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Comparative overview of drug patent linkage systems in China and the United States

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I. INTRODUCTION

On October 17, 2020, the Standing Committee of the National People's Congress of China passed an amended Patent Law, which takes effect on June 1, 2021. The amended Patent Law introduces a patent linkage system in Article 76, which outlines a general framework allowing early patent dispute resolution before generic drug approval.[1]

Draft measures to implement Article 76 are proposed by three government agencies:

(1) "Draft Measures on the Early Resolution Mechanism for Drug-Related Patent Disputes" jointly by the National Medical Products Administration (NMPA) and the China National Intellectual Property Administration (CNIPA),

(2) "Draft Legal Provisions on Several Issues Concerning the Application of Laws in the Trial of Disputes over Drug Patent Linkage" by the Supreme People's Court, and

(3 "Draft Measures on Administrative Adjudication in the Early Resolution Mechanism for Drug-Related Patent Disputes" by the CNIPA.

Like the Hatch-Waxman framework in the U.S., China's patent linkage system aims to balance the interests of innovative drug developers and generic drug manufacturers, encouraging therapeutic innovations and, in the meantime, not unduly impeding the public's access to inexpensive, generic drugs.

In the past, generic drugs could be approved in China and enter the market even though they may be infringing certain patents. The patent owner had no cause of action to bring a patent infringement suit until a generic drug had actually entered the market, because filing a generic application per se, even when it entirely relies on an approved drug's efficacy and safety data, was not an infringing act in China.

But at the same time, a generic company in China enjoys a safe harbor for manufacturing, using, or importing a patented drug for the purpose of providing information needed for regulatory approval.[2] These practices in China resulted in a system that tilted in favor of the generic drug industry.

China's amended Patent Law now provides several bargains to the innovative drug industry. It provides a public platform where the patent owner/NDA holder can monitor whether a generic version of its patented, approved drug product or medical use is seeking market approval.[3]

The amended law also provides the patent owner/NDA holder a cause of action regarding whether the generic product falls within the scope of the registered patent.

Thus, the patent owner/NDA holder can initiate civil judicial proceedings or administrative adjudications ("an Article 76 action") *priorto* marketing approval of an allegedly infringing generic product.[4] Once an Article 76 action is initiated, the NMPA will not approve the generic drug during the 9 months after the docketing date of the Article 76 action.[5]

Like the Hatch-Waxman framework in the U.S., China's patent linkage system aims to balance the interests of innovative drug developers and generic drug manufacturers.

