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China's 'Hatch-Waxman' system: a comparative overview

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I. Introduction

China's 2020 Amended Patent Law ("2020 Amendment") introduces a "Hatch-Waxman"-like patent linkage system, which took effect on June 1, 2021. Article 76 of the 2020 Amendment outlines a general framework, allowing early patent dispute resolution before generic drug approval.

In the past, generic drugs could be approved and enter the market in China even though they may be infringing certain patents. A 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* was not an infringement act in China.

China adopts a bifurcated system regarding patent infringement and validity.

Under the new framework, a patent owner/new drug application (NDA) holder can initiate a civil judicial proceeding or an administrative adjudication proceeding (collectively "an Article 76 action") *prior to* marketing approval of an allegedly infringing generic drug product.

Article 76 of the 2020 Amendment is extremely brief, which states in its entirety the following:

> 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 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.

Three Chinese government agencies, the National Medical Products Administration (NMPA), the China National Intellectual Property Administration (CNIPA), and the Supreme People's Court were tasked to implement Article 76 of the 2020 Amendment. After about a month of delay from the anticipated release date, three sets of implementing measures were issued in early July this year. They are

(1) "Measures on the Early Resolution Mechanism for Drug-Related Patent Disputes" (referred to as "the Early Dispute Resolution Measures" herein) jointly by NMPA and CNIPA, issued and effective on July 4, 2021, accompanied with a policy interpretation presented in a form of questions and answers ("Policy Interpretation");

(2) "Legal Provisions on Several Issues Concerning the Application of Laws in the Trial of Disputes over Drug Patent Linkage" ("Legal Provisions") by the Supreme People's Court, issued and effective on July 5, 2021, and

(3) "Measures on Administrative Adjudication in the Early Resolution Mechanism for Drug-Related Patent Disputes" ("Administrative Adjudication Measures") by the CNIPA, issued and effective on July 5, 2021.

This Article provides a preliminary overview of the Chinese patent linkage system and a comparison with the United States Hatch-Waxman framework.

