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Early Resolution Mechanism for Drug Patent Disputes

As core necessities that concern the national economy and people's livelihoods, the importance of pharmaceutical products is self-evident. Whether it is tackling emerging complex diseases or meeting the everyday medication needs of the general public, pharmaceutical products play an indispensable role. However, the process of developing new drugs is lengthy and fraught with challenges. It requires massive financial investment, extensive human resources, and material inputs, while faces an extremely low success rate. This often leads to prohibitively high prices for new drugs, placing them out of reach for many patients. Meanwhile, generic drugs, with their affordability and high accessibility, have become an important option for reducing healthcare costs and meeting public medication needs. However, balancing the encouragement of drug innovation and the protection of original drug patents - and meanwhile promoting generic drug development and effectively preventing substantial economic losses due to patent infringement disputes - has become a critical challenge that demands proper resolution. To safeguard the legitimate rights and interests of drug patent holders, incentivize new drug research, and foster the development of high-quality generic drugs, China has established both an Early Resolution Mechanism for Drug Patent Disputes and a patent term compensation system for drug patents in recent years.

This article aims to introduce readers to the Early Resolution Mechanism for Drug Patent Disputes (also known as the drug patent linkage system) along with several Supreme Court cases, with the hope of aiding readers' understanding of this framework.

1. Early Resolution Mechanism for Drug Patent Disputes

According to the Medicinal Product Administration Law of China, drugs to be marketed in China shall be subject to the approval of the drug regulatory department of the State Council, and registration certificates shall be obtained for them. Enterprises or research institutions that obtain a drug marketing authorization certificate are designated as the marketing authorization holders. They are responsible for the nonclinical laboratory studies, clinical trials, manufacture, distribution, post-market studies, and surveillance, reporting, and disposition of adverse reactions, among others, of medicinal products in accordance with the provisions of this Law. Any other entity or individual engaged in the research and

development, manufacture, distribution, storage, transportation, or use, among others, of medicinal products shall assume corresponding responsibility in accordance with the law.

The Fourth Amendment to the Patent Law in 2020, which took effect on June 1, 2021, introduced key revisions, with Article 76 explicitly establishing the legal principles for resolving drug patent disputes:

> In the process of review and approval of drug marketing, if a dispute arises between the applicant for drug marketing authorization and the relevant patentee or interested party due to the patent of the drug applied for registration, the relevant party may file a lawsuit with the people's court and request a judgment on whether the drug-related technical solution applied for registration falls within the scope of protection of the patent of others' drugs. The drug regulatory department under the State Council may, within the prescribed time limit, make a decision on whether to suspend the approval of the marketing of relevant drugs based on the effective judgment of the people's court.
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> The applicant for drug marketing authorization and the relevant patentees or interested party may also request the patent administration department under the State Council for an administrative ruling on the dispute over patents related to the drug applied for registration.
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> The drug regulatory department under the State Council, in conjunction with the patent administration department under the State Council, shall formulate specific measures for the connection of patent dispute resolution at the stage of drug marketing license approval and drug marketing license application, which shall be implemented after the approval of the State Council.

In 2021, the National Medical Products Administration (NMPA) and the China National Intellectual Property Administration (CNIPA) jointly formulated the *Implementation Measures for the Early Resolution Mechanism for Drug Patent Disputes (Trial Implementation)* (hereinafter referred to as the "Resolution Mechanism"), which was promulgated and implemented on July 4, 2021. This Resolution Mechanism establishes a concrete connection framework to bridge drug marketing authorization approval with patent dispute resolution during the drug marketing application stage.

The following sections will provide a detailed introduction to the Resolution Mechanism.

2. Patent Information Registration for Marketed Drugs and Declaration for Genetic Drugs

2.1 China's Patent Information Registration Platform for Marketed Drugs

The Resolution Mechanism first introduced the "China's Patent Information Registration Platform for Marketed Drugs" (hereinafter referred to as "Patent Information Registration Platform") to facilitate the connection between drug marketing authorization approvals and the resolution of patent disputes during the application phase for drug marketing authorization.