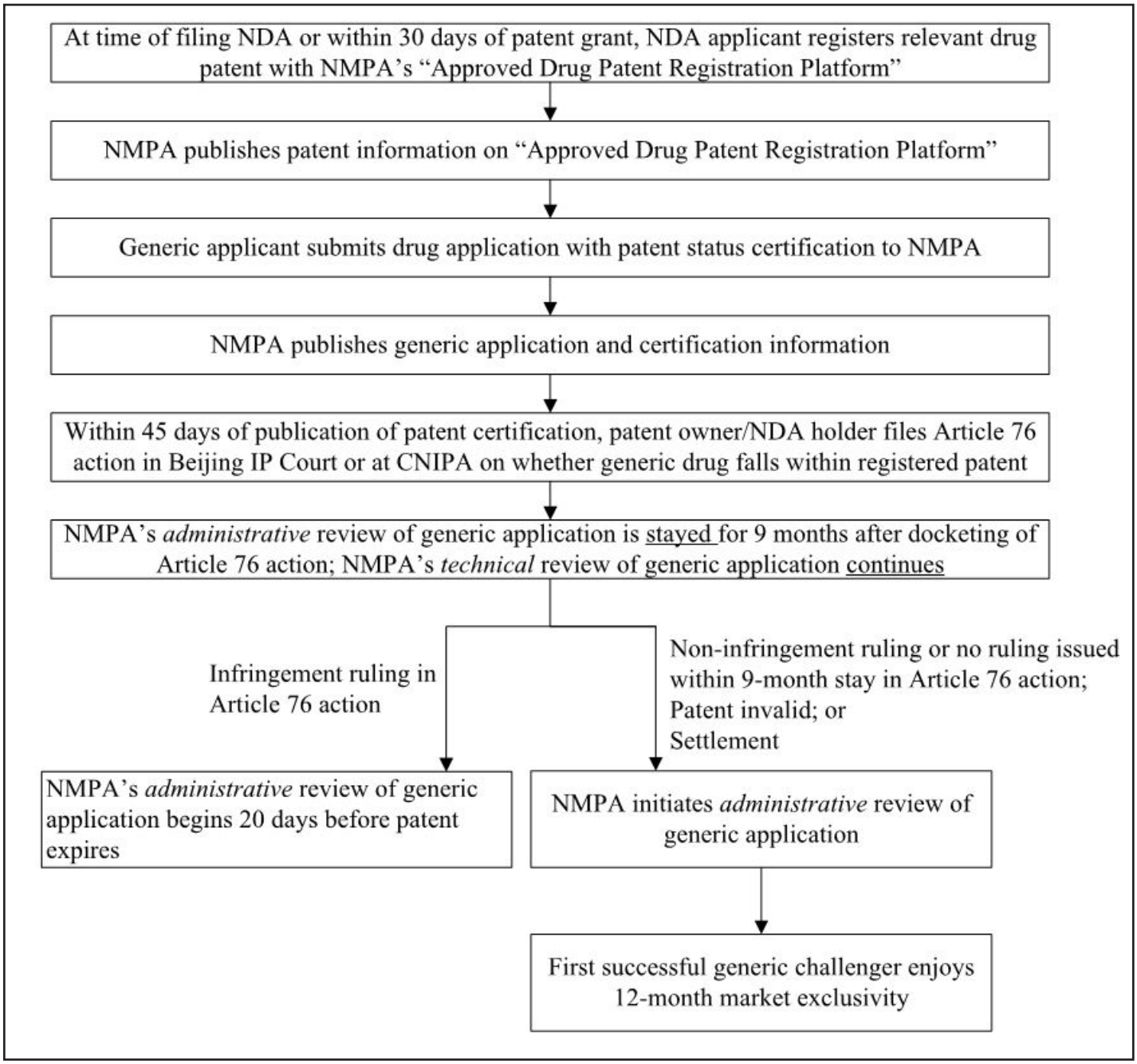
The amended patent law also provides patent term extensions for innovative drug patents to remedy delays incurred during the regulatory approval process, subject to two restrictions: (1) the total extension cannot exceed 5 years, and (2) the total patent term after drug approval cannot exceed 14 years.[6]

On balance, China's patent linkage system also encourages generic applicants to challenge innovators' drug patents, providing the first successful generic challenger a 12-month market exclusivity.[7]

In this article, we will focus on the *draft* measures relating to Article 76 of China's amended patent law, and its comparison with the Hatch-Waxman framework in the U.S. The draft measures may change when the amended Patent Law takes effect on June 1, 2021.

II. OVERVIEW OF CHINA'S PATENT LINKAGE SYSTEM

The sequence of events and general requirements relating to an Article 76 action are illustrated in the flowchart and briefly discussed below.



A. NDA APPLICANT REGISTERS PATENT INFORMATION

In order to have its patents eligible for an Article 76 action, a new drug applicant must submit relevant Chinese patent information to NMPA's Approved Drug Patent Registration Platform ("the patent platform") at the time of filing a New Drug Applications (NDA), or within 30 days of a patent grant date if the patent is granted after the NDA filing. These patents are *registered and published* on NMPA's "Approved Drug Patent Registration Platform."[8]

B. GENERIC APPLICANT SUBMITS PATENT STATUS CERTIFICATION

When a generic applicant files a generic drug application, it must include a patent status certification for each relevant patent that is registered on the patent platform.[9] The generic applicant can make one of four types of certifications:

- Type 1: no relevant patent information is registered on the patent platform;
- Type 2: the relevant patent has been terminated or declared invalid;

- Type 3: the relevant patent is listed on the patent platform, and the generic drug applicant agrees not to market the generic drug until the registered patent expires;
- Type 4: the relevant patent listed on the platform is invalid or not infringed by the generic drug applicant.

NMPA publishes relevant information regarding the generic application and patent certification. The generic applicant has *noobligation* to notify relevant patent owner/NDA holder about the generic filing.