II. Overview of China's patent linkage system

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

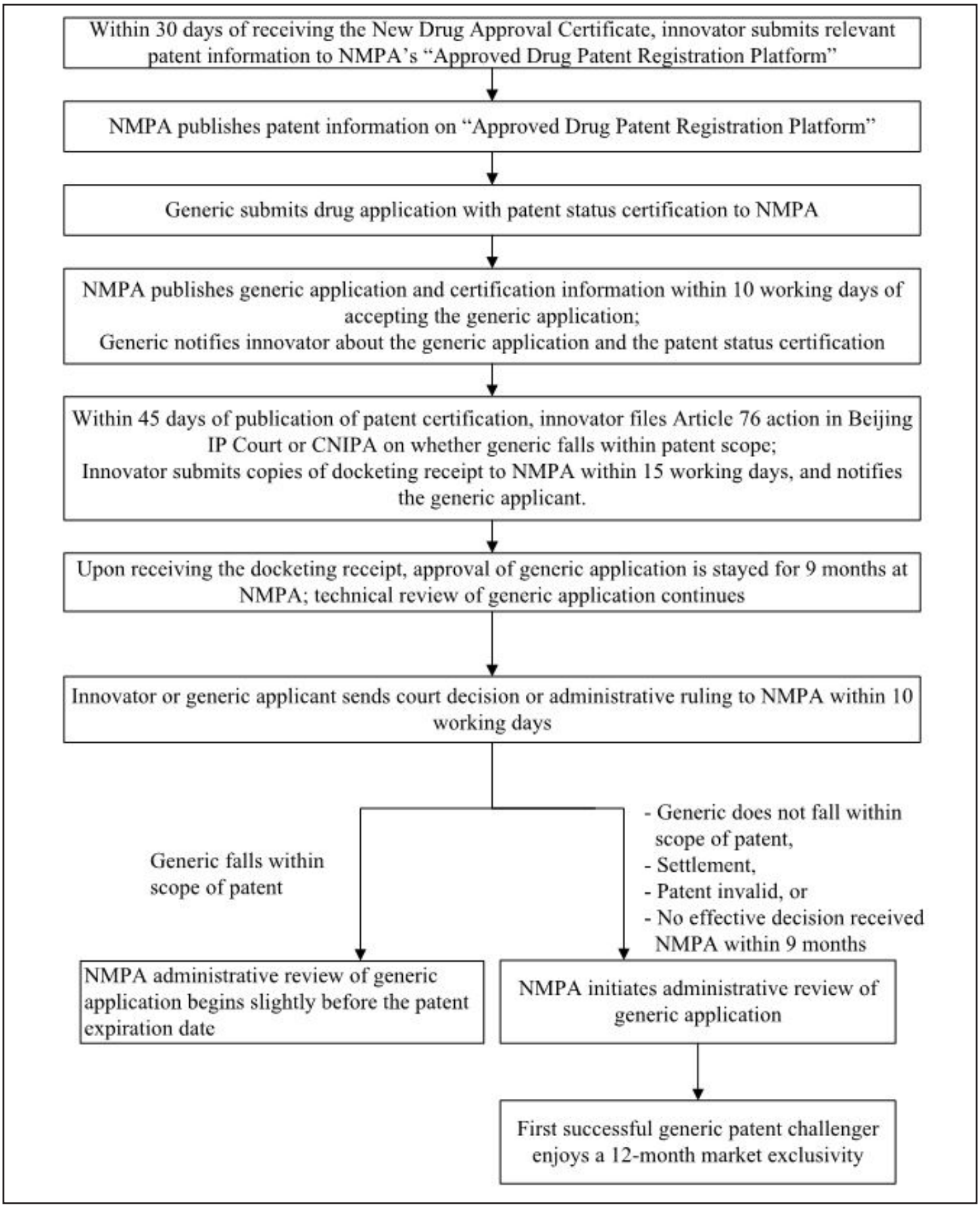
A. NDA applicant registers patent information

In order to have its patents eligible for an Article 76 action, a new drug applicant must submit relevant Chinese patent information to the NMPA's Approved Drug Patent Registration Platform ("the Patent Platform") within 30 days of receiving the Approval Certificate.[1]

These patents will be *registered and published* on the Patent Platform.[2,3] If relevant patent information changes, the new drug applicant must update the patent registration within 30 days of the change.

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.[4] 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, or the generic applicant has obtained license for the relevant patent;
- 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 Patent Platform should be invalidated or the generic drug does not fall within the scope of the relevant patent listed.

The NMPA publishes relevant information regarding the generic application and patent certification within 10 working days of accepting the generic application.[5] The generic applicant is required to notify the NDA holder of the generic filing.[6]

If a Type 4 certification is made, the generic applicant needs to provide supporting documents for its certification, including a comparative chart of the generic drug's technical details and the relevant patent, and any other relevant technical documents.[7]

In addition to paper copies of the relevant materials, the generic applicant is also required to email the certification and supporting documents to the NDA holder's email address registered on the Patent Platform, and keep the relevant record.[8]

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 (first *technical* review and then *administrative* review) of the generic applications, and grant market authorizations to qualified generic drugs.[9]

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.[10] 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, an Article 76 action does not have subject matter jurisdiction over patent validity issues; the main issue to be decided in an Article 76 action is whether the generic drug falls within the scope of the registered patent.[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.[12] The patent owner/NDA holder needs to submit a copy of the Article 76 action docketing receipt to the NMPA within 15 working days and notify the generic applicant.[13]

Once receiving the docketing receipt, the NMPA will stay its *administrative* review for 9 months after the case docketing date, but will not stay the *technical* review.[14] If the generic drug does fall within the scope of the registered patent based on a ruling made within the 9-month stay period, the NMPA will not conduct its *administrative* review until slightly before the patent expiration date.[15]

