Studies on Scope of Application of Patent Linkage System

Ke Ke

Article 76 of the China's Patent Law, which was implemented on 1 June 2021, stipulates for the first time an early resolution mechanism for drug patent disputes, which is referred to as "drug patent linkage" or "patent linkage" in practice. In 2021, the competent authority has successively promulgated the implementing measures and regulations in relation to patent linkage, and launched the China's Patent Information Listing Platform for Marketed Drugs. This marks the official entry of the China's patent linkage system into the practical operation stage after years-long calls and legislative preparations. For more than two years ever since the implementation of the patent linkage system, a number of judicial judgments and administrative rulings in relation to patent linkage have been published and some controversies have occurred in practice.

In comparison with ordinary patent infringement judicial litigation or administrative adjudication, patent linkage should be consistent in terms of the substantive judging criteria and be special in terms of the scope of application and procedures. Judging from the published judicial judgments and administrative rulings and discussions in the IP field since the two-year implementation of patent linkage system, the patent linkage system, as a new scheme, is still criticized for unclear boundaries and controversial scope of application.

This article intends to make preliminary studies and summary about the scope of application of China's patent linkage system, including the scope of products and the scope of patents which are subject to patent linkage, the scope of patent statements that give rise to patent linkage litigation or administrative adjudication, and the scope of trials of patent linkage litigation or administrative adjudication.

1. Types of products which are subject to patent linkage

The patent linkage as stipulated in Article 76 of the China's Patent Law is aimed to resolve disputes over "relevant patent right associated with the pharmaceutical product applied for registration" "in the review and approval process before the marketing of a pharmaceutical product". Thus, the products which are subject to patent linkage are pharmaceutical products, i.e. drugs, under the review and approval for marketing.

Article 2.2 of the Drug Administration Law reads that "drugs in this Law refer to substances used in the prevention, treatment, and diagnosis of human diseases and intended for the physiological regulation of the body's functions, for which indications or functions, dosage, and administration are stipulated, including traditional Chinese medicines, chemical drugs and biological products." Article 24.1 thereof stipulates that "drugs to be marketed in the territory of the People's Republic of China shall be subject to approval by the drug regulatory department under the State Council to obtain the drug approval license, except for Chinese medicinal materials and prepared slices of Chinese crude drugs which are not subject to review and approval administration. The list of Chinese medicinal materials and prepared slices of Chinese crude drugs subject to review and approval shall be formulated by the drug regulatory department under the State Council jointly with the administra-

tive department for traditional Chinese medicine under the State Council."

According to the above provisions, the China's patent linkage is applicable to chemical drugs, biological products, and traditional Chinese medicines that are subject to review and approval administration. The drugs include those used not only in disease prevention and treatment, but also disease diagnosis. However, it should be noted that in the light of Article 103 of the Regulations on the Supervision and Administration of Medical Devices, *in-vitro* diagnostic reagents belong to medical devices, rather than drugs as mentioned in the Pharmaceutical Administration Law. Therefore, the *in-vitro* diagnostic reagents are not subject to the patent linkage system.

In addition, veterinary drugs are subject to the Regulations on the Administration of Veterinary Drugs. The Ministry of Agriculture and Rural Affairs is currently in charge of the review and approval of veterinary drugs. The veterinary drugs do not belong to drugs as mentioned in the Pharmaceutical Administration Law and therefore are not subject to the patent linkage system.

As compared with the U.S. laws, the product types which are subject to the patent linkage system in China are different. According to 35 U.S.C.§271(e)(2), artificial infringement applies to a human drug or veterinary drug reviewed and approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Chapter 9) and a biological product reviewed and approved under the Public Health Service Act (42 U.S.C. Chapter 6A). The U.S. Food and Drug Administration has launched patent listing platforms respectively for human drugs, veterinary drugs and biological products, namely the Orange Book, Green Book and Purple Book.[1] However, the artificial infringement by biological products is different from that by other drugs. In the light of Section 351 (l) of the 42 U.S.C., the procedure for resolving disputes over artificial infringement by biological products includes the steps of: the notification of the biosimilar applicant, patent list provided by the reference product sponsor, patent resolution negotiations, first-phase patent litigation, notice of commercial marketing, second-phase patent litigation, etc., which is often called the "patent dance". This procedure is a dispute resolution mechanism that is completely different from the patent linkage system. Hence, the U.S. patent linkage system is actually applicable to human chemical drugs and veterinary drugs, whereas the China's patent linkage system is applicable to human chemical drugs, biological products and traditional Chinese medicines, but not veterinary drugs.

Nevertheless, it should be noted that Article 12 of the Implementing Measures for the Early Resolution Mechanism for Drug Patent Disputes (Trial) (hereinafter referred to as the Implementing Measures) that are currently in force in China stipulates that biological products and traditional Chinese medicines cannot enjoy the stay period or marketing exclusivity for first follow-on applicants, whereas only chemical drugs can do so. Since the stay period and marketing exclusivity for first follow-on applicants are the kernel of the patent linkage system, it is doubtful whether the biological products and traditional Chinese medicines can substantially benefit from the patent linkage system under the current rules. In contrast, although the U.S. biological products are not subject to the patent linkage procedure like chemical drugs, they are subject to artificial infringement, and "patent dance", another patent dispute resolution mechanism during the review and approval stage. Furthermore, according to Section 351(k)(7) of the 42 U.S.C., the reference product (namely, the brand-name biological product) can enjoy the benefits such as the 12-year exclusivity period, and according to Section 351(k)(6) of the 42 U.S.C., the first interchangeable biosimilar biological product can also enjoy a certain exclusivity period. It can be seen that the U.S. provides much stronger protection for biological products than China. In recent years, the biopharmaceutical industry has been booming in China, and traditional Chinese medicines are also unique in China. If we intend to bring the innovation incentivizing role of the patent system into full play and allow the patent linkage system to resolve patent disputes as early as possible, the right holders of the biological products and traditional Chinese medicines must be allowed to substantially benefit from the patent linkage system or other early resolution mechanisms for patent disputes.

2. Types of drugs which are subject to patent linkage

According to Articles 6 and 7 of the Implementing Measures, the submission of the patent statement is the prerequisite for triggering patent linkage litigation or administrative adjudication, and according to Articles 6 and 12 of the Implementing Measures, the applicants for chemical generic drugs, biosimilar drugs and traditional Chinese medicines of the same name and prescription shall make the relevant

patent statement.

According to the Requirements for Registration Classification and Application Dossiers of Chemical Drugs and the Guidelines for Acceptance and Review of Listed Chemical Drugs, the generic drugs in chemical drugs include: … Class 3: drugs manufactured by domestic applicants by imitating the brand-name drugs that have been marketed overseas but not yet in China; Class 4: drugs manufactured by domestic applicants by imitating the brand-name drugs that have been marketed in China; … Class 5.2: generic drugs that have been marketed overseas and are under application for market launch in China. During the listing process of these types of drugs, documents are required to be submitted to prove that these drugs are consistent with reference listed drugs in terms of quality and efficacy.