The medical products administration of the State Council is responsible for the establishment of the Patent Information Registration Platform so that marketing authorization holders for drugs may register patent information on drugs registered and marketed in China. The national drug evaluation institution is responsible for maintaining the Patent Information Registration Platform, and for disclosing the patent information on drugs that have been approved for marketing. The Resolution Mechanism shall apply only to the disputes with patent information registered on the platform.

2.2 Registration by Marketing Authorization Holder

A marketing authorization holder for drugs shall, within 30 days of obtaining the drug registration certificate, independently register the drug name, dosage form, specifications, marketing authorization holder, relevant patent number, patent title, patentee, patent licensee, patent grant date, and patent term expiration date, patent status, patent type, correspondence between the drug and relevant patent claims, mailing address, contact person, and contact information, etc. Where the relevant information changes, the marketing authorization holder shall complete the update within 30 days after the change takes effect.

The marketing authorization holder for drugs shall be responsible for the authenticity, accuracy, and completeness of the relevant information registered by it, and shall verify and handle in a timely manner the relevant oppositions received and record them. The registration information shall be consistent with the information in the patent register, patent gazette, and drug registration certificate. The patent for medical use shall be consistent with the indications or functions in the instructions of the approved drug. The protection scope of the relevant patent shall cover the corresponding technical solutions of

the approved drug. For a modification of relevant information, the reasons thereof shall be explained, and such modification shall be made public.

A marketing authorization holder for chemical drugs may register patents for active pharmaceutical ingredient compounds, patents for pharmaceutical compositions containing active ingredients, and patents for medical uses on the Patent Information Registration Platform.

The registration and update of drug registration and related patent information by the marketing authorization holder provide the foundation for applying this dispute resolution mechanism to drug related disputes.

2.3 Declarations by Chemical Generic Drug Applicants

When a chemical generic drug applicant submits an application for marketing authorization, it shall refer to the patent information disclosed on the Patent Information Registration Platform and make a declaration for each drug patent related to the reference listed drug. The declaration falls into four types:

Type I: There is no relevant patent information about the reference listed drug on the China's Patent Information Registration Platform for Marketed Drugs;

Type II: The patent related to the reference listed drug included in the China's Patent Information Registration Platform for Marketed Drugs has been terminated or declared invalid, or the generic drug applicant has obtained a license from the patentee to exploit the relevant patent;

Type III: The patent related to the reference listed drug has been included in the China's Patent Information Registration Platform for Marketed Drugs, and the generic drug applicant undertakes not to market the generic drug applied for before the expiration of the corresponding patent term;

Type IV: The patent related to the reference listed drugs included in the China's Patent Information Registration Platform for Marketed Drugs shall be declared invalid, or its generic drug does not fall into the protection scope of the relevant patent.

The generic drug applicant shall be responsible for the authenticity and accuracy of the

relevant declaration. Within ten working days after the application for the generic drug is accepted, the national drug evaluation institution shall disclose the application information and the corresponding declaration on the information platform to the public. The generic drug applicant shall notify the marketing authorization holder of the corresponding declaration and the basis therefor. Where the marketing authorization holder is not the patentee, the marketing authorization holder shall notify the patentee. Where a declaration does not fall within the protection scope of the relevant patent, the basis for the declaration shall include a comparison table of the technical solutions of the generic drug and the relevant claims of the relevant patent as well as relevant technical materials. In addition to the paper materials, the generic drug applicant shall also send the declaration and the basis therefor to the email address registered by the marketing authorization holder on the Patent Information Registration Platform, and keep relevant records.

The participation and declarations made by the chemical generic drug applicants help preventing potential patent infringement disputes and promote fair competition.

2.4 Registration by Marketing Authorization Holders of Traditional Chinese Medicines and Biological Products

Marketing authorization holders for traditional Chinese medicines and biological products may register patent information on the Patent Information Registration Platform in accordance with the registration procedures outlined in the above Section 2.2 for drug marketing authorization holders.