Otherwise, NMPA will continue its *administrative* review and grant approval to qualified generic drugs.[16] Note that this 9-month regulatory stay is only available for chemical drugs, but not for biologic or traditional Chinese medicine (TCM) drugs.[17]

In an Article 76 action initiated at the BIPC, the patent owner/NDA holder may apply for a preliminary injunction to prevent the generic applicant from manufacturing, using, offering to sell, selling, or importing the drug for commercial purposes.[18]

However, the preliminary injunction will not stay the NMPA's review or approval of the generic application.[19] In other words, the preliminary injunction mechanism was designed to prevent a certain action by a party in the lawsuit, but not a government agency.

After a generic drug obtains marketing authorization and enters the market, a patent owner/NDA holder may also sue the generic manufacturer in a regular patent infringement suit.[20] The outcome of the Article 76 action may be applied in these subsequent infringement suits.[21] But the generic drug's marketing authorization will not be revoked by the NMPA.[22]

D. First successful generic challenger enjoys 12-month market exclusivity

The generic applicant that first successfully *invalidates* the patent and gets its generic drug approved through a Type 4 certification is rewarded with a 12-month market exclusivity.[23] To enjoy market exclusivity, the generic applicant must successfully invalidate the patent, not merely be successful in an "noninfringement" defense.

Within 12 months after the first generic approval, the NMPA will not grant approval to other generics of the same reference drug. Note that the 12-month generic market exclusivity is not available to generic applicants of biologics and TCM.

E. Biologics and traditional Chinese medicine

The China patent linkage system treats chemical, biologic, and TCM drugs generally the same with two main 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.[24]

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. Comparative discussion of key features

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 on the next page.

	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 - *Excluding: intermediate, metabolite, crystalline form, manufacturing method, and detecting method*	**Chemical drugs**: drug substance (active ingredient), drug product (formulation or composition), approved method of using the approved drug product.
	Biologic drugs: sequence structure of the biological product	**Biologic drugs**: *Patent dance under BPCIA*
	TCM: composition having the TCM, extraction methods of the TCM, medical use of the TCM	
Time to List	Within 30 days from receiving new drug Approval Certificate; or within 30 days of patent information change	**Before NDA Approval**: submit patent information with NDA filing; **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, or obtained license; Type 3: Market after patent expires; Type 4: Patent invalid/not fall within the scope of the registered patent	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; CNIPA (Reexamination and Invalidation Department) for validity	Federal court for validity and infringement; Patent Office for validity
Certification Notice to Patent Owner/NDA Holder	Yes, but no clear time limit for notification	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. 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 its Paragraph IV certification to the patent owner and NDA holder.[25] The 45-day period for the patent owner/NDA holder to sue starts from the date of receiving the paragraph IV certification notice.[26]

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."[27]

The Early Dispute Resolution Measures in China include a requirement for a generic applicant to notify the patent owner/NDA holder of its generic filing and patent certification. The Early Dispute Resolution Measures state that

> within 10 days of accepting a generic application the NMPA shall publish the generic application information and corresponding certification; the generic applicant shall notify the market authorization holder of the certification.

It is unclear, however, whether the 10-day time limit also applies to the certification notice by the generic applicant because there is a semicolon before the clause of the generic applicant's obligation.

Without clearly setting a time limit for the generic notification and because the 45-day period starts from the NMPA's *publication date* of the certification, this notice requirement upon the generic applicant is not very helpful to the patent owner/NDA holder to meet the 45-day filing deadline.

Therefore, a patent owner/NDA holder should not solely rely on a generic applicant's notification and should closely monitor the NMPA's Patent Platform for publication of generic application information. 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.

