [https://perma.cc/HAU6-TWM8] (China) ("China is a big generic drugs country, and more than 95% of nearly 170,000 official documents for drug approvals involve generic drugs.").

113. See discussion *supra* Part II.A.2.b.

114. *Yuananyao Zhuanli Daoqi Weihe Jiage Reng Nanjiang?* (原研药专利到期 为何价格仍难降?) [Why Is It Hard for Drug Prices to Decrease After Patents of Original Drugs Expired?], SOHU (July 12, 2018, 6:19AM), http://www.sohu.com/a/240668215_161795 [https://perma.cc/3CFG-KLSC] (China).

115. *Yaopin Zhuce Guanli Banfa* (药品注册管理办法) [Drug Registration Management Measures] (promulgated by the St. Food & Drug Admin., June 18, 2007, effective Oct. 1, 2007) NAT'L MED. PROD. ADMIN., <http://www.nmpa.gov.cn/WS04/CL2174/300629.html> [https://perma.cc/UUC7-VGDM] (China).

116. *Id.*

117. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1111(6), 117 Stat. 2066, 2461 (codified at 21 U.S.C. § 355) ("The term 'generic drug' means a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act is approved").

118. ST. FOOD AND DRUG ADMIN., *supra* note 13.

119. See discussion *supra* Part II.A.2.b.

120. See, e.g., Chen Yongshun (程永顺) & Wu Lijuan (吴莉娟), *Lundao Yiyao Zhuanli | Meiguo Yaopin Zhuanli Lianjie Lianguan Fa'an Shishi Xiaoguo* (论道医药专利 | 美国药品专利链接相关法案实施效果)

achieved. The proposed provision can best force innovator companies to sue during the GDA and obviate hard implementation of the PPLS.

Also in consideration of the current background, it is necessary for the link system to bias generic companies a bit, which will ultimately be in favor of public welfare. Especially where litigation costs are still relatively low in China, innovator companies pay fewer costs when bringing an action than in the U.S.¹²¹ On the contrary, generic companies would lose 30- or 24-months' worth on the market, during which they can earn a large amount of sales volume, particularly where generic drugs are not cheap in China. This proposed provision can thus force innovator companies to bring an action against generic companies after a prudent analysis, rather than intentionally try to delay generic drugs' listing simply by means of a Stay-of-Effectiveness Period.

As seen from the above discussion, it is clear that the proposed provision manages to harmonize with the status quo of China's pharmaceutical industry and is specifically formulated to better serve it.

2. Better Exertion of Chinese Administrative Agency Power and Gaining High Efficiency in Handling Pay-for-Delay Settlements

Preliminary supervision is a more effective approach to decrease illegal acts than subsequent litigation. After the U.S. Supreme Court in *FTC v. Actavis*¹²² ruled that reverse payment settlements in patent infringement litigation were subject to antitrust laws, pay-for-delay settlements greatly reduced in the last 5 years.¹²³ This shows that as long as pay-for-delay settlements are subject to antitrust laws, pharmaceutical enterprises will be deterred from entering into such agreements. This kind of effect can also be brought about by administrative supervision, especially preliminary supervision.

If pay-for-delay settlements are subjected to the strict scrutiny of the Anti-Monopoly Bureau, this sort of review will put pressure on the parties to the settlements. Actually, Chinese administrative agencies have great power in enforcing law and also significant authority that is revered by ordinary Chinese people.¹²⁴ This is part of Chinese culture.¹²⁵ Also, administrative agencies handle cases very efficiently. Taking the cases involving

[On the Pharmaceutical Patent Implementation Effects of the Acts Relating to Patent Linkage System in the U.S.], ZHICHANLI (Jan. 8, 2018, 4:17PM), <http://news.zhichanli.cn/article/5611.html> [<https://perma.cc/GWB8-5N93>] (China).

121. See, e.g., *Zhongguo Lvshi Shouru Xianzhuang* (中国律师收入现状) [Status Quo of Chinese Lawyers' Salaries], ZHIHU (知乎) (Sept. 13, 2017), <https://zhuanlan.zhihu.com/p/29296870> [<https://perma.cc/UR4G-GB62>] (China) (stating that the average monthly salary for Chinese lawyers is RMB 7090, about USD 1015; attorney fees account for a major part of litigation costs).