For traditional Chinese medicines, patents for traditional Chinese medicine compositions, patents for traditional Chinese medicine extracts, and patents for medical use may be registered; for biological products, patents for the sequence structure of active ingredients and patents for medicinal use may be registered.

2.5 Declarations by Applicants of Traditional Chinese Medicines with the Same Name and Formula, and Biosimilars

Applicants for traditional Chinese medicines with the same name and formula, as well as biosimilars, may make relevant patent declarations in accordance with the procedures outlined in above Section 2.3 for chemical generic drug applicants.

All such registrations and declarations must be made in good faith and in adherence to

the principle of honesty. Where an individual or entity commits fraud by submitting false declarations, or intentionally registers on the Patent Information Registration Platform a patent whose protection scope is not related to the drug approved for marketing or which does not belong to the types of patents that should be registered, infringing on the relevant patent of the patentee or otherwise causing losses to the party, the individual or entity shall bear corresponding liabilities according to law.

3. Connection between Dispute Remedies, Dispute Adjudication, Drug Evaluation

3.1 Remedies Available to Patentees or Interested Parties

Where the patentee or any interested party has objections to any of the four types of patent declarations, it or he or she may, within 45 days from the date when the national drug evaluation institution discloses the application for marketing authorization, file a lawsuit with a people's court or request the patent administrative department under the State Council for administrative adjudication in relation to whether the relevant technical solutions of the drug for which marketing authorization is sought fall within the protection scope of the relevant patent.

Where the patentee or any interested party files a lawsuit or requests administrative adjudication within the prescribed time limit, it or he or she shall, within 15 working days from the date on which the people's court dockets the case or the patent administrative department under the State Council accepts the case, submit a copy of the notice of case filing or case acceptance to the national drug evaluation institution, and notify the generic drug applicant.

Where a party is dissatisfied with the administrative adjudication made by the patent administrative department under the State Council, it or he or she may file a lawsuit in a people's court according to law after receiving the administrative adjudication order.

3.2 Connection between Judicial/Administrative Adjudication and Drug Evaluation

Upon receipt of the copy of the notice of case filing issued by the people's court or notice of case acceptance issued by the patent administrative department under the State Council, the medical products administration under the State Council shall set a nine-month waiting period for the application for registration of the chemical generic drug. The waiting period shall start from the date when the people's court dockets the case or the patent

administrative department under the State Council accepts the case and shall be set only once. During the waiting period, the national drug evaluation institution shall not stop technical evaluation.

With respect to any chemical generic drug registration application that triggers a waiting period, the patentee or any interested party and the chemical generic drug applicant shall, within ten working days of receipt of the judgment or written decision, submit the relevant documents to the national drug evaluation institution.

With respect to any chemical generic drug registration application that has passed the technical evaluation, the national drug evaluation institution shall handle it accordingly in light of the effective judgment of the people's court or the administrative adjudication order of the patent administrative department under the State Council:

(1) If the chemical generic drug is confirmed to fall within the protection scope of the relevant patent, the relevant chemical generic drug registration application shall be transferred to the administrative examination process before the expiration of the patent;

(2) If the chemical generic drug is confirmed not to fall within the protection scope of the relevant patent or the two parties reconcile, the relevant chemical generic drug registration application shall be transferred to the administrative examination process according to the procedures;

(3) If the relevant patent is invalidated according to law, the relevant chemical generic drug registration application shall be transferred to the administrative examination process according to the procedures;

(4) If, after the waiting period, the medical products administration under the State Council has not received the effective judgment or mediation statement from the people's court or the administrative adjudication order of the patent administrative department under the State Council, the relevant chemical generic drug registration application shall be transferred to the administrative examination process according to the procedures; and

(5) If, during the period of administrative examination, the medical products administration under the State Council receives the effective judgment of the people's court or the administrative adjudication order of the patent administrative department under the State Council, which confirms that the chemical generic drug falls within the protection scope of the relevant patent, the relevant chemical generic drug registration application shall be submitted to the national drug evaluation institution, which will handle it in accordance with the provisions of paragraph 2 (1) of this Article.

