

A Practical Review and Improvement of the Early Dispute Resolution Mechanism for Pharmaceutical Patent Linkage in China

Yuhan Xie*

School of Law, Qingdao University of Science and Technology, Qingdao 266000, China

*Corresponding email: 3251128252@qq.com

Abstract

Article 76 of the Patent Law of the People's Republic of China (2020 Amendment) establishes an early dispute resolution mechanism for pharmaceutical patent linkage. This mechanism aims to shift patent infringement conflicts to the generic drug approval stage, thereby reconciling the competing interests of originator and generic drug companies while accommodating public health imperatives. The framework establishes a comprehensive set of rules covering patent registration, patent declarations, dual-track dispute resolution, and first-generic exclusivity. However, in practice, a gap persists between the intended institutional design and its actual implementation. The mere transplantation of foreign rules has proven insufficient to address the specific context of China's pharmaceutical sector. Consequently, challenges such as the constrained scope of patent registration review, procedural conflicts within the dual-track remedial system, and the prohibitive cost of patent challenges have become increasingly apparent. Moving beyond a restatement of statutory provisions, this paper utilizes China's inaugural first-generic exclusivity case as a lens to analyse the systemic causes underlying these operational difficulties. It subsequently proposes actionable pathways for refinement, with the ultimate goal of advancing the system's dual objectives: incentivizing pharmaceutical innovation and ensuring drug accessibility.

Keywords

Pharmaceutical patent linkage, Patent disputes, Generic drug, Dual-track system, Drug accessibility

Introduction

An intellectual property regime for pharmaceuticals must strike a balance between incentivizing drug innovation and ensuring public access to affordable medicines. Prior to the implementation of the pharmaceutical patent linkage mechanism in China, disputes over drug patents were typically addressed through post-marketing infringement litigation - an ex post facto remedial model. The practical tensions inherent in this approach are well documented. Generic drug manufacturers make substantial investments in research and development and obtain marketing approval. Yet they may still encounter infringement lawsuits afterward.

Consequently, the risks associated with their investment become unpredictable [1]. Innovator companies that prevail in litigation often find that market share has already been eroded, significantly diminishing the effectiveness of the patent remedy. Meanwhile, patients endure prolonged delays in accessing lower-cost generic drugs due to protracted legal proceedings.

To address this dilemma, China incorporated insights from international practices by introducing Article 76 in the Patent Law of the People's Republic of China (2020 Amendment). Thereby establishing an early dispute resolution mechanism for pharmaceutical patent disputes. However, the adoption of this mechanism was not a mere transplantation of foreign regulations. In judicial practice, it has revealed several practical tensions that were not fully anticipated by the legislative text.

Some existing scholarships tend to focus on elucidating statutory provisions and outlining institutional rules, while paying insufficient attention to the practical obstacles encountered during implementation. This observation serves as the foundation for the present study. The study uses the operational experience of this mechanism as its basis. It analyzes practical challenges that hinder the mechanism's effective implementation. It also explores improvement pathways adapted to the context of China's pharmaceutical industry.

The rationale and core framework of the pharmaceutical patent linkage mechanism

The practical drivers behind the mechanism

The Bolar exemption and patent term extension have already put in place the basic rule system of pharmaceutical patents in China. But the two institutions have clear functional boundaries and cannot resolve patent conflicts at the generic drug application stage [2]. The Bolar exemption only exempts experimental and research activities from infringement liability. It cannot predict infringement risk after marketing. Patent term extension lengthens the protection period of originator drugs and objectively further delays the market entry of generic drugs. The drawbacks of the post-marketing enforcement model gave rise to the legislative demand for a patent linkage mechanism.

The mechanism sets four objectives: (1) To resolve patent disputes in advance. (2) To balance the interests of originator and generic drug companies. (3) To safeguard public health. (4) To improve the pharmaceutical intellectual property system. Given the technical differences in the protection of different drug patents, the legislation adopts an incremental approach to reform and, at the present stage, applies only to chemical generic drugs.

The core logic of how the mechanism operates

The underlying logic of the whole mechanism is the interface between the administrative review procedure and the patent dispute remedy procedure [3]. Patent information registration defines the scope of patents that take part in the linkage procedure, requiring patent holders to truthfully declare relevant patent information of the listed innovative drugs on designated platforms. Generic drug companies submit patent declarations that distinguish whether a substantive patent conflict exists. Where a dispute arises, resolution takes place prior to generic drug approval under the dual-track model of “judicial litigation + administrative adjudication”. A first-generic exclusivity period is also provided. It incentivizes generic drug companies to challenge improper patent barriers erected by originator pharmaceutical enterprises.