For Class 4 drugs, the reference listed drugs thereof have been marketed in China, and are definitely subject to the patent linkage system. But for Classes 3 and 5.2 drugs, the reference listed drugs thereof have not been marketed in China, patents in relation to the reference listed drugs are not listed on the pharmaceutical patent listing platform, and there are controversies over whether such reference listed drugs are subject to the patent linkage system. Some people think that Class 3 drug applications are not subject to the patent linkage system except those which are actually Class 4 drug applications but are mistakenly submitted as Class 3 drugs. [2]

In addition, for Class 1 chemical drugs (innovative drugs which contain new compounds with clear structures and pharmacological effects, and have clinical values), Class 2 chemical drugs (improved new drugs which are optimized on the basis of the known active ingredients and have better clinical performance before improvement) and Class 5.1 chemical drugs (brand-name and improved drugs which have been marketed overseas and are under application for market launch in China), these drugs belong to brand-name drugs, rather than generic drugs under the current Chinese laws, and therefore are not subject to the patent linkage system. No public controversies in this regard have been seen in practice.

Reference can be made to the U.S. practice before discussing the above issues. Artificial infringement under 35 U.S.C.§271(e)(2)(A) is directed to two types of drug applications, which are applications filed under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.§355(j)) and applications filed under Section 505(b)(2) thereof (21 U.S.C.§355(b)(2)). The former applications are abbreviated new drug applications (ANDAs), also called generic drug applications in practice, and the latter applications are new drug applications, the approval of which relied upon the investigations and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. They are also called paper new drug applications (paper NDAs) in practice. The paper NDA under Section 505(b)(2) may differ from reference listed drugs with respect to dose, dosage form, route of administration, or, in the case of combination products, active ingredient, [3] and judging from the approved drugs, paper NDAs may even be classified into Class 1 (new molecular entities). [4] According to Sections 505(b)(2) and 505(c)(3) of the Federal Food, Drug, and Cosmetic Act, the applicants of the paper NDAs are also required to submit patent certifications just like the applicants of the ANDAs, and the paper NDAs are also subject to the patent linkage system. It can be seen that the paper NDAs in the U.S. practice are similar to the Class 2 improved new drugs of the chemical drugs in China (of course, there are dissimilarities therebetween) and subject to the U.S. patent linkage system. It means that a great majority of studies in China are incomplete or inaccurate as their discussions about the U.S. patent linkage system are only confined to the generic drugs, i.e. the ANDAs.

By way of comparison, it can be seen that the types of drugs which are subject to the patent linkage system in the U.S. are more than those in China. Article 76 of the China's Patent Law only stipulates that the patent linkage system is aimed to resolve disputes over "relevant patent right associated with the pharmaceutical product applied for registration" "in the review and approval process before the marketing of a pharmaceutical product", but does not require the drug to be a generic drug. However, the Implementing Measures limit the subjects applying for drug listing to generic drug applicants, and narrows down the scope of drugs in comparison with that provided in the Patent Law. From the perspective of the legislative purpose of the patent linkage system for early resolution of drug patent disputes, such a limitation actually functions to postpone the resolution of a considerable portion of disputes that would have been resolved by means of patent linkage to a time after drug market launch, which increases the right safeguarding costs for brand-name companies, and the risks for generic drug applicants. This may not be in line with the

legislative purpose of the patent linkage system.

If the patent linkage system is aimed to resolve drug patent disputes as much as possible prior to the launch of drugs into the market, it is suggested that the scope of drug types which are subject to the patent linkage system should be expanded to cover not only Classes 3 and 5.2 chemical drugs, but also Class 2 chemical drugs. These drugs more or less rely on the clinical trial data of the reference listed drugs, and it is reasonable to allow the reference listed drugs (namely, brand-name drugs) to benefit from the patent linkage system. Furthermore, according to the Procedure for Selection and Determination of Reference Listed Drugs for Chemical Generic Drugs (No. 25/2019) released by the China's National Medical Product Administration, the reference listed drugs include non-imported brand-name drugs, which indicates that the clinical trial data of the brand-name drugs which have been marketed overseas and not marketed in China can also be utilized for the market launch of drugs in China. Therefore, allowing the application of the patent linkage system to the Classes 3 and 5.2 drugs also sounds reasonable.

Of course, if such a change is made, the drug patent listing and statement system also needs to be adjusted accordingly. The brand-name drugs which have been marketed overseas and not marketed in China cannot be listed as Chinese patents under current practice. It is suggested to allow the marketing authorization holders of drugs which have been marketed overseas or the holders of Chinese patents to list relevant patents on the drug patent information listing platform to enable the patent statements for these patents to be submitted and the subsequent procedures to be conducted under the patent linkage system. Meanwhile, applicants for Classes 2, 3 and 5.2 drugs should be required to file patent statements while submitting marketing applications.

Similarly, for biological products, it is suggested that the application scope of the patent linkage system should be expanded to improved biological products and those which have been marketed overseas and not marketed in China. For traditional Chinese medicines, it is suggested that the application scope of the patent linkage system should be expanded to improved new drugs.

3. Scope of patents which are subject to patent linkage

For patents that are subject to patent linkage and listed on the China's Patent Information Listing Platform for Marketed Drugs, there are requirements in at least three aspects: (1) patent type, (2) correspondence between the scope of patent protection and the drug, and (3) listing timeline.

3.1 Patent type

Article 5 of the Implementing Measures reads that "the marketing authorization holders of chemical medicine can list patents claiming pharmaceutical active ingredient compounds, pharmaceutical compositions containing the active ingredient(s), and medical uses on the China's Patent Information Listing Platform for Marketed Drugs." Article 12 of the Implementing Measures reads that "for traditional Chinese medicines, patents claiming Chinese medicine compositions, Chinese medicine extracts and medical uses can be listed. For biological products, patents claiming the sequence structure of active ingredient(s) and medical uses can be listed." According to the Policy Interpretation of the Implementing Measures for the Early Resolution Mechanism for Drug Patent Disputes (Trial) (hereinafter referred to as the Policy Interpretation), "specific drug patents that can be listed in the China's Patent Information Listing Platform for Marketed Drugs … do not include patents on intermediates, metabolites, polymorphs, preparation methods, testing methods, etc."