Where, after the medical products administration under the State Council decides to suspend the approval, the people's court reverses the original administrative adjudication order, the two parties reconcile, the relevant patent is declared invalid, or the patentee or any interested party withdraws the lawsuit or the request for administrative adjudication, the generic drug applicant may apply to the medical products administration under the State Council for marketing approval of the generic drug, and the medical products administration under the State Council may decide whether to grant the approval or not.

For chemical generic drug registration applications with Type I or II declarations, the medical products administration under the State Council shall directly make a decision on whether to grant marketing approval based on the conclusion of the technical evaluation. For chemical generic drug registration applications with a Type III declaration, if the technical evaluation is passed, a marketing approval decision shall be made, and the relevant drugs shall not be marketed until the expiration of the relevant patent term and market exclusivity period.

For an application for registration of a traditional Chinese medicine of the same name and formula or a biosimilar, the medical products administration under the State Council shall directly make a decision on whether to grant marketing approval based on the conclusion of the technical evaluation. Where the people's court or the patent administrative department under the State Council confirms that the relevant technical solutions fall within the protection scope of the relevant patent, the relevant drug may be marketed only after the expiration of the corresponding patent term.

3.3 Implied Approval Due to Non Legal Action within the Prescribed Time

Where the patentee or any interested party fails to file a lawsuit or request administrative adjudication within the prescribed time limit, the medical products administration under the State Council shall directly decide whether to approve the marketing of the generic drug based on the conclusions of the technical evaluation and the declaration submitted by the generic drug applicant. The generic drug applicant may file a lawsuit or request administrative adjudication in accordance with relevant regulations.

3.4 Incentives for the First Successful Patent Challenge and Approval

The first chemical generic drug that successfully challenges a patent and is approved for marketing shall be granted a market exclusivity period. Within 12 months of the date of

approval of the drug, the medical products administration under the State Council shall no longer approve the marketing of generic drugs of the same variety, except those that jointly challenge a patent successfully. The market exclusivity period shall not exceed the original patent term of the challenged drug. Within the market exclusivity period, the national drug evaluation institution shall not stop the technical evaluation. For a chemical generic drug registration application that has passed the technical evaluation, the application shall be transferred to the administrative examination process before the market exclusivity period expires.

Successfully challenging a patent means that a chemical generic drug applicant submits a Type IV declaration, and that the relevant patent is declared invalid according to the applicant's request for invalidation of the patent, so that the generic drug may be approved for marketing.

3.5 Patent Disputes after Generic Drug Marketing Approval

Where, after a chemical generic drug, a traditional Chinese medicine of the same name and formula, or a biosimilar is approved for marketing, the patentee or any interested party considers that the relevant drug infringes on the corresponding patent and a dispute arises, the dispute shall be resolved in accordance with the Patent Law of the People's Republic of China and other relevant laws and regulations.

A marketing authorization decision for a drug already approved according to law shall not be cancelled, nor shall its effectiveness be affected.

As above outlined, the Early Resolution Mechanism for Drug Patent Disputes functions through: 1) marketing authorization holders register the information of drug registration and relevant patent information on the Patent Information Registration Platform; 2) generic drug applicants submit declarations regarding these patents; 3) patentees or interested parties may initiate litigation or request administrative adjudication to challenge such declarations; and 4) the outcomes of judicial or administrative determinations directly impact the drug evaluation process. This mechanism resolves patent disputes between original drug and generic drug during the approval process of the generic drug, thereby facilitating coordinated development of both innovative and generic drugs while promoting the healthy growth of the pharmaceutical industry.

However, this Resolution Mechanism is only one of many ways to solve drug patent

disputes, not the only way. Relevant rights holders may also, according to other provisions of the Patent Law and based on their patents, directly file lawsuits with the People's Court or request administrative action regarding patent infringement.