122. *FTC v. Actavis Inc.*, 570 U.S. 136, 158 (2013).

123. See, e.g., Carrier, *supra* note 106.

124. See, e.g., Renwen Liu, *Weishenme Guanbenwei hui Shengxing?* (为什么官本位会盛行?) [Why do Official Standards Prevail?] IOLAW (中国法学网), <https://www.iolaw.org.cn/showArticle.aspx?id=3526> [<https://perma.cc/9ET7-PFJ9>] (last visited Jan. 20, 2020) (China).

125. *Id.*

concentration of business operators as an example, simple cases can be handled within nearly 30 days during the preliminary examination stage.¹²⁶

On the other hand, Chinese administrative agencies are more experienced in handling anti-monopoly cases. The Anti-monopoly Law was enacted in 2008, and until 2017, Chinese courts accepted a total 700 cases of the first instance.¹²⁷ In contrast, the Commerce Ministry handled a total 1936 cases, the State Administration for Industry and Commerce handled 82 cases, and the National Development and Reform Commission also handled a certain number of cases.¹²⁸ As a result, Chinese courts were not the main forums to judge anti-monopoly cases in China.

In view of the rich experience and quick handling of anti-monopoly cases of Chinese administrative agencies, the proposed provision imparts the function of examining pay-for-delay settlements on the Anti-Monopoly Bureau. Of course, if pharmaceutical enterprises are not satisfied with administrative examination results, they have a right to continue to bring actions against the Anti-Monopoly Bureau to courts.

For China, which never has PPLS, let alone pay-for-delay settlements, it may be more feasible for the Anti-Monopoly Bureau to first examine these settlement agreements in line with its experience in handling anti-monopoly cases over the last decade, and then enact corresponding examination guidelines based on its practical experience.

III. RESPONSE TO CRITICISMS OF THE PROPOSAL

The proposed provision is a comprehensive artificial infringement, which contains the basic artificial infringement provision of the U.S., restrictions to innovator companies, and authorization on administrative agencies examining potential pay-for-delay settlements. Some critics might doubt the necessity of introducing artificial infringement. Some might be concerned about adverse impacts on innovator companies brought about by bias towards generic companies. Others might object to authorizing on administrative agency to examine pay-for-delay settlements. Part III addresses these potential criticisms of the proposal.

126. See, e.g., Gan Lin, Deputy Director, State Administration of Markets and Administration, Information Office, Xinwenban Jiu Zhongguo Fanlongduanfa Shishi Shizhoumian Youguan Qingkuang ji Zhanwang Juxing Xinwen Fabuhui (新闻办就中国《反垄断法》实施十周年有关情况及展望举行新闻发布会) [Press Conference on the 10th Anniversary of the Implementation of China's "Anti-Monopoly Law"] (Nov. 16, 2018, 10:34 AM), http://www.gov.cn/xinwen/2018-11/16/content_5341034.htm#1 [<https://perma.cc/FA52-N8ZR>] (China).

127. See, e.g., Zhu Li (朱理), *Fanlongduan Minshi Susong Shinian* (反垄断民事诉讼十年: 回顾与展望) [Civil Litigation of Anti-Monopoly in the Past 10 Years: Retrospection and Vision], PEOPLE (Aug. 28, 2018, 8:34 AM), <http://ip.people.com.cn/n1/2018/0828/c179663-30255146.html> [<https://perma.cc/E84R-Y6E9>] (China).

128. See, e.g., Fanlongduan "Sanjia Mache" Geshai Chengjidan (反垄断“三驾马车”各筛成绩单) [Anti-Monopoly "Troika" Revealing Respective Achievements], LEGALDAILY (Aug. 30, 2017, 10:43 PM), http://www.legaldaily.com.cn/index/content/2017-08/30/content_7301456.htm?node=20908 [<https://perma.cc/Z386-MN8H>] (China).

A. NECESSITY OF ARTIFICIAL INFRINGEMENT

The first objection to consider is that current regulations in China can achieve the goal of artificial infringement, i.e., resolving patent infringement disputes before generic drugs are listed,¹²⁹ so it is unnecessary to introduce it. Specifically, a generic company can submit an application for registering its generic drug two years prior to the expiry date of the relevant patent, according to current regulations.¹³⁰ During this stage, the patent holder can file an opposition with NMPA to this application.¹³¹ Further, if the generic company, based on this opposition, brings an action against the holder for ascertaining its patent is not infringed,¹³² a court of jurisdiction would substantively adjudicate whether the patent is infringed,¹³³ so that the patent infringement dispute can also be resolved before the generic drug is listed.