In comparison with the U.S. practice, types of chemical drug patents for which information must be submitted do not include crystal form patents. According to 21 C.F.R. §314.53(b)(1), patents for which information must be submitted consist of drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents, wherein polymorph patents are definitely mentioned, and patents for which information must not be submitted consist of process patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates. There is currently no official explanation to why China excludes crystal form patents from listable patents. According to the understanding of IP professionals, it is likely because the innovation height of crystal form patents can hardly be recognized and the crystal form patents are at a high risk of being invalidated. [5]

A resulting question is what kind of crystal form patents (crystalline compound patents only, or crystalline composition patents and medical use patents) should be excluded from the listable patents. In *Meishi Biopharmaceutical Co.*

v. Shanghai Acebright Pharmaceuticals Co., Ltd., a patent linkage dispute related to neratinib maleate tablets, the China National Intellectual Property Administration (CNIPA) held that claims relating to the medical use of the crystal form belong to the "crystal form patents" that should be excluded according to the Policy Interpretation, and therefore rejected the request for administrative adjudication as it does not meet the requirements for acceptance. [6] As interpreted by an informed examiner, the excluded "crystal form patent" refers to the claimed technical solution which contains the "crystal form" of a compound or is defined by an expression that is unique to the "crystal form" of the compound, and does not include the crystal claim which does not define the "crystal form". [7]

In *Sichuan Guowei Pharmaceutical Co., Ltd. v. AstraZeneca (Sweden) AB*, a patent linkage dispute related to dapagliflozin tablets, the Supreme People's Court also held a similar view. [8] In the Ruling, the Supreme People's Court stated that from the perspective of literal interpretation, "medical use patents" in Article 5 of the Implementing Measures shall be interpreted as medical use patents claiming pharmaceutical active ingredient compounds and medical use patents claiming pharmaceutical compositions containing the active ingredient(s); from the perspective of purpose interpretation, the early resolution mechanism for drug patent disputes is not the sole route to resolve drug patent disputes and is currently in the trial stage, and the disputes related to pharmaceutical active ingredients, which serve as the key of drug R&D and production technologies, should be solved with priority; and from the perspective of historical interpretation, the competent administration authority has taken into account the so-called crystal form patents when formulating the Implementing Measures and purposefully excluded them from the scope of listable patents. Therefore, compound patents that are further characterized by the crystal structures such as lattice or other features on the basis of the existing compounds defined by molecular structures should not belong to "patents claiming pharmaceutical active ingredient compounds" as stipulated in Article 5 of the Implementing Measures, and the medical use claims thereof also do not belong to the medical use patents as stipulated in the Implementing Measures. Hence, the Supreme People's Court ruled to dismiss the plaintiff's action.

The author holds that under the current laws and regulations, the interpretation provided in the above administrative and judicial rulings are reasonable to some extent. If the "crystal form patents are literally interpreted as crystalline compound patents and excluded from listing, but the crystalline composition patents and medical use patents are allowed for listing, the above provisions will be in vain and not consistent systematically. However, there are always controversies over the innovation of crystal form patents. The historic standards are inconsistent with current standards, and substantive examination standards are different from invalidation standards in practice. There are also examples in the pharmaceutical industry where drugs fail or succeed due to crystal forms. [9] If in the future, the innovation of the crystal form patents is well recognized in practice in China, law revision may be considered to incorporate the crystal form patents into the scope of listable patents.

Similar to crystal form patents, controversies also exist for listable patent types relating to biological products, that is, how to interpret "patents claiming the sequence structure of active ingredient(s) and medical uses"? To be specific, do the "patents claiming the sequence structure of active ingredient(s)" include patents claiming proteins or nucleic acids defined by the sequence structure of active ingredient(s) only, or also include those directed to compositions or constructs or microorganisms comprising proteins or nucleic acids defined by the sequence structure of active ingredient(s), or even related use patents? Do "medical use patents" include all biological product medical use patents, or patents claiming the medical use of the sequence structure of active ingredient(s) only? There have not been any official answers to these questions yet. Nor have relevant cases been found.

As for the former question, if reference is directly made to the interpretation of the crystal form patents, the "patents claiming the sequence structure of active ingredient(s)" should be interpreted in a broad sense, including not only patents claiming proteins or nucleic acids defined by the sequence structure of active ingredient(s), but also compositions, constructs, and microorganism patents comprising proteins or nucleic acids defined by the sequence structure of active ingredient(s), as well as the use patents thereof. If we prudently refer to the administrative and judicial rulings instead of directly following the interpretation of the crystal form patents and confine the function of the patent linkage system to resolve key disputes, the "patents claiming the sequence structure of active ingredient(s)" can also be interpreted in a narrow sense in the current particular period,

including patents claiming proteins or nucleic acids defined by the sequence structure of active ingredient(s), but not composition or construct or microorganism patents.

As for the latter question, if the "medical use patents" are understood to encompass all biological product medical use patents and not limited to patents claiming the medical use of the sequence structure of active ingredient(s), it almost makes no sense to confine listable biological product patents to the "patents claiming the sequence structure of active ingredient(s)" on the grounds that nearly all biological products not defined by sequence structures can be drafted as medical use patents. From the perspective of system consistency, it may be more appropriate to interpret the "medical use patents" as patents claiming the medical use of the sequence structure of active ingredient(s). Of course, due to policy reasons, it also sounds reasonable to expand the scope of application of biological product patent linkage as board as possible and interpret the "medical use patents" to be directed to the medical use of any biological product. In practice, a huge number of medical use patents for biological products without defining any sequence structure have been listed in the China's Patent Information Listing Platform for Marketed Drugs.

3.2 Correspondence between the scope of patent protection and the drug

Article 4.2 of the Implementing Measures reads that "the patent right for medical use shall be consistent with the indications or major functions recited in the instruction of the drug products approved for marketing; and the scope of protection of relevant patents shall cover the corresponding technical solutions of the drugs approved for marketing".

The "scope of protection of patent" shall include literal scope and equivalent scope according to the current patent practice. For instance, Article 13 of the Several Provisions of the Supreme People's Court on the Application of Law in Hearing Patent Disputes stipulates: "the provision that 'the scope of protection of the patent right for invention or utility model shall be determined by the terms of the claims, and the description and the appended drawings may be used to interpret the claims' as prescribed in Article 59.1 of the China's Patent Law means that the scope of protection of the patent right shall be based on the scope determined by all the technical features of the claims, as well as by the features equivalent to those technical features". Regarding patent linkage, there may arise a question as to whether the "scope of protection of relevant patents" in the provision that "the scope of protection of relevant patents shall cover the corresponding technical solutions of the drugs approved for marketing" includes the literal scope and the equivalent scope. For instance, the literal scope of a patent claim does not cover marketed drugs, but the equivalent scope thereof may cover marketed drugs. Is such a patent allowed for listing? No related case has been found yet. But from the literal meaning of the legal provision and its original legislative intention for early resolution of drug patent disputes, such patents should be allowed for listing.