4. Further Study on Specific Cases

4.1 Patent for Medical Use of Crystal Forms Not Applicable to the Resolution Mechanism

Company A of Sweden registered Claim 9 of its invention patent for a chemical drug used to treat diabetes on the Patent Information Registration Platform. The registered patent type was a chemical medical product patent for medical use, and the claim is linked to the company's already approved original drug.

Sichuan Company B submitted an application for marketing authorization for a generic version of the original drug to the National Medical Products Administration (NMPA), along with a Type IV declaration. The application was accepted.

Company A believed that the generic drug fell within the protection scope of Claim 9 of its patent and filed a lawsuit under Article 76 of the Patent Law, requesting the court to confirm that the generic drug fell within the protection scope of Claim 9.

Sichuan Company B argued that Claim 9 essentially sought protection for a crystal form patent, which does not fall under the types of patents covered by the Implementation Measures for the Early Resolution Mechanism for Drug Patent Disputes. Therefore, Company A had no standing to file the lawsuit under Article 76.

The court of first instance ruled that the technical solution of the generic drug did fall within the protection scope of Claim 9.

Sichuan Company B appealed, reiterating that Claim 9 was a crystal form patent and thus not eligible under the patent types specified in the Implementation Measures for the Early Resolution Mechanism for Drug Patent Disputes.

The Supreme People's Court overturned the first-instance ruling and dismissed the lawsuit filed by Company A.

From this court decision, it can be inferred that: the types of patents that can be registered for chemical medicinal products under the Resolution Mechanism are:

pharmaceutical active ingredient compound patents, patents for pharmaceutical composition containing active ingredients, and patents for medical use of the foregoing two types. Patents for crystalline compounds characterized by crystal cell parameters, which are based on a prior disclosed compound defined by its molecular structure; composition patents containing such crystalline compounds; and medical use patents for these two categories, do not yet fall within the types of patents eligible for registration under the Measures. Company A of Sweden registered Claim 9 as a specific use of a crystalline structure, which does not fall within the categories of patent types stipulated by the Early Resolution Mechanism. It thus had no standing to file the present lawsuit under Article 76 of the Patent Law. Therefore, the case should be dismissed.

According to the policy interpretation of the Implementation Measures for the Early Resolution Mechanism for Drug Patent Disputes issued by the NMPA on July 4, 2021, the types of drug patents eligible for registration include the following:

For Chemical drugs (excluding bulk drug), patents eligible for registration include patents for active pharmaceutical ingredient compounds, patents for pharmaceutical compositions containing active ingredients, and patents for medical uses.

For traditional Chinese medicines, patents eligible for registration include patents for traditional Chinese medicine compositions, patents for traditional Chinese medicine extracts, and patents for medical use.

For biological products, patents eligible for registration include patents for the sequence structure of active ingredients and patents for medicinal use.

Drug patents excluded from registration under this Resolution Mechanism cannot be used to resolve disputes through it. However, patentees may still protect their legitimate rights and interests by relying on other relevant provisions of the Patent Law and may seek judicial or administrative remedies when appropriate.

4.2 Original drug's Technical Solution Falls outside the Protection Scope of Patent Claims Does Not Meet the Conditions for Filing a Lawsuit

Corporation A of Japan alleged that: it is the patentee of two invention patents titled "Method for Treating Interleukin-6 Related Diseases" (referred to as Patents 1 and 2). The marketing authorization holder of the original drug involved in this case had registered the relevant patent information on the Patent Information Registration Platform, and the

information was made public. Zhuhai Company B applied for registration of a biosimilar drug, "Tocilizumab Injection" (the biosimilar in question), which was approved by the National Medical Products Administration for use in combination with methotrexate (MTX) to treat rheumatoid arthritis (RA), Tocilizumab is defined as MRA in the claims of the involved patents. Zhuhai Company B used the biosimilar in combination with MTX to treat RA, with the same dosage and administration as the original drug. Therefore, the technical solution of the Disputed Biosimilar fell within the protection scope of Claims 1–9 of Patent 1 and Claims 1–5 of Patent 2. Furthermore, in both its patent declaration on the Patent Information Registration Platform for Marketed Drugs and its email correspondence with the original drug's marketing authorization holder (a third party outside the case), Zhuhai Company B contended that the Disputed Patents should be declared invalid; in other words, Company B admitted that the technical solution of its Disputed Biosimilar for which registration was sought fell within the protection scopes of Claims 1–9 of Patent 1 and Claims 1–5 of Patent 2. Accordingly, Corporation A requested the court to determine that the Disputed Biosimilar's technical solution fell within the protection scopes of Claims 1–9 of Patent 1 and Claims 1–5 of Patent 2.