B. Listable patents for chemical drug

An NDA holder of an innovative chemical drug can register patents of active pharmaceutical ingredient, pharmaceutical composition, or medical use.[28]

The Policy Interpretation published together with the Early Dispute Resolution Measures provides several examples of patents that are not eligible for patent registration, such as patents of intermediate, metabolite, crystalline form, manufacturing method, and detecting method.

This would mean that some important follow-up patents such as polymorph patents are kept off China's drug patent registry.

C. Dispute resolution forums on infringement

The 2020 Amendment provides two forums for a patent owner/NDA holder to initiate an Article 76 action. The NDA holder/patent owner can either start a judicial litigation at the BIPC, which has the exclusive first instance judicial jurisdiction over the Article 76 action, or go to the CNIPA for administrative adjudication.[29]

In an administrative adjudication, the CNIPA's administrative ruling in favor of the patent owner/NDA holder could be effective to halt NMPA's review immediately after the ruling is issued. Although CNIPA's administrative ruling is also appealable to a court, it appears that it does not need to be confirmed by a court on appeal in order to halt the NMPA's review.

On the other hand, the BIPC's judicial judgment is not effective until a decision on appeal at the Supreme People's Court. Even if the patent owner/NDA holder wins an Article 76 action at the BIPC, that favorable ruling would not be effective to halt NMPA's review if the generic applicant appeals.

Due to this disparity in "effectiveness" of a ruling in the two forums, it seems more likely for the patent owner/NDA holder to get a ruling effective to halt the NMPA's review from the CNIPA, instead of the BIPC, within the 9-month stay period, at least from a procedural standpoint.

In China, the formality requirements for filing a lawsuit in court can be more complicated than those for an administrative adjudication.

Perhaps to address this "effectiveness" delay in a judicial proceeding, the Legal Provisions by the Supreme People's Court makes preliminary injunction available in an Article 76 proceeding in the BIPC.

Thus, if the court(s) cannot make an effective judgment within the 9-month stay period, the patent owner/NDA holder could ask for a preliminary injunction, preventing the generic from manufacturing, using, and selling relevant drug.

Moreover, unlike the administrative ruling,[30] the judicial judgment from the court could be applied in a subsequent infringement suit directly.[31] Thus, initiating an Article 76 action in the BIPC may eventually save a lot of time and effort for the patent owner/NDA holder by avoiding repetitive litigation on the infringement issue if they fail to stop the generic drug from entering the market during the stay period of the NMPA review.

Despite the pros and cons for the respective forums, it may be advantageous for the patent owner/NDA holder to bring suit in both forums to ensure that the case is accepted in at least one of the forums within the 45-day time limit. The patent owner/NDA holder could then decide in which forum to continue the case.

In China, the formality requirements for filing a lawsuit in court can be more complicated than those for an administrative adjudication. It may be a daunting task for an international corporation to get its formality documents notarized and legalized timely for an Article 76 action in court, especially in such a challenging Covid era.

To file suit in both forums, however, the order is important: the patent owner/NDA holder should bring the suit at the CNIPA first, and the BIPC second. That is because the BIPC will not dismiss a case on the basis that the CNIPA has already accepted the case,[32]

but the CNIPA will not accept the case if there is already a court proceeding on the same matter.[33]

D. Interplay of infringement and validity proceedings

As noted above, an Article 76 action centers on whether the generic drug falls within the scope of the registered patent, but not patent validity issues. If the generic applicant wishes to challenge patent validity, it should start a separate invalidation proceeding at the CNIPA's Reexamination and Invalidation Department.

According to the Chinese Patent Law Article 45, any individual or entity can petition to invalidate a patent *anytime* from the date of patent issuance at the Reexamination and Invalidation Department of the CNIPA. When both an Article 76 action and an invalidation proceeding on the same patent are before the CNIPA, the CNIPA may consolidate the two proceedings.

An invalidation proceeding generally will not stay an Article 76 action. However, an Article 76 action would be dismissed at both forums if the relevant patent is found invalid at the CNIPA.