Here is another question. Where a patent does not cover a brand-name drug neither literally nor under the doctrine of equivalents, if a person manufactures, sells, offers to sell, uses or imports a generic drug that is identical to the brand-name drug for production and business purposes without authorization, which may constitute contributory or induced infringement of said patent, can such a patent be allowed for listing? Here is a case in practice. In *Novartis AG v. Suzhou Thery Pharmaceutical Co., Ltd.*, a patent linkage dispute related to nilotinib capsules, the patent in suit claims the use of an active ingredient (nilotinib) in the preparation of drugs for the treatment of diseases, wherein nilotinib and a pharmaceutically acceptable carrier are dispersed in applesauce, and the brand-name drug in suit contains nilotinib and a pharmaceutically acceptable carrier, but not applesauce. The instruction states that the medicine can be mixed with applesauce before taking. The Beijing Intellectual Property Court interpreted the claim in suit as that the prepared drug includes three ingredients, namely, nilotinib, a pharmaceutically acceptable carrier and applesauce, holding that the applesauce is not an ingredient of the brand-name drug and therefore ruling to reject the lawsuit on the grounds that the patent in suit does not cover the brand-name drug in suit and should not be listed. [10]

This article is not going to make any comments on the claim construction in the above case. Based on the claim construction of the patent in suit gave by the Beijing Intellectual Property Court, the author deems that in the context of China's current legal provisions, the above ruling made by the Beijing Intellectual Property Court is reasonable. The expression in China's relevant regulation is "whether the scope of protection…covers… ", which means only the scope of protection of patent needs to be taken into account. Contributory infringement or induced infringement involves the issues regarding infringement forms, rather than

the scope of patent protection.

However, things may be different in this regard if reference is made to the U.S. legislation. Section 505(b)(1)(viii) of the Federal Food, Drug, and Cosmetic Act stipulates that "(such persons shall submit) (viii) the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that—

(I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or

(II) claims a method of using such drug for which approval is sought or has been granted in the application."

According to the above provision, patent listing is premised on that a claim of patent infringement could reasonable be asserted and a drug or a method for using the same is claimed. Since U.S. laws allow the protection of medical use method patents, if the above-mentioned case occurred in the U.S., there would be no controversy over the ruling. But if China follows the legislation of the U.S., like "a claim of patent infringement could reasonably be asserted and a drug or a method for preparing the same is claimed", this may leave some room for listing of the abovementioned patents.

3.3 Listing time

Article 4.1 of the Implementing Measures reads that "the marketing authorization holder shall, within 30 days after obtaining the Drug Listing Certificate, list the drug name … relevant patent number … In case of any change to the relevant information, the marketing authorization holder shall complete the updates within 30 days after such a change takes effect."

The question is what legal consequences may result from listing after the expiration of the time limit? Will the relevant right holder lose its right to file a lawsuit or request administrative adjudication under the patent linkage system? [11] There are currently no laws or regulations in this regard.

The time limit for patent listing is also set forth in the U.S. practice. According to 21 C.F.R.§314.53(d)(1), an applicant must submit patent information before the NDA is filed, and if a patent is issued after the NDA is filed with FDA but before the NDA is approved, the applicant must, within 30 days of the date of issuance of the patent, submit the required patent information. According to 21 C.F.R.§314.53(d)(3), if a patent is issued after an NDA is approved, the applicant must submit the required patent information within 30 days of the date of issuance of the patent. The consequences of untimely filing of patent information are also stipulated. According to 21 C.F.R.§314.50(i)(4) and 21 C.F.R.§314.94(a)(12)(vi)(B), if a patent on an NDA is filed after 30 days of the date of issuance of the patent and the "paper NDA" application under Section 505(b)(2) or the ANDA application under Section 505(j) is submitted earlier than the submission of the patent information, the applicant is not required to submit a patent certification; however, if the "paper NDA" under Section 505(b)(2) or the ANDA under Section 505(j) is submitted later than the submission of the patent information, the applicant is still required to submit a patent certification. In addition, according to 21C.F.R.§314.50(i)(6) and 21 C.F.R.§314.94(a)(12)(viii), for untimely filed patent, the applicant of the "paper NDA" under Section 505(b)(2) or the ANDA under Section 505(j) can voluntarily submit a patent certification or withdraw the patent certification. As known from the U.S. precedents, in the case of untimely patent listing or even no patent listing at the time of filing a lawsuit, the court may still accept the lawsuit and make a judgment on substantive issues. In *Vanda Pharm., Inc. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018), the NDA was approved in 2009, the ANDA was submitted in 2013, the patent in suit was granted in November 2013, later than the filing date of the ANDA. The NDA holder filed a lawsuit against the ANDA in June 2014. It was not until January 2015 that the patent in suit was listed in the Orange Book. The ANDA applicant submitted a Paragraph IV certification in May 2015. The United States Court of Appeals for the Federal Court (CAFC) confirmed that the district court has jurisdiction over the case and upheld the infringement judgment made by the district court. Regarding jurisdiction, the CAFC pointed out that "Vanda's complaint alleged that West-Ward infringed the '610 patent under 35 U.S.C. § 271(e)(2)(A) by filing the ANDA…Nothing more was required to establish the district court's subject matter jurisdiction pursuant to 28 U.S.C. § 1338(a) … West-Ward had filed an ANDA and Vanda had sued it. The mere fact that West-Ward had not submitted a Paragraph IV certification for the '610 patent until after Vanda filed suit does not establish that there was not a justiciable controversy over which the court could exercise jurisdiction."

The author deems that untimely filed patents, in princi-

ple, have no publicity effect on drug applications submitted before listing and are not subject to the patent linkage (unless drug applicants voluntarily submit a patent certification after patent listing and are willing to resolve disputes under the patent linkage system); or otherwise, the time limit for patent listing exists in name only, and generic drug applicants cannot have a stable anticipation on future legal status, which is not conducive to the operation of the patent linkage system. In contrast, untimely filed patents have a publicity effect on drug applications submitted after listing. For the legislative purpose of early resolution of drug patent disputes, applicants who submit drug applications after listing should be required to submit patent statements and the patent linkage should be applicable.

There exists a special situation in practice, that is, where a patent is submitted for listing in due time, and a generic drug application is filed after the approval of the brand-name drug and before the patent listing, [12] shall the generic drug applicant be required to submit a patent statement and the patent linkage be applicable? The author holds that under such circumstances, the generic drug applicant intends to apply for the marketing of the generic drug based on the research on the brand-name drug and willfully applies for the marketing of the generic drug after the approval of the brand-name drug and before the patent listing, and the marketing authorization holder of the brand-name drug is not at fault. If the patent linkage does not apply under such circumstances, it leaves a loophole in the system for generic drug applicants, in such a way that the rights and interests of the parties are obviously imbalanced, which does not comply with the legislative purpose of the patent linkage system. Therefore, the application of the patent linkage should be allowed under such circumstances, and generic drug applicants are required to submit patent statements for the listed patents.