Zhuhai Company B contended that neither Patent 1 nor Patent 2 qualified as a "relevant patent" under Article 76 of the Patent Law and thus Corporation A lacked standing to bring the lawsuits pursuant to said provision, and the lawsuits should be dismissed.

The court of first instance made a decision, confirming that the technical solution of the biosimilar drug fall within the scope of Claims 1–9 of Patent 1 and Claims 1–5 of Patent 2.

Following the ruling, Zhuhai Company B appealed, arguing that Claim 1 of Patent 1 and Claim 1 of Patent 2 did not qualify as "patents related to a drug pending registration" under Article 76 of the Patent Law. Therefore, Corporation A lacked standing to bring the case.

The Supreme People's Court ruled to overturn the first-instance ruling and dismissed Corporation A's lawsuit.

From the judgement of the Supreme People's Court, it can be inferred that:

Claim 1 of Patent 1 should be interpreted as defining the use of MRA and methotrexate (MTX) for the production of a specifically packaged drug combination product for the treatment of rheumatoid arthritis. However, the Disputed Original Drug is a tocilizumab injection, and only in its prescribing information was it stated that it may be used in combination with methotrexate; that is, it involves only a single substance and does not

constitute a specifically packaged drug combination product. Therefore, it certainly did not fall within the protection scope of Claims 1–9 of Patent 1. Claim 1 of Patent 2 should be interpreted as defining the use of MRA and MTX for the production of a specifically packaged drug combination product for the treatment of rheumatoid arthritis. However, the Disputed Original Drug is a tocilizumab injection, and only in its prescribing information was it stated that it may be used in combination with MTX; that is, it involves only a single substance and does not constitute a specifically packaged drug combination product. Therefore, it certainly did not fall within the protection scope of claims 1–5 of Patent 2.

Accordingly, the Supreme Court determined that Corporation A's lawsuits did not comply with the provisions of Article 76(1) of the Patent Law and shall be dismissed.

This case illustrates that, under the Resolution Mechanism for drug patent disputes, patent information must be registered on the Patent Information Registration Platform, and the drug must correspond to the relevant patent claims. Patent information that is not registered on the platform does not fall within the scope of this Mechanism. If the technical solution of the original drug does not fall within the protection scope of the registered patent claims, the conditions necessary to initiate a lawsuit under this Mechanism are not met.

That said, if the technical solution of a generic drug does fall within the scope of protection of a patent claim, the patent holder may still, in accordance with other relevant provisions of the Patent Law, protect their legitimate rights and interests by seeking judicial or administrative remedies when appropriate.

4.3 Where the Only Difference between the Generic Drug and the Original Drug Is in Specification, the Generic Drug Applicant Shall Make Declarations with Reference to Patents Registered Under Other Specifications of the Original Drug

Company A is the patentee of the invention patent involved in the case. The protection scope of the patent involved in the case covers all dosage forms of drugs containing the active ingredient of palbociclib, including palbociclib capsules and palbociclib tablets. Company A is the patentee of the invention patent involved in the case. The protection scope of the patent involved in the case covers all dosage forms of drugs containing the active ingredient of palbociclib, including palbociclib capsules and palbociclib tablets. On June 30, 2021, Company A registered the patent involved in the case as a patent related to

palbociclib capsules in three specifications of 75mg, 100mg and 125mg on the Patent Information Registration Platform, and the registered claims are 1-4. The original drug "palbociclib" with specifications of 25mg and 125mg and dosage form of tablets were approved for marketing in China on August 10, 2022. On September 6, 2022, Company A registered the patent involved in the case as a patent related to palbociclib tablets with the specifications of 25mg and 125mg on the Patent Information Registration Platform, and the registered claims are 1-4.