Currently, it typically takes about 6 months to conclude an invalidation proceeding at the CNIPA. Therefore, the parties could expect a decision on patent validity within the 9-month stay period if a concurrent invalidation proceeding is initiated.

E. 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.[34]

The 30-month stay will also be cut short if a court decides that the patent is invalid, unenforceable, or not infringed before end of the 30-month stay.[35] 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.[36]

China's 9-month regulatory stay period is much shorter than the U.S. 30-month stay. But given that the CNIPA could complete an invalidation proceeding within 6 months, it is not unreasonable to expect the CNIPA to conclude an Article 76 proceeding within 9 months.

For a judicial Article 76 proceeding, however, since only an *effective* court judgment can halt NMPA's regulatory review, a 9-month period is too short, if not impossible, for the courts to complete both a first instance and second instance proceedings in order to issue an effective judgment.

But since the BIPC is given the exclusive first instance jurisdiction for a judicial Article 76 proceeding, the parties could at least save some time as there would be no dispute on jurisdiction. As noted above, if the judicial proceeding does not conclude within 9 months, the patent owner/NDA holder could turn to preliminary injunction as an alternative remedy.

In practice, the court may also accelerate Article 76 proceedings in order to attract more cases in the jurisdictional competition with 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) certain drug patents (e.g., patents covering crystalline forms of a drug substance) are not eligible for early dispute resolution in China,

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

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

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

It will be exciting to watch how the patent linkage system works in practice and what impact it will bring to the dynamics of drug innovation and generic activities.

Notes

[1] "Measures on the Early Resolution Mechanism for Drug-related Patent Disputes" (07.04.2021), Rule 4. Note that for brevity, the term "infringement" is used in the context of discussing an Article 76 action. However, in an Article 76 action, the relevant "infringement" issue is defined as "whether the [generic] drug falls within the patent protection scope."

[2] *Id*. Rule 3

[3] Approved Drug Patent Registration Platform: https://zldj.cde.org.cn/home.

[4] *Supra* note 1, Rule 6

[5] *Id*.

[6] *Id*.

[7] *Id*. Rule 6

[8] *Id*.

[9] *Id*. Rule 10

[10] *Id*. Rule 7

[11] *Id*. Rule 7

[12] *Id*.

[13] *Id*.

[14] *Id*. Rule 8

[15] *Id*. Rule 9

[16] *Id*.

[17] *Id*. Rule 8, Rule 12

[18] "Legal Provisions on Several Issues Concerning the Application of Laws in the Trial of Disputes over Drug Patent Linkage" (07.04.2021), Provision 10

[19] *Id*.

[20] *Supra* note 1, Rule 14.

[21] *Supra* note 18, Provision 11

[22] *Supra* note 1, Rule 14

[23] *Id*. Rule 11

[24] *Id*. Rule 12, 13

[25] 21 C.F.R. 314.95(a)

[26] 21 C.F.R. 314.95(f)

[27] 21 C.F.R. 314.107(b)(3)(i)(A)

[28] *Supra* note 1, Rule 5

[29] *Id*. Rule 7; Patent Law (2020), Article 76

[30] Administrative ruling could not be applied directly in a subsequent court proceeding unless it has been confirmed by a court on appeal. *See* "Legal Provisions on Issues Concerning the Application of Laws in the Trial of Patent Disputes" (01.19.2015), Provision 25

[31] *Supra* note 18 Provision 11

[32] *Id*. Provision 5

[33] "Measures on Administrative Adjudication in the Early Resolution Mechanism for Drug-Related Patent Disputes," Rule 4(5)(6)

[34] 21 C.F.R. 314.107(b)(3)(i)(A); *see Eli Lilly & Co. v. Teva Pharm. 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 LP 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).

[35] 21 C.F.R. 314.107(b)(3)(ii),(iii),(iv)

[36] 21 C.F.R. 314.107(b)(3)(i)(B)

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