It should be made clear that registration is not a condition for the validity of a patent but merely confers the procedural standing to “block the marketing of a generic drug at the review and approval stage”. An unregistered

patent remains valid, except that the right holder can only bring ordinary post-marketing infringement litigation after the generic product obtains marketing authorization [4]. Dual-track dispute resolution gives right holders a choice of procedure, with a 45-day period for initiating proceedings and a waiting period of up to 9 months. The waiting period only suspends marketing approval, and the technical review does not stop during this period. The 12-month first-generic exclusivity period serves as an incentive tool, rewarding the first generic drug applicant that successfully challenges patent validity through the patent linkage adjudication procedure. *Novartis AG v. Nanjing Chia Tai Tianqing Pharmaceutical Co., Ltd. (the Everolimus case)*, China’s first case under the drug patent linkage mechanism, marks the transition of the mechanism from rules on paper to judicial practice [5].

This landmark case examined the system’s core procedural and substantive issues. It established practical precedents for subsequent patent linkage disputes in China. With these references, courts and administrative authorities can interpret unclear provisions. They can also strike a balance among the interests of patentees, generic drug manufacturers, and public access to affordable medicines.

Practical difficulties and causes in the operation of China’s pharmaceutical patent linkage mechanism

Formal examination-oriented patent registration and its difficulty in curbing disguised registration of peripheral patents

Patent registration marks the starting point of this entire mechanism. The legislation imposes explicit restrictions on eligible patent types for registration. It excludes peripheral patents, including pure crystal form patents, intermediate patents, and equipment patents. This rule aims to stop originator firms from abusing patent rights and unreasonably delaying the market entry of affordable generic medicines. In practice, however, the registration platform relies mainly on formal examination rather than substantive assessment of patent relevance. Originator companies can, by rewriting claims and repackaging the technology, package peripheral patents as composition patents or crystal form - active ingredient combination patents and register them [6].

Although the legislation establishes a social objection mechanism, generic drug companies are the main parties that file objections. Objectors are responsible for the

burden of proof. In addition, the review criteria and time limits for handling objections remain unclear. As a result, the filtering function of this objection mechanism is weakened. Originator companies register a large portfolio of patents. This raises the legal risks facing generic drug applications.

In this way, they extend their market monopoly in a disguised manner. Such practice deviates from the original purpose of the registration system. The system is designed to strike a balance between patent protection and public access to medicines [7]. Such strategic patent filing and registration tactics may distort the operation of the patent linkage system and impose extra time and financial burdens on generic drug developers in their pre-application preparation.

Risk of procedural conflicts in the dual-track dispute resolution model

China has innovatively built a dual-track remedial path. Under this path, civil litigation and administrative adjudication operate in parallel. The design intends to offer right holders more options for rights protection. It also seeks to boost the efficiency of dispute resolution within the drug patent linkage framework. Running the two procedures in parallel, however, creates potential conflicts. For the same patent infringement dispute, administrative adjudication and civil litigation may arrive at different conclusions. This leads to inconsistent rulings in similar cases. It further weakens the predictability of the patent linkage system [8].

When it comes to procedural interface, a party dissatisfied with the result of administrative adjudication may file administrative litigation. Nevertheless, there is currently no case referral mechanism. Nor is there a mechanism for cross-referencing judgments. These connections remain absent between this administrative litigation and civil patent infringement litigation [9].

In practice it easily happens that administrative adjudication finds no infringement while civil litigation finds infringement, leaving the Center for Drug Evaluation, faced with two contradictory effective instruments, in a dilemma in its review and approval work. The dual-track design pursues procedural pluralism, but the absence of supporting rules for resolving conflicts has instead increased the uncertainty of disputes. This institutional defect may prolong the review cycle of generic drugs and hinder timely access to

low-cost medicines for patients, weakening the expected benefits brought by the patent linkage mechanism.