This objection is misplaced because current policy cannot fully serve the purposes of artificial infringement. Firstly, these kinds of patent disputes do not take place until two years prior to the expiration date of relevant patents according to current policy,¹³⁴ while pursuant to PPLS, the disputes can take place at any time after the expiration date of data exclusivity of the patented drug.¹³⁵ Secondly, patent holders have no legal basis yet to actively sue generic companies if they desire, especially where the generic companies do not bring an action for ascertaining no infringement. Lastly, although patent holders can file oppositions, NMPA can take no action since there is no regulation on how to treat the oppositions. Accordingly, current policy cannot grant a fundamental right to patent holders to sue when generic companies file a GDA.

129. See Yongshun & Lijuan, *supra* note 120.

130. Drug Registration Management Measures, ch. 2, art. 19.

131. Yaopin Zhuce Guanli Banfa (药品注册管理办法) [Drug Registration Management Measures] (promulgated by the St. Food & Drug Admin., June 18, 2007, effective Oct. 1, 2007) NAT'L MED. PROD. ADMIN., <http://www.nmpa.gov.cn/WS04/CL2174/300629.html> [<https://perma.cc/UCU7-VGDM>] (China).

132. Zuigao Renmin Fayuan Guanyu Shenli Qinfan Zhuanliquan Jiufen Anjian Yingyong Falv Ruogan Wenti de Jieshi (最高人民法院关于审理侵犯专利权纠纷案件应用法律若干问题的解释) [Certain Provisions of the Supreme People's Court on Issues Concerning the Application of Law in the Hearing of Patent Dispute Cases] (promulgated by the Sup. People's Ct., Dec. 21, 2009, effective Jan. 1, 2010) SUP. PEOPLE'S CT., Jan. 29, 2010, <http://www.court.gov.cn/fabu-xiangqing-1.html> [<https://perma.cc/3NXW-NRP7>] (China) (Rule 18: "The right holder issues a warning of his/its patent being infringed. The warned party or the privy, in written notice, prompts the right holder to bring an action, and after one month from the date the right holder received the written notice or two months from the date the written notice was issued, the right holder neither withdraws the warning nor brings an action. In this situation, if the warned party or the privy files a lawsuit with court to confirm that whose conduct does not infringe the patent, the court shall accept the case.").

133. See, e.g., Huaihua Zhenghao Zhiyao Youxian Gongsi Su Hunan Fangsheng Zhiyao Gufen Youxian Gongsi (怀化正好制药有限公司诉湖南方盛制药股份有限公司) [Huaihua Zhenghao Pharmaceutical Ltd. v. Hunan Fangsheng Pharmaceutical Ltd.] (Hunan Higher People's Ct. May 22, 2014).

134. Drug Registration Management Measures, ch. 2, art. 19.

135. See Mossinghoff, *supra* note 5 (stating that during the period, no generic version of the drug can be approved); 21 U.S.C. § 355(j)(2)(A)(iv) (2013).

B. IMPACT ON INNOVATOR COMPANIES

The second objection to consider is that the stringent restrictions to innovator companies—i.e., being required to sue in time and bear any loss incurred to generic companies if losing the lawsuit—would have an adverse influence on interests of innovator companies and defeat their incentive to further innovate.

This objection actually makes no sense. As stated above in Introduction and Part I, the pharmaceutical patent linkage system tries to strike a balance between generic companies and innovator companies, and hence includes a bunch of regulations on stimulating R&D of branded drugs.¹³⁶ For example, a few year period of data exclusivity (6 years in China) is awarded to innovator companies, and during the period, no generic version of the drug can be approved.¹³⁷ The data exclusivity means innovator companies can earn a large amount of money since they monopolize the complete market of the drug and the drug can be sold at the high price of a patented drug during the period. As shown from the above, 180 days of Administrative exclusivity period is very appealing to generic companies, because they can make money through monopolizing the market of the generic drug during that time period.¹³⁸ It is therefore no wonder that innovator companies can earn much more during the longer period of data exclusivity. As opposed to defeating innovator companies, this proposal would urge them to invent better and develop patents of higher stability. Otherwise, innovator companies will pay if they lose the lawsuits.