4. Patent statement that triggers patent linkage litigation or administrative adjudication

According to Article 3 of the Provisions on Several Issues Concerning the Application of Law in the Trial of Civil Disputes over Drug-Related Patents Applied for Listing (No. Fa Shi 13/2021) released by the Supreme People's Court, the conditions for accepting patent linkage lawsuits include that marketing authorization holders had made a Type 4 statement. In multiple published judgments or rulings of cases accepted by the courts, the Type 4 statement based on which lawsuits are filed includes Type 4.2 (generic drugs do not fall within the scope of protection of relevant patents), [13] Type 4.1 (relevant patents should be declared invalid), [14] or even Type 1 (no information on patents related to brand-name drugs is presented in the China's Patent Information Listing Platform for Marketed Drugs) [15] and Type 2 (patents related to brand-name drugs in the China's Patent Information Listing Platform for Marketed Drugs have terminated or been declared invalid) [16] made by the generic drug applicants. Patentees deemed that the statements made by the generic drug applicants were wrong and should be changed to Type 4 statement. It indicates that the courts' conditions for accepting patent linkage lawsuits are relatively loose. As long as the generic drug applicants make Type 4 statement, or the patentees or interested parties deem that the statements of the generic drug applicants are wrong and should be changed to Type 4 statement though Type 4 statement is not made by the generic drug applicants, the courts will accept the cases at the filing stage and conduct examination as to whether the statements are wrong at the substantive trial stage.

According to Article 7 of the Administrative Adjudication Measures for Early Resolution Mechanism for Drug Patent Disputes released by the CNIPA, the applicant who requests for administrative adjudication for a drug patent dispute shall submit "the statement that the generic drug does not fall within the scope of protection of relevant patents", namely, Type 4.2 statement. Literally speaking, Type 4.1 statement (relevant patents should be declared invalid) seems to fail to trigger administration adjudication for patent linkage disputes. However, judging from the published administrative rulings, there are also cases where the requests for administrative adjudication have been filed and accepted based on Type 4.1 statement. [17] Nevertheless, as known from the published administrative adjudication documents, there are no accepted cases where the requests for administrative adjudication were filed based on Type 1 or 2 statement. According to practical experience, the CNIPA usually does not accept such cases at present, but only accepts the request for administrative adjudication filed where the generic drug applicant revises Type 1 or 2 statement to Type 4 statement.

In the U.S. practice, although, as known from the legal

provisions, only the Paragraph IV certification needs to be notified to the patentee and triggers the patent linkage litigation, [18] the condition for accepting patent linkage disputes is not limited to the Paragraph IV certification according to precedents. For instance, in *AstraZeneca Pharmaceuticals LP v. Apotex Corp*, 669 F. 3d 1370 (Fed. Cir. 2012), the CAFC stated that "by enacting §271(e)(2), Congress thus established a specialized new cause of action for patent infringement. When patentees pursue this route, their claims necessarily arise under an Act of Congress relating to patents. In short, '[o]nce Congress creates an act of infringement, jurisdiction in the district courts is proper under 28 U. S.C. § 1338(a).' … The requirements for jurisdiction in the district courts are met once a patent owner alleges that another's filing of an ANDA infringes its patent under § 271(e)(2), and this threshold jurisdictional determination does not depend on the ultimate merits of the claims."

5. Scope of trial of patent linkage litigation or administrative adjudication

According to Article 76 of the China's Patent Law, patent linkage litigation or administrative adjudication examines "whether the relevant technical solution falls within the scope of protection of others' drug patents", which belongs to a special declaratory action and does not involve any judgment on injunction or damages. In addition, as compared with the infringement determination in ordinary infringement litigation or administrative adjudication, the scope of trial of patent linkage litigation or administrative adjudication also has certain characteristics.

5.1 Examination as to whether patent listing is correct

It is clearly stipulated in the U.S. law that for patent listing errors, the applicant of a "paper NDA" submitted under Section 505(b)(2) or an ANDA submitted under Section 505 (j) may assert a counterclaim to correct or delete the patent information. [19]

Although there are no explicit provisions in this regard in China's laws and regulations, the cases cited in sections 3.1 and 3.2 herein show that the courts or administrative authority may examine whether the relevant listed patents should be listed during the substantive trial, and can rule to dismiss the lawsuit or the request for administrative adjudication if incorrect listing is found. [20] It means that in Chinese practice, whether the patent listing by the marketing authorization holder of the brand-name drug is correct falls within the scope of trial of patent linkage litigation or administrative adjudication.

A related issue is whether patent listing is correct can be examined *ex officio* or upon request by the party concerned. In *Daiichi Sankyo Company Limited v. Nanjing Hailing Pharmaceutical Co., Ltd. under Yangtze River Pharmaceutical Group*, a patent linkage dispute related to edoxaban tosilate tablets, the CNIPA held that "no law requires that whether a listed patent covers the technical solution of the brand-name drug shall be examined *ex officio* in administrative adjudication procedures for drug patent disputes. Where the generic drug applicant disputes such issue and proves by evidence that the accuracy of patent listing is indeed doubtful, the collegial panel can examine this defense." [21] According to the ruling, it seems that the CNIPA holds that the correspondence between the patent and the brand-name drug should be examined upon request, not *ex officio*. The author deems that correct patent listing, including correct status of a listed patent, the compliance of the listed patent type with the law, correspondence between the patent and the brand-name drug and the like, is the substantive requirement for a patent holder to file a patent linkage lawsuit or request administrative adjudication. Incorrect patent listing shall constitute a defense nullifying a right (rechtshindernde einrede), which renders the right substantively nonexistent and shall be considered *ex officio* by the courts or administrative authority. [22] In contrast, untimely patent listing cannot render the right substantively nonexistent, and is a procedural defense available for the opposing party and shall be examined by the courts or administrative authority at the request of the party concerned.

5.2 Examination on whether patent statement is correct

As mentioned in the above section 4, China's courts set relatively loose requirements for patent statements made by the generic drug applicants at the filing stage, and cases have been accepted except for Type 3 statement (patents related to brand-name drugs are recorded in the China's Patent Information Listing Platform for Marketed Drugs, and generic drug applicants promise that the generic drug applied for will not be launched in the market until a corresponding patent expires) that is nearly impossible to trigger patent linkage disputes. This demonstrates that in Chinese practice, whether patent statements are correct may be examined during patent linkage litigation. At present, the CNIPA has adopted more stringent standards for

accepting patent statements, i. e., it only accepts the request for administrative adjudication filed on the basis of Type 4 statement. Accordingly, the administrative adjudication usually does not involve the examination as to whether a patent statement is correct.