High costs of patent challenges and structural imbalance in first generic exclusivity incentives

The first-generic exclusivity period is intended to encourage generic drug companies to challenge unreasonable originator patents, but patent invalidation declarations and infringement litigation are very costly in both time and money. Patent challenges are time-consuming. Litigation and patent invalidation representation also incur high costs. Small and medium-sized generic drug companies often lack sufficient capital reserves. They also maintain slim research and legal teams. For these reasons, they cannot bear the expenses of launching a patent challenge. In the end, those able to obtain the dividend of first-generic exclusivity are mostly leading pharmaceutical companies with strong financial resources and mature legal departments.

The incentive therefore favours large companies. Most small and medium-sized pharmaceutical enterprises can only adopt patent design-around strategies. They tend to wait until the relevant patent expires before submitting applications. This greatly diminishes the inclusive effect of the mechanism [10]. At the same time, although the exception rules to first-generic exclusivity have been laid down, the criteria for determining that “several applicants succeed in their challenges at the same time” remain unclear in practice. This ambiguity creates extra strategic uncertainty for all applicants and may trigger additional disputes over the qualification for exclusivity, further raising the compliance burden for market participants.

Narrow scope of application and lack of sanctions for malicious proceedings

At present the mechanism applies only to chemical generic drugs. Biologics and traditional Chinese medicines also face numerous patent disputes. Biologics feature complex structures and ambiguous claim boundaries. Traditional Chinese medicine, by contrast, follows a special patent protection system. This system originates from its distinctive technical characteristics. neither has yet been brought into the linkage mechanism. This narrow scope of application limits the full-scale role of the patent linkage system and leaves a considerable number of pharmaceutical patent disputes outside this specialized pre-approval dispute resolution framework.

In addition, the existing mechanism lacks a disciplinary mechanism for abuse of procedure. An originator company may maliciously register peripheral patents. It may also abuse dispute proceedings to delay generic drug marketing. Alternatively, a generic drug company may file a malicious action for a declaration of non-infringement. Current law sets out no corresponding penalties for such behaviours. It only relies on ex post infringement damages as a remedy.

Thus, the ex ante constraint is inadequate. In the absence of targeted sanctions, such strategic abuses of procedure may persist. They can disrupt the normal drug review process. They also harm the balanced distribution of interests. The relevant stakeholders include innovators, generic manufacturers and patients.

Paths for improving the early dispute resolution mechanism of pharmaceutical patent linkage in China

Introducing limited substantive examination into patent registration and activating the social objection mechanism

The current model of purely formal examination needs to be reformed. A limited substantive examination should be applied to patents submitted for registration. The examination focuses on judging whether a patent qualifies under the statutory scope of registrable patents. It also screens out peripheral patents. Examples include pure crystal form patents and intermediate patents. Such targeted review does not require full assessment of patent validity, but merely checks the relevance between the claimed patent and the marketed drug product.

Reviewers may examine the connection between patent claims and the active pharmaceutical ingredient or therapeutic function of the listed innovative drug to avoid irrelevant patents entering the registration catalogue. The patent objection procedure requires further refinement. Regulators should specify the time limits for accepting, examining and responding to objections. They should also clarify the burden of proof borne by objectors. Moreover, the results of objection handling should be disclosed to the public.

These measures can enhance transparency and facilitate social supervision. Such adjustments can curb patent stacking at the source. They stop originator companies from exploiting the registration system. These firms cannot use it to build market-entry barriers for generic

drugs. This protects the original legislative goal. The goal is to balance patent protection and public access to affordable medicines. Strengthening these front-end regulatory measures can effectively curb strategic patent registration practices and maintain the orderly operation of the whole patent linkage system.

Rationalizing the dual-track dispute resolution procedures and unifying the standards of adjudication

In response to the potential conflicts of the dual-track system, a case communication mechanism should be established between the Beijing Intellectual Property Court and the China National Intellectual Property Administration.

For the same patent in dispute, the procedure accepted later should refer to the findings of fact in the earlier procedure, so as to avoid conflicting conclusions as far as possible. This coordination framework does not interfere with each authority's independent adjudication power. It prioritizes consistent fact-finding instead of mandating identical final judgments. This approach respects the inherent distinctions between administrative and civil procedures.

The rules governing the review and approval work of the Center for Drug Evaluation should be clarified for situations where the conclusions of an administrative adjudication and of an effective instrument in civil litigation conflict. The boundary of effect between administrative adjudication and civil litigation should be defined. This definition keeps intact the parties' right to select a procedure. At the same time, it lowers legal uncertainty arising from procedural conflicts.

