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Special Issue

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Supervision Dynamics

The implementation of *Measures for the Quality Supervision and Administration of the Distribution and Use of Medicinal Products*

The State Administration for Market Regulation has promulgated *Measures for the Quality Supervision and Administration of the Distribution and Use of Medicinal Products (Order No. 84 of the State Administration for Market Regulation)*, which came into effect on January 1, 2024. The Measures consists of 7 chapters and 79 articles, which strengthen the quality management responsibilities of pharmaceutical marketing authorization holders, detail their management requirements for pharmaceutical sales personnel and sales activities, etc., and emphasize the quality management requirements for the entrusted storage and transportation activities of pharmaceutical marketing authorization holders. The main contents include: pharmaceutical traceability, signing of agreements for entrusted sales, filing at both sites for entrusted sales, entrusted storage and transportation, assessment and signing of agreements, filing at both sites for entrusted storage, training of pharmaceutical company sales personnel, the retention of records for at least 5 years and no less than one year after the expiration date, etc.

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The promulgation of *Technical Guidelines for the Pharmaceutical Research on Radiopharmaceutical Generics*

On January 31, 2024, in order to implement and advance the work related to the National Medical Products Administration (NMPA)'s *Opinions on Reforming and Improving the Review and Approval Management System for Radiopharmaceuticals*, and to promote the research and development of radiopharmaceuticals and scientific supervision, under the deployment by the National Medical Products Administration, the Center for Drug Evaluation has organized the formulation of *Technical Guidelines for the Pharmaceutical Research on Radiopharmaceutical Generics*. After being reviewed and approved by the NMPA, the *Guidelines* is hereby promulgated and shall come into effect upon promulgation.

This document aims to clarify the special technical requirements of radiopharmaceutical generics for the pharmaceutical research compared to conventional chemical drugs, providing technical guidance for the research and development of radionuclides, chemical precursors, ligands for radiopharmaceutical kits, automated synthesis of radiopharmaceuticals (including PET radiopharmaceuticals), radiopharmaceuticals prepared by radionuclide generators, radiopharmaceutical kits, etc.

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The NMPA announces the implementation of electronic administrative license documents for drug registration

In order to further optimize the business environment, stimulate the vitality of market entities, and provide more

efficient and convenient government affairs services for enterprises, the National Medical Products Administration (NMPA) has made a decision through research that started from May 1, 2024, NMPA will implement the electronic issuance of administrative license documents for drug registration, which include the promulgation document of national drug standards, notices of termination of drug registration applications, one-time import approval opinion notices for reference drugs, etc. Electronic administrative license documents for drug registration shall have the same legal force as their paper counterparts.

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The promulgation of *Q&A on Active Pharmaceutical Ingredient (API) Changes in "Technical Guidelines for Pharmaceutical Changes in Marketed Chemical Drugs (For Trial Implementation)"*

On June 7, the Center for Drug Evaluation of the NMPA promulgated *Q&A on Active Pharmaceutical Ingredient (API) Changes in "Technical Guidelines for Pharmaceutical Changes in Marketed Chemical Drugs (For Trial Implementation)"*, which shall come into effect upon promulgation. This specification aims to regulate and guide the research activities that pharmaceutical preparation holders should undertake when there is a change in the production process, production site, batch size, quality standards, etc., of the chemical APIs. It further delineates the technical requirements for related preparations when there is a change in the supplier of the APIs used for the preparations.

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The promulgation of *Technical Guidelines for the Pharmaceutical Research on Chemical Generic Suspension Nasal Sprays*

In order to regulate and guide the pharmaceutical research and development of chemical generic suspension nasal sprays, under the deployment by the National Medical Products Administration (NMPA), the Center for Drug Evaluation has organized the formulation of *Technical Guidelines for the Pharmaceutical Research on Chemical Generic Suspension Nasal Sprays*. In accordance with the requirements of the Notice on the Procedures for Release of Technical Guidelines for Drugs (No. 9 [2020] of the Department of Comprehensive Affairs, Planning, and Finance Affairs of the National Medical Products Administration), after being reviewed and approved by the NMPA, the Guidelines is hereby promulgated and shall come into effect upon promulgation (June 07).

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The promulgation of *Technical Guidelines for the Pharmaceutical Research on Compatibility and Stability of Chemical Injection (For Trial Implementation)*

To further clarify the technical requirements for the pharmaceutical research on the compatibility and stability of chemical injection and to improve the evaluation standard system for chemical injection, under the deployment by the NMPA, the Center for Drug Evaluation has organized the formulation of *Technical Guidelines for the Pharmaceutical Research on Compatibility and Stability of Chemical Injection (For Trial Implementation)*. In accordance with the requirements of *Notice of the Department of Comprehensive Affairs, Planning, and Finance Affairs of the NMPA on the Procedures for Release of Technical Guidelines for Drugs (No. 9 [2020] of the Department of Comprehensive Affairs, Planning, and Finance Affairs of the National Medical Products Administration)*, after being reviewed and approved by the NMPA, the Guidelines is hereby promulgated and shall come into effect upon promulgation (June 07).

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The National Medical Products Administration promulgates revised draft of the blood products appendix to *Good Manufacturing Practice for Drugs (2010 Revision)*

Following the implementation of *Drug Administration Law of the People's Republic of China*, the National Medical Products Administration, in accordance with Article 310 of *Good Manufacturing Practice for Drugs (2010 Revision)*, has revised the Blood Products Appendix. It is now promulgated as a supporting document of *Good Manufacturing Practice for Drugs (2010 Revision)* and shall come into effect upon promulgation (June 04). Specifically, for Articles 25 and 35 of the Appendix, the informatization construction of enterprise requires a certain period, and should comply with the relevant requirements by January 1, 2027; newly built workshops or production lines should meet the aforementioned requirements.

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The General Office of the State Council promulgates *Key Tasks for Deepening Medical System Reform in 2024*

On June 3, the General Office of the State Council promulgated *Key Tasks for Deepening Medical System Reform in 2024*, in which 22 specific measures, including the deepening of the reform of the medical insurance payment method, the deepening of the reform of the drug review and approval system, etc. are proposed across 7 areas, including the in-depth promotion of experience of medical reform in Sanming city, the deepening of reform and innovation in the pharmaceutical sector, etc.

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The promulgation of *Technical Guidelines for the Application of Decentralized Clinical Trials (DCT) in the Clinical Research and Development of Rare Disease Drugs*

On May 28, the Center for Drug Evaluation of the National Medical Products Administration promulgated *Technical Guidelines for the Application of Decentralized Clinical Trials (DCT) in the Clinical Research