Type 4.1 patent statement is that "relevant patents should be declared invalid". According to Chinese laws, whether a patent should be declared invalid is examined in invalidation proceedings and administrative proceedings, and the validity of a patent should not be examined in civil proceedings or administrative adjudication. Therefore, regarding Type 4.1 patent statement, there is no need to examine whether a patent should be declared invalid in patent linkage litigation or administrative adjudication, but a judgment or ruling on "whether the technical solution in relation to a drug applied for listing falls within the scope of protection of others' drug patents" shall be directly made. Furthermore, in Chinese practice, where a patent in suit is declared invalid by the CNIPA, the court can rule to dismiss the lawsuit and the CNIPA to dismiss the request for administrative adjudication irrespective of whether the party concerned files an administrative lawsuit against the invalidation decision. [23]

Regarding Type 1 statement (no information on patents related to brand-name drugs is presented in the China's Patent Information Listing Platform for Marketed Drugs) or Type 2 statement (patents related to brand-name drugs in the China's Patent Information Listing Platform for Marketed Drugs have terminated or been declared invalid), the content thereof may be untrue and the truthiness thereof directly determines whether a patent linkage dispute exists legally, and the party who files a lawsuit will also claim that the statement shall be changed to Type 4 statement (or otherwise the party has no right to file a lawsuit or a request for administrative adjudication), which must be examined by the courts.

5.3 Determination of the accused technical solution

According to Article 76 of the China's Patent Law, the disputed technical solution is "the technical solution related to the pharmaceutical product that is applied for registration", rather than the technical solution of the commercially available drug, and therefore will be determined only according to the documentations used for marketing approval in a patent linkage dispute. In the first published patent linkage judicial case, *Chugai Pharmaceutical Co., Ltd. v. Wenzhou Haihe Pharmaceutical Co., Ltd.*, the Supreme People's Court made the following clarification: "when judging whether the technical solution of the generic drug falls within the scope of protection of the patent right, the declaration material for marketing approval of the generic drug applicant shall, in principle, be taken as the basis for comparison and evaluation. If the technical solution actually implemented by the generic drug applicant is inconsistent with the technical solution applied for marketing approval, the generic drug applicant has to take legal liability in accordance with the relevant laws and regulations on drug supervision and management. If the patentee or an interested party deems that the technical solution actually implemented by the generic drug applicant constitutes infringement, he or it can file a dispute over patent infringement separately. Therefore, whether the technical solution actually implemented by the generic drug applicant is identical with the declaration material for marketing approval generally does not fall within the scope of trial of a declaratory action on whether a technical solution falls within the scope of protection of a patent." [24]

Similarly, in the U.S. practice, in *AstraZeneca Pharmaceuticals LP v. Apotex Corp*, 669 F. 3d 1370 (Fed. Cir. 2012), the CAFC decided that "regardless what may or may not occur in the future, the infringement analysis under §271 (e)(2) is limited to whether the accused infringer's ANDA seeks approval for activities that would constitute infringement of the asserted patents".

A resulting procedural issue is who should bear the burden of proving the accused technical solution? Since the declaration materials for drugs applied for marketing approval are not publicly available, the patentee or interested party has no access to the declaration materials submitted by the generic drug applicant. Thus, the generic drug applicant shall bear the burden of proof, or the declaration materials shall be retrieved by the courts or administrative authority *ex officio*.

In this regard, according to Article 6 of the Implementing Measures, if the generic drug applicant files a statement that the generic drug does not fall within the scope of protection of a relevant patent, the basis for the statement shall be provided, and "the basis for statement shall include the claim chart between the technical solution of the generic drug and the relevant claim of the relevant patent, as well as the relevant technical materials". Article 3 of the Provisions on Several Issues Concerning the Application of Law in the Trial of Civil Disputes over Drug-Related Patents Applied for Listing also stipulates that "the marketing approval

applicant shall, within the time limit for filing the statement of defense in the first instance, submit to the People's Court the copy of necessary technical materials provided to the national drug evaluation angecy for determining whether the generic drug falls within the scope of protection of a relevant patent".

In the practice of administrative adjudication, in the series of cases concerning the patent linkage disputes related to ruxolitinib phosphate tablets between Novartis Pharma Switzerland AG and Nanjing Chia-Tai Tianqing Pharmaceutical Co., Ltd., the CNIPA decided that the technical solution of the generic drug falls within the scope of protection of the patent, holding that "in the administrative adjudication procedure under the early resolution mechanism for drug patent disputes, the generic drug applicant is responsible for submitting the technical solution of the generic drug. If he or it fails to submit the technical solution of the generic drug within the time limit specified by the collegial panel, he or it shall bear the legal consequences of failure to adduce evidence." [25]

5.4 Scope of trial for patent infringement determination

According to the provisions of Article 76 of the China's Patent Law, patent linkage litigation or administrative adjudication examines "whether the technical solution related to the pharmaceutical product that is applied for registration falls within the protection scope of any pharmaceutical product patent owned by others", rather than artificial infringement under 35 U.S.C. §271(e)(2) which reads "it shall be an act of infringement to submit …". The two legislations have both similarities and differences.

According to the Chinese legislation, "falling within the scope of protection of a patent" includes falling within the literal scope and the equivalent scope of a patent. The first published patent linkage judicial case as mentioned above (*Chugai Pharmaceutical Co., Ltd. v. Wenzhou Haihe Pharmaceutical Co., Ltd.*, a patent linkage dispute) involves equivalent infringement and limitations to equivalent infringement such as the doctrine of estoppel and the dedication rule, for which the same judging criteria as those for ordinary infringement determination are applied. In the U.S. practice, artificial infringement under 35 U.S.C. §271(e)(2) also includes literal infringement and equivalent infringement. For instance, in *Merck & Co., Inc. v. Mylan Pharmaceuticals, Inc.*, 190 F.3d 1335 (Fed. Cir. 1999), the court denied the equivalent infringement based on the doctrine of estoppel.

According to the U.S. legislation, artificial infringement under 35 U.S.C. §271(e)(2) may cover induced infringement and contributory infringement under 35 U.S.C. §271 (b) and (c). For instance, in *Sanofi v. Watson Labs. Inc.*, 875 F.3d 636 (Fed. Cir. 2017), the CAFC addressed induced infringement under 35 U.S.C. §271(b) and affirmed the district court's finding of inducement. According to the Chinese legislation, there is no definite answer to whether the circumstances of falling within the scope of protection of a patent include induced infringement and contributory infringement. According to the literal interpretation, when judging whether a technical solution falls within the scope of protection of a patent, it is only necessary to define the scope of protection of the patent (including the literal scope and equivalent scope) and then determine whether the accused technical solution falls within the defined scope of protection of the patent, whereas the infringement form is not examined. According to the system interpretation, compared with Article 65 of the China's Patent Law stipulating "the exploitation of a patent without the authorization of the patentee, that is, the infringement of the patent right of the patentee", Article 76 thereof adopts a different expression, i.e., "falling within the scope of protection of a patent". Different expressions generally should not be interpreted as the same. So far, I have not seen any interpretation of Article 76 made by legislators, or found any relevant cases in practice. In my opinion, according to the current expression of Article 76 of the China's Patent Law, "falling within the scope of protection of a patent" should not be interpreted as covering abetted infringement and contributory infringement. But for the sake of early resolution of drug patent disputes through the patent linkage system, it seems more reasonable to incorporate abetted infringement and contributory infringement into the patent linkage system, which requires the revision of relevant expressions of Article 76 of the China's Patent Law.