Without clear coordination rules, contradictory rulings may confuse market participants and disrupt the orderly progress of generic drug review. It is also advisable to set up a unified information sharing platform for patent linkage cases, enabling relevant authorities to track case progress in real time. This can help judges and administrative adjudicators grasp the full picture of parallel proceedings at an early stage.

Furthermore, guiding opinions can be formulated to specify the priority of different legal instruments when conflicts emerge, offering stable operational guidelines for the Center for Drug Evaluation. These arrangements will maintain the advantage of procedural pluralism while mitigating institutional friction and stabilizing expectations for both patentees and generic drug

developers.

Optimizing the patent challenge incentive and lowering the threshold for SMEs to participate

The first-generic exclusivity incentive should not favour only leading companies. Regulators may explore ways to streamline certain invalidation and adjudication procedures. This can cut the time cost incurred by patent challenges. In addition, diversified institutional support can be considered. Such support targets patent challenges initiated by small and medium-sized enterprises.

This support can take several forms. They include professional legal guidance, accessible case databases and proper cost-sharing arrangements. These measures ease the financial and technical burdens. Such burdens usually discourage smaller firms from bringing patent challenges. The criteria for determining that “several applicants succeed in their challenges at the same time” should be refined to reduce disputes in practice. Clear quantitative and qualitative indicators need to be formulated to judge concurrent successful challenges, so that regulators can objectively identify eligible applicants without subjective discretion. The incentive effect of first-generic exclusivity should be retained, while guarding against the incentive mechanism degenerating into a privilege reserved for a few large companies.

A more inclusive framework can encourage wider participation in patent challenges, promote healthy competition within the pharmaceutical industry, and accelerate the launch of affordable generic medicines. This design aligns the exclusivity reward with the original policy goal of breaking unreasonable patent monopolies and balancing the interests of innovators, generic manufacturers and patients.

Expanding the scope of application gradually and building a disciplinary mechanism for abuse of procedure

On the basis of experience accumulated with chemical generic drugs, research should be carried out on the patent characteristics of biosimilars, and their step-by-step inclusion in the patent linkage mechanism should be explored. As for traditional Chinese medicine, the rules for chemical drugs should not be copied directly; an independent dispute resolution path suited to the technical features of traditional Chinese medicine should be built.

Rules constraining abuse of the patent linkage procedure

should be added.

Clear adverse legal consequences should be stipulated for malicious registration. Sanctions also apply where parties initiate dispute proceedings in bad faith to delay generic drug marketing. One remedy is compensation for losses incurred by the opposing party. In serious cases, the patent may lose its qualification for patent linkage registration. These safeguards prevent the mechanism from being abused as a tool for monopoly.

Conclusion

The pharmaceutical patent linkage mechanism is an important legislative innovation in the field of pharmaceutical intellectual property in China. It departs from the prior handling model. That earlier model relied wholly on post-marketing litigation. This new approach settles patent disputes before generic drugs receive marketing approval. In this way, it strikes a balance between innovation incentives and public access to medicines. The realisation of the mechanism’s value, however, cannot rest solely on the design of the statutory text. It requires that supporting rules and industry reality be adapted to each other, and continuous dynamic adjustment is needed to respond to new forms of patent strategies adopted by pharmaceutical enterprises.

In current practice, such practical problems as insufficient supervision of patent registration, conflicts between the dual-track procedures. A high threshold for patent challenges and the absence of sanctions for abuse of procedure constrain the effect of the mechanism. These defects may weaken the predictability of the whole system and hinder the timely launch of low-cost generic drugs for patients. Going forward, China should take the current conditions of its domestic pharmaceutical industry as the foundation. It needs to optimise registration examination. It should rationalise the dual-track remedial procedures. It must balance the institutional rights and interests of enterprises of different sizes.

Meanwhile, a constraint mechanism for procedural abuse should be established. The applicable scenarios of this mechanism can also be expanded gradually. When expanding coverage, policymakers may first carry out pilot exploration for biologic products before gradually incorporating traditional Chinese medicines. In this way, the mechanism can fulfil its function of early dispute resolution via patent linkage. It can support the

innovative development of China's pharmaceutical industry. It also helps build a more mature pharmaceutical intellectual property governance system. This system fits China's national conditions.

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Conflicts of Interest

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