C. PATENT OWNER/NDA HOLDER MAY BRING ARTICLE 76 ACTION IN COURT OR AT CNIPA

With respect to the first three types of patent certifications, the NMPA will proceed with its review (*technical* review and then *administrative* review) of the generic applications, and grant market authorizations to qualified generic drugs.[10]

Upon a Type 4 patent certification, where a generic applicant challenges the scope or validity of a registered drug patent, the patent owner/NDA holder may file an Article 76 action against the generic applicant in two forums: the Beijing IP court (BIPC) and/or the CNIPA.[11]

In an Article 76 action, the patent owner/NDA holder must file the suit within 45 days after the generic application information is published on the patent platform. Once the action is docketed, NMPA's administrative review will be stayed for 9 months after the case docketing date, while NMPA's technical review will not be stayed. Note that this 9-month regulatory stay is only available for chemical drugs, but not for biologic or TCM drugs.[12]

China adopts a bifurcated system regarding patent infringement and validity. The Reexamination and Invalidation Department of the CNIPA has exclusive administrative jurisdiction over patent validity. Thus, the main issue to be decided in an Article 76 action is whether the generic drug falls within the scope of the registered patent.[13]

If the generic drug does fall within the scope of the registered patent based on a ruling made within 9 months, NMPA will not conduct its administrative review until 20 working days before the patent expiration date.[14] Otherwise, NMPA will continue its administrative review and grant approval to qualified generic drugs.[15]

In an Article 76 action at BIPC, the patent owner/NDA holder may apply for a preliminary injunction (with bond required) to prevent the generic applicant from manufacturing, using, offering to sell, selling, or importing the drug for commercial purposes.[16] However, the preliminary injunction will not stay NMPA's review or approval of the generic application.[17]

After the generic drug obtains marketing authorization and enters the market, a patent owner/NDA holder may sue the generic manufacturer for regular patent infringement.[18] The outcome of the Article 76 action may be applied in these subsequent infringement suits.[19] But the generic drug's marketing authorization will not be revoked by the NMPA.[20]

D. FIRST SUCCESSFUL GENERIC CHALLENGER ENJOYS 12-MONTH MARKET EXCLUSIVITY

The generic applicant that first successfully challenges the patent and gets its generic drug approved is rewarded with a 12-month market exclusivity. Within 12 months after the first generic approval, NMPA will not grant approval to other generics of the same reference drug.[21] Note that the 12-month generic market exclusivity is not available to generic applicants of biologics or TCM.

E. BIOLOGICS AND TRADITIONAL CHINESE MEDICINE

The draft measures in China treat chemical, biologic, and traditional Chinese medication (TCM) drugs generally the same with two key exceptions: (1) the 9-month stay period is not applicable to biologics and TCM, and (2) the 12-month market exclusivity is not available to generic applicants of biologics and TCM.

Although the patent owner/NDA holder of biologics and TCM are provided with the same opportunity to bring an Article 76 action, they enjoy substantially less benefit from this type of action due to the lack of a stay period.

III. MAJOR DIFFERENCES BETWEEN THE CHINA AND U.S. FRAMEWORKS

In the U.S., pre-drug approval patent disputes are governed by two separate legal frameworks: The Hatch Waxman Act for chemical drugs and the Biologics Price Competition and Innovation Act (BPCIA) for biologic drugs.

Since China's patent linkage system largely mirrors the Hatch Waxman framework, we discuss below a few major differences between these two frameworks, with additional items outlined in a comparative chart below.

	China	**United States (Hatch Waxman)**
Types of Patents to be Registered or Listed	Chemical drugs: compound of active pharmaceutical ingredient (API), composition/formulation of API, medical use of API	Chemical drugs: drug substance (active ingredient), drug product (formulation or composition), and/or approved method of using the approved drug product
	Biologic drugs: sequence structure of the biological product	*Patent dance under BPCIA*
	TCM: composition having the TCM, extraction methods of the TCM, medical use of the TCM	
Time to List	At time of NDA filing or 30 days from patent grant	Before NDA Approval: submit patent information with NDA filing; and After NDA approval: list patent in Orange Book within 30 days after NDA approval/supplement or within 30 days of patent grant
Generic Certifications	Type 1: No patent information registered; Type 2: Patent expired or invalidated; Type 3: Market after patent expires; Type 4: Patent invalid/not infringed	Paragraph I: Patent information not filed; Paragraph II: Patent expired; Paragraph III: Date patent will expire; Paragraph IV: Patent invalid/not infringed
Forums	Beijing IP Court or CNIPA for infringement suit; CNIPA (Reexamination and Invalidation Department) for validity	Federal court for validity and infringement; Patent Office for validity
Certification Notice to Patent Owner/NDA Holder	No	Yes
Time to Sue	45 days from publication of Type 4 certification	45 days from receiving Paragraph IV certification
Stay of Generic Approval	9 months	30 months (generally)
Market Exclusivity for First Successful Generic Challenger	12 months	180 days