5.5 Examination of reverse payment

In patent linkage litigation or administrative adjudication, the parties concerned may request to withdraw the lawsuit or request for administrative adjudication, possibly because of the settlement agreement reached between them. A typical situation is that the brand-name drug patentee or interested party offers certain benefits to a generic drug applicant, especially the one who may enjoy an exclusivity period as the first follow-on applicant, in exchange for delayed marketing of the generic drug or not challenging the pat-

ents related to the brand-name drug, which is also called "drug patent reverse payment" in practice. This may prohibit or restrict competition, and require antitrust examination in patent linkage disputes.

In this regard, Article 17 of the Administrative Adjudication Measures for the Early Resolution Mechanism for Drug Patent Disputes stipulates:

"Before the CNIPA makes an administrative ruling, the requester may withdraw his request. If the requester withdraws his request or his request is deemed to have been withdrawn, the administrative adjudication procedure for drug patent disputes shall be terminated.

Where the requester withdraws his request after the conclusion of the administrative ruling has been announced, the effectiveness of the administrative ruling shall not be affected."

According to this provision, during the administrative adjudication, the CNIPA usually does not examine the withdrawal of the request for administrative adjudication, and therefore does not examine "drug patent reverse payment". As seen in the issued administrative rulings, a large proportion of cases were closed due to the withdrawal of the request for administrative adjudication by the requester. [26]

The Supreme People's Court does not set forth clear provisions in this regard in the Provisions on Several Issues Concerning the Application of Law in the Trial of Civil Disputes over Drug-Related Patents Applied for Listing. However, in *AstraZeneca AB v. Jiangsu Aosaikang Pharmaceutical Co., Ltd.*, a dispute over invention patent infringement, the Supreme People's Court analyzed for the first time whether a "drug patent reverse payment agreement" constitutes a monopoly agreement under the antitrust law, holding that "the examination on the illegal monopoly that may occur when a party concerned requests to withdraw the lawsuit or appeals in a non-monopoly case is usually confined to preliminary examination … As for the judgment on whether the 'drug patent reverse payment agreement' with the purpose of preventing the validity of patent from being challenged constitutes a monopoly agreement under the antitrust law, the key is to decide whether such an agreement will exclude or restrict competition in a relevant market …The examination should focus on the likelihood of the drug-related patent being declared invalid supposing the generic drug applicant does not withdraw the request for invalidation, and efforts shall be made to further analyze, based thereon, whether and to what extent the relevant agreement can harm the competition in the relevant market …In principle, if the patentee offers high compensation to the generic drug applicant without justifiable reasons in order to induce him or it to withdraw the request for invalidation, it can be taken as an important factor to determine that the patent is highly likely to be invalidated due to the request for invalidation submitted by the generic drug applicant, and meanwhile it is usually necessary to predict the examination result on the assumption that the generic drug applicant doesn't withdraw the request for invalidation." [27] This case involves an ordinary patent infringement dispute after the marketing of the generic drug, rather than a patent linkage dispute. Since the "drug patent reverse payment" often occurs in patent linkage disputes, it is quite necessary to hold discussions about the scope of examination of "drug patent reverse payment" in patent linkage disputes. Due to the subject matters of the article, no more discussion is conducted on the specific examination criteria.

According to the opinion of the Supreme People's Court in the above-mentioned case, the first thing to examine for the "drug patent reverse payment" is the likelihood of successful patent invalidation, and then harm to competition will be examined based thereon. However, in practice, people may have the following questions. First, does the court have jurisdiction to examine the validity of a patent on its own initiative? According to the Chinese laws, the validity of a patent shall be determined by the CNIPA in the invalidation decision. If the party concerned files an administrative lawsuit, the court can examine whether the invalidation decision is legal in administrative proceedings, but the court cannot take the initiative to declare the patent invalid in civil proceedings. Second, how can the court examine the validity of the patent without the participation of the parties concerned? Third, is the court's finding of the validity of the patent legally binding? May the court's finding be in conflict with the CNIPA's invalidation decision?

In the U.S. practice, although the court has jurisdiction to examine the validity of a patent in civil proceedings, the validity of the patent is not the court's priority in the examination on the "drug patent reverse payment". For instance, in *FTC v. Actavis, Inc. et al.*, 133 S. Ct. 2223 (2013), a case regarding "drug patent reverse payment", the U.S. Supreme Court reversed the decision made by a lower court, holding that "an antitrust action is likely to prove more feasible administratively than the Eleventh Circuit believed. The Circuit's holding does avoid the need to litigate the patent's

validity (and also, any question of infringement). But to do so, it throws the baby out with the bath water … It is normally not necessary to litigate patent validity to answer the antitrust question … A large, unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the patent's validity … a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent." According to the explanation of some U.S. scholars, the core insight of Actavis is the Actavis Inference: a large and otherwise unexplained payment, combined with delayed entry, supports a reasonable inference of harm to consumers from lessened competition. A trial court need not determine patent validity or infringement in order to assess the legality of the settlement. The antitrust question depends upon the *ex ante* prospects in patent litigation and not *ex post* litigation of the patent. Litigating the patent is thus of limited probative value and not dispositive regarding a potential antitrust violation. A subsequent finding of patent invalidity does not imply that there was an antitrust violation. [28]

The author holds that in view of the current infringement-validity dual track system in China and the court's difficulties in examining patent validity on its own, the antitrust examination of the "drug patent reverse payment agreement" should not take patent validity as the uppermost priority.

Another practical issue is that under the China's laws, how the court can obtain the settlement agreement in order to examine the "drug patent reverse payment"? In practice, the party concerned does not need to furnish the settlement agreement when filing a request to withdraw a lawsuit. [29] In the absence of definite legal provisions, it is impracticable for the court to require the parties concerned to provide a settlement agreement for every withdrawal request. In the U.S. practice, the settlement agreement reached between an NDA applicant and an ANDA applicant shall be reported to the Assistant Attorney General for the Department of Justice's Antitrust Division and the Federal Trade Commission (FTC) within ten working days from the date of execution of the agreement, [30] which renders the antitrust examination feasible. If the issues concerning "drug patent reverse payment" occur more frequently and have a significant impact in China in the future, it will be necessary to set forth as appropriate a system for ascertaining settlement agreements in patent linkage disputes by legislation. ■

The author: Deputy Manager of China Patent Agent (H.K.) LTD.