C. Qualification of Administrative Agency to Handle Pay-for-Delay Settlements

The third objection to consider is that the Anti-Monopoly Bureau, as the executive branch for pay-for-delay settlements, does not carry the hallmarks of independence like courts in the eyes of U.S. scholars, who recognize independence as the most important aspect of tribunals. Even when the FTC finds some settlements to be anti-competitive, the FTC will, as the plaintiff, bring actions within its own administrative system or to courts against the parties of the settlements, instead of directly treating the settlements themselves.¹³⁹ Similar to the FTC, the Anti-Monopoly Bureau is a member institution of the State Administration for Market Regulation and cannot be immune from political pressures. Therefore, it is inappropriate to authorize the Anti-Monopoly Bureau to directly treat settlements.

136. See, e.g., *Policies Relevant to Encouraging Innovation in Pharmaceutical and Medical Devices and Protecting the Rights of Innovators*, ST. FOOD & DRUG ADMIN., No. 55 (2017); see also Mossinghoff, *supra* note 5; see also Boehm et al., *supra* note 26; see also SCHACHT & THOMAS, *supra* note 30.

137. *Policies Relevant to Encouraging Innovation in Pharmaceutical and Medical Devices and Protecting the Rights of Innovators*, ST. FOOD & DRUG ADMIN., No. 55 (2017).

138. 21 U.S.C. § 355(j)(5)(B)(iv) (2013); see *infra* Part I.B.1 (explaining that a “180-day exclusivity period” means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective).

139. See, e.g., *Schering-Plough v. FTC*, 402 F.3d 1056 (11th Cir. 2005); see also *FTC v. Actavis Inc.*, 570 U.S. 136 (2013).

The above objection is derived from a lack of knowledge of China's national system, and it is thus a weak argument. In the U.S., courts primarily function to restrict and balance legislative and executive powers. Administrative agencies cannot be free from political influence, which may impact the independence of the agencies in enforcing laws.¹⁴⁰ In comparison, Chinese courts mainly function to enforce laws enacted by the legislature.¹⁴¹ In this sense, Chinese administrative agencies have similar functions to courts. This is why Chinese judges are selected by means of taking National Civil Service Exam, like administrative staff.¹⁴²

In terms of legal hierarchy, the State Administration for Market Regulation would likely be responsible for enactment and approval of PPLS. This agency could authorize its own subordinate institute, the Anti-Monopoly Bureau, to treat affairs on PPLS. On the other hand, as stated above, Chinese administrative agencies are more experienced and efficient in treating anti-monopoly affairs than courts. Additionally, the results of the Anti-Monopoly Bureau can be appealed to courts, thereby pay-for-delay settlements would be supervised by another layer of institutions.

CONCLUSION

The pharmaceutical patent link system is a system that benefits both innovator companies and generic companies, and ultimately benefits the public. Its implementation in the U.S. and Canada has substantiated this outcome. Since China's national system is different from that in the U.S., China cannot completely duplicate the U.S. system. This article proposes a comprehensive artificial infringement, which contains basic artificial infringement of the U.S., restrictions to innovator companies and precaution against pay-for-delay settlements. As discussed above, this proposal would be tailored to China and hopefully provide for ease in implementation, since China takes into sufficient consideration its own system, as well as the experiences of the U.S. and Canada.

140. Fan Mingzhi (范明志), *Zhongguo Guoqing Weihe bu Yunxu Zhaoban Xifang Sifa Duli* (中国国情为何不允许照搬西方司法独立) [Why Do Chinese National Conditions Disallow Copying of Western Judicial Independence?], CHINACOURT (中国法院网) [Jan. 16, 2017, 11:05 PM], <https://www.chinacourt.org/article/detail/2017/01/id/2514518.shtml> [https://perma.cc/AD32-KSG6] (China).

141. *Id.*

142. Gongwuyuan Fa (公务员法) [Civil Service Law] (promulgated by the Standing Comm., Nat'l People's Cong., Dec. 29, 2018, effective Jun. 1, 2019) Article 2, http://www.xinhuanet.com/legal/2018-12/30/c_1123927123.htm [https://perma.cc/9FZ7-6MD6] (China).