Pharmaceutical Company B filed an application for registering the generic drug Palbociclib tablets with three specifications of 75mg, 100mg and 125mg and the dosage form being tablet. The National Medical Products Administration accepted the registration on April 12, 2022. In response to the patent involved in the case, Pharmaceutical Company B made a Type 1 Declaration on the Patent Information Registration Platform, that is, there is no relevant patent information of the generic drug on the Patent Information Registration Platform.

Company A filed a lawsuit and claimed: the Type 1 Declaration made by Pharmaceutical Company B was false and inaccurate. Pharmaceutical Company B had filed an invalidation request against the patent involved in the case, so its true intention was a Type 4.1 Declaration. Company A requested to confirm that the technical solution of the generic drug involved in the case that Pharmaceutical Company B applied for registration fell within the protection scope of claims 1-4 of the patent involved in the case.

Pharmaceutical Company B argued that: for the palbociclib tablets with specifications of 75mg and 100mg that were applied for, there were no corresponding generic drugs or the related patents published on the Patent Information Registration Platform. For the palbociclib tablets with specifications of 125mg that was applied for, the related patent was published later than the time of its declaration. In addition, its invalidation request and the administrative litigation against the patent involved in the case was filed before the implementation of China's drug patent linkage system, and also earlier than the application date of the generic drugs in question. Therefore, Company A's opinion that its declaration on the patent in question should be a Type 4.1 declaration lacked basis. Therefore, Company B had factual and legal basis for making a Type 1 Declaration, and Company A's lawsuit did not meet the statutory conditions.

The first instance court made a civil ruling to dismiss Company A's lawsuit.

Company A was dissatisfied and appealed, claiming that: "The generic drugs" are not limited to drugs approved for marketing, and the applicant for generic drugs should make a declaration for each "related drug patent" corresponding to the generic drugs registered on the Patent Information Registration Platform. The case is special, as the patent involved in the case has been registered on the Patent Information Registration Platform, and the technical solution of the generic drug fell within the protection scope of the patent. Pharmaceutical Company B, while knowing the above facts, made the Type 1 Declaration, so the Declaration was untrue and inaccurate, and in essence belonged to the Type 4 Declaration.

The Supreme People's Court ruled to dismiss the appeal and uphold the original decisions.

From the judgements of the Supreme People's Court, it can be inferred that:

The marketed referenced drug in China must correspond to the patent claims registered on the Patent Information Registration Platform. Since the patent involved in the case is not a patent registered for the corresponding palbociclib tablets that have been marketed in China, it does not belong to the "related patent" of palbociclib tablets. Therefore, Company A's lawsuit does not meet the conditions stipulated in Article 76 of the Patent Law and should be rejected.

Although in China's current drug management system requires separate applications and different approved batch numbers for chemical drugs that only differ in specifications, generic drugs of the same dosage form may use original drugs of different specifications as reference preparations, and use the data demonstrating consistency in quality and efficacy with the reference preparations as the basis for registration. Therefore, when the original drug that differs from the generic drug only in specifications has been registered on the Patent Information Registration Platform, the generic drug applicant should, in principle, make a declaration in accordance with the relevant patents registered under other specifications of the generic drug registered on the Patent Information Registration Platform.

Similarly, the Early Resolution Mechanism for Drug Patent Disputes is not the sole means of resolving such disputes. Patent holders may still rely on other relevant provisions of the Patent Law to safeguard their legitimate rights and interests and may seek judicial or administrative remedies when appropriate.

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We hope you find the above information helpful. The resolution mechanism for drug patent dispute continues to evolve. AFD China will keep monitoring relevant legal developments and provide you with ongoing updates.

If you have any question about the protection of intellectual property rights, please feel free to send us emails. For patent-related matters, please send to info@afdip.com. For trademark/litigation/legal matters, please send to info@bhtdlaw.com.