A. CERTIFICATION NOTICE TO PATENT OWNER/NDA HOLDER

In the U.S., a generic drug applicant that certifies under Paragraph IV has the obligation to send a notice of Paragraph IV certification to the patent owner and NDA holder.[22] The 45-day period for the patent owner/NDA holder to sue starts from the date of receiving the paragraph IV certification notice.[23]

The regulatory stay (generally 30 months) starts ticking from "the later of the date of the receipt of the notice of certification by any owner of the listed patent or by the NDA holder."[24]

In China, however, a generic applicant has no obligation to notify the patent owner/NDA holder regarding a Type 4 certification.

In order to timely respond to a Type 4 certification within the 45-day limit (which begins on the publication date of the generic application information), a patent owner/NDA holder bears the burden to closely monitor NMPA's publication of generic drug application.

If the patent owner/NDA holder fails to timely file an Article 76 action, NMPA will continue its review and grant approval to qualified generic drugs.[25]

B. REGULATORY STAY

In the U.S., if a patent owner/NDA holder brings a Hatch Waxman action within 45 days of receiving a paragraph IV certification notice, the Food and Drug Administration will stay the generic approval for 30 months unless the court has extended or reduced the stay period because of a failure of either the plaintiff or defendant to cooperate reasonably in expediting the action.[26]

The 30-month stay will also be cut short if the court decides that the patent is invalid, unenforceable, or not infringed before end of the 30-month stay.[27]

A longer stay period is available for a new chemical entity drug if a Hatch-Waxman action is brought within the one year period beginning 4 years after the date of the patented drug approval and within 45 days of receipt of the paragraph IV certification, in which case the regulatory stay ends 7.5 years from the NDA approval date.[28]

China's 9-month regulatory stay period is much shorter than the U.S. 30-month stay. Nine months may be too short for BIPC or CNIPA to render a ruling on an Article 76 action, especially when involving an international party.

Moreover, according to the amended Patent Law, only an *effective* judgment can pause NMPA's regulatory review, while BIPC's judgment is not effective until a decision on appeal at the Supreme People's Court unless both parties decide not to appeal.

C. DISPUTE RESOLUTION FORUMS

In the U.S., in response to a Paragraph IV certification, the patent owner/NDA holder can file a patent infringement action in a federal district court.[29] In defense, the generic applicant can dispute both patent validity and infringement in the district court.

Before or during the course of the district court action, the generic can also petition for a post-grant proceeding (inter partes review or post grant review) to challenge patent validity at the United States Patent and Trademark Office.[30]

China provides two forums for the patent owner/NDA holder to initiate an Article 76 action. The NDA holder/patent owner can either go to BIPC for a judicial judgment, or go to CNIPA for administrative adjudication, which is appealable to a court.

The patent owner/NDA holder can even go to both forums and have two parallel proceedings, if an Article 76 action is brought at CNIPA first. If an Article 76 action is brought in the court first, such an action cannot be brought in an administrative adjudication at CNIPA.[31]

In addition, an Article 76 action in China is only an action to determine whether the generic drug falls within the scope of the registered patent, but not patent validity issues.[32] If the generic applicant wishes to challenge patent validity, it could start a separate invalidation proceeding at CNIPA.[33]

According to Patent Law Article 45, any individual or entity can petition to invalidate a patent any time from the date of patent issuance at the Reexamination and Invalidation Department of the CNIPA.

IV. CONCLUSION

Although China's patent linkage system adopts the skeleton of the U.S. Hatch Waxman framework, it differs significantly in some aspects:

(1) a generic applicant has no obligation to notify the patent owner/NDA holder of a Type 4 certification,

(2) there is a much shorter stay period for the generic drug approval,

(3) the first successful generic applicant enjoys a longer market exclusivity, and

(4) infringement issues can be determined either in court or at CNIPA, but validity issues must be determined at CNIPA.

The views in this article are solely of the authors, not of Finnegan or LexField or their respective clients.

Notes

[1] Article 76 of the Patent Law (2020 Amendment) states in its entirety: "During the drug marketing authorization review period, if disputes arise around the drug-related patents, the applicant and the patent holder or other interested party may file suit before a court to seek legal judgment on whether the drug falls within the patent protection scope. The National Medical Products Administration (NMPA) may decide to stay the drug marketing authorization based on an effective court ruling. Alternatively, the parties may petition for an administrative ruling at the China National Intellectual Property Administration (CNIPA).

[2] Article 69(5) of the Patent Law (2008 Amendment, currently effective) or Article 75(5) of the Patent Law (2020 Amendment).

[3] Draft Measures on the Early Resolution Mechanism for Drug-related Patent Disputes (published on 09.11.2020), Rule 2, 6.

[4] Draft Measures on the Early Resolution Mechanism for Drug-related Patent Disputes, Rule 7.

[5] *Id.*, Rule 8.

[6] Article 42 of the Patent Law (2020 Amendment). The CNIPA proposed the period of patent term to be the period between NDA approval and patent application filing date minus 5 years, subject to the 5-year and 14-year limits.

[7] *Id.*, Rule 11.

[8] Draft Measures on the Early Resolution Mechanism for Drug-related Patent Disputes, Rule 3

[9] *Id.*, Rule 13

[10] *Id.*, Rule 9

[11] *Id.*, Rule 10

[12] *Id.*, Rule 8

[13] *Id.*, Rule 10

[14] *Id.*

[15] *Id.*

[16] Draft Legal Provisions on Several Issues Concerning the Application of Laws in the Trial of Disputes over Drug Patent Linkage (published on 10.29.2020), Provision 10

[17] *Id.*

[18] Draft Measures on the Early Resolution Mechanism for Drug-related Patent Disputes, Rule 14; Draft Legal Provisions on Several Issues Concerning the Application of Laws in the Trial of Disputes over Drug Patent Linkage, Provision 15

[19] Draft Legal Provisions on Several Issues Concerning the Application of Laws in the Trial of Disputes over Drug Patent Linkage, Provision 16

[20] Draft Measures on the Early Resolution Mechanism for Drug-related Patent Disputes, Rule 14

[21] *Id.*, Rule 11

[22] 21 C.F.R. 314.95(a)

[23] 21 C.F.R. 314.95(f)

[24] 21 C.F.R. 314.107(b)(3)(i)(A)

[25] Draft Measures on the Early Resolution Mechanism for Drug-related Patent Disputes, Rule 7

[26] 21 C.F.R. 314.107(b)(3)(i)(A); *see EliLilly & Co. v. TevaPharm.USA Inc.*, 557 F.3d 1346 (Fed. Cir. 2009) (holding that the U.S. District Court for the Southern District of Indiana did not abuse its discretion in extending the 30-month stay by 4 months based on the generic drug company's changing its proposed generic drug late in the litigation and providing samples of the changed drug after the close of discovery); *Dey L.P. v. Ivax Pharm.Inc.*, 233 F.R.D. 567 (C.D. Cal. 2005) (shortening the 30-month stay based on Dey's repeatedly changing its position on the key issue of inventorship and failing to produce documents related to a study comparing the invention to alleged prior art).

[27] 21 C.F.R. 314.107(b)(3)(ii),(iii),(iv)

[28] 21 C.F.R. 314.107(b)(3)(i)(B)

[29] 21 U.S.C.A. 355(c)(3)(C)

[30] Inter Partes Review (IPR) must be filed after 9 months of patent issuance and within 1 year after the generic applicant being served with the complaint alleging infringement of the patent. 35 U.S.C.A, 315(b). Post-grant review (PGR) must be filed within 9 months of patent issuance. 35 U.S.C.A. 321.

[31] Draft Legal Provisions on Several Issues Concerning the Application of Laws in the Trial of Disputes over Drug Patent Linkage, Provision 6; Draft Measures on Administrative Adjudication in the Early Resolution Mechanism for Drug-related Patent Disputes (published on 02.09.2021), Rule 4(5)

[32] Draft Measures on the Early Resolution Mechanism for Drug-related Patent Disputes, Rule 10

[33] Patent Law of the People's Republic of China, Article 45

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