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[1] Retrieved from https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book; https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book; https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or.

[2] Wei Cong and Ren Xiaolan. Discussion on whether patent disputes related to Type 3 chemical generic drugs should be incorporated into the scope of administrative adjudication for early resolution mechanism for drug patent disputes. Retrieved from http://www.iprdaily.cn/article_32576.html.

[3] Where a drug differs from a reference listed drug with respect to active ingredient, route of administration, dosage form and specification, the applicant may also submit a "suitability petition" under Section 505(j)(2)(C) of the Food, Drug and Cosmetic Act. If approved, the applicant can submit an ANDA application under Section 505(j); and if not approved, the applicant can only submit a "paper NDA" under Section 505(b)(2). Jonathan J. Darrow et al. The 505(b)(2) drug approval pathway. *Food and Drug Law Journal, 74, 403-439*. For the specific content, please refer to pages 404, 405 and 414.

[4] For instance, the application for the drug Austedo submitted under Section 505(b)(2) differs from a reference listed drug merely in that some hydrogen atoms of the active ingredient are replaced by deuterium atoms. Retrieved from https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208082.

[5] According to the statistics collected by the author, almost all crystal form patents were invalidated in the invalidation cases before 2018. Things have been changed in 2018 and thereafter. Except for several years, more than 50% of crystal from patents on average were invalidated, and no invalidation decisions on crystal form patents have been revoked by the courts in administrative proceedings. As for the overview of invalidation against crystal form patents and the CNIPA's current examination criteria for invalidation against crystal form patents, see Hu Yang, Wang Yi and Ren Xiaolan (2022). Discussion on inventive step assessment in cases involving invalidation of pharmaceutical crystal inventions. *China Patents & Trademarks, 2*.

[6] See the Administrative Ruling No. Guozhiyaocaizi 0015/2022.

[7] He Wei and Ren Xiaolan (2023). Understanding of "crystal form" patents in administrative adjudication under early resolution mechanism for drug patent disputes. *China Patents & Trademarks, 3*.

[8] See the Civil Ruling No. Zuigaofazhiminzhong 7/2023.

[9] For instance, the ABBVIE's drug Ritonavir.

Xin Yao, *et al*. (2023). Ritonavir Form III: A new polymorph after 24 years. *Journal of Pharmaceutical Sciences 112, 237-242*.

[10] See the Civil Rulings Nos. Jing73minchu 208/2022 and 210/2022.

[11] In practice, untimely listing is not necessarily caused by negligence, and may be a strategy chosen on purpose by the marketing authorization holder of a brand-name drug. For instance, the data of the brand-name drug enjoys protection, and the right holder thereof usually has no incentive to list the patent during the protection period, and may choose to list the patent when the protection period is to expire.

[12] For instance, on the eve of the official launch of the patent linkage system, CSPC OUYI Pharmaceutical Co., Ltd. filed a generic drug application within three months after the approval of Roche Pharmaceuticals' baloxavir marboxil tablets. The generic drug was approved for marketing about 15 months later. Retrieved from https://www.163.com/dy/article/HJVOQH8D0553GIRG.html.

[13] For instance, see the Civil Judgment No. Zuigaofazhiminzhong 905/2022.

[14] For instance, see the Civil Ruling No. Zuigaofazhiminzhong 7/2023.

[15] For instance, see the Civil Ruling No. Jing73minchu 878/2022. The case was accepted by the case-filing division, but the patent was declared invalid by the CNIPA. Therefore, the trial penal ruled to dismiss the action.

[16] For instance, see the Civil Ruling No. Jing73minchu 574/2022. The case was accepted by the case-filing division, but the patent was declared invalid by the CNIPA. Therefore, the trial penal ruled to dismiss the action.

[17] For instance, see the Administrative Rulings Nos. Guozhiyaocai 0031/2022, 0006/2022 and 0013/2022.

[18] See 21 U.S.C.§355(b)(3), 21 U.S.C.§355(c)(3)(C), 21 U.S.C.§355(j)(2)(B)(ii) and 21 U.S.C.§355(j)(5)(B)(iii).

[19] See 21 U.S.C.§355(c)(3)(D)(ii), 21 U.S.C.§355(j)(5)(C)(ii), *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399 (2012).

[20] For instance, see the Administrative Ruling No. Guozhiyaocai 0015/2022, and the Civil Rulings Nos. Jing73minchu 208/2022 and 210/2022.

[21] See the Administrative Ruling No. Guozhiyaocai 0011/2022.

[22] Wang Zejian (2009). *General Principles of Civil Law* (1st edition, p. 104). Peking University Press.

[23] For instance, the Civil Ruling No. Zuigaofazhiminzhong 2177/2022 and the Administrative Ruling No. Guozhiyaocai 0006/2022.

[24] See the Civil Judgment No. Zuigaofazhiminzhong 905/2022.

[25] See the Administrative Rulings Nos. Guozhiyaocai 0035/2022 to 0040/2022.

[26] See, e.g., the Administrative Ruling No. Guozhiyaocai 0044/2022.

[27] See the Civil Ruling No. Zuigaofazhiminzhong 388/2021.

[28] Aaron S. Edlin *et al* (2015). The Actavis inference: Theory and practice. *Rutgers University Law Review, Vol. 67:585, 585-635*.

[29] *AstraZeneca AB v. Jiangsu Aosaikang Pharmaceutical Co., Ltd.*, a dispute over invention patent infringement. The settlement agreement was voluntarily provided by the party concerned to the court so as to prove that its accused infringement has been agreed in the settlement agreement, which is a special event.

[30] U.S.C. §§1112-1113, 117 Stat. 2461-2462.

CNIPA and SAIP Extend PPH Pilot Program

The China National Intellectual Property Administration (CNIPA) and the Saudi Authority for Intellectual Property (SAIP) have jointly decided to extend their Patent Prosecution Highway (PPH) pilot program for an infinite period of time from 1 November 2023. The established Guidance of CNIPA-SAIP PPH Request remains controlling the pertinent requirements and procedures governing applicants' PPH requests.

PPH is a fast track linking patent examination duties of different countries or regions, allowing patent examination authorities to speed up patent examination by work sharing. Since the initiation of the first PPH pilot program in November 2011, the CNIPA has built PPH ties with patent examination authorities of 32 countries or regions.

The extension of the CNIPA-SAIP PPH pilot program will continuously advance the two offices' cooperation in patent examination, provide better services to both Chinese and Saudi innovators and speed up patent examination process.

Source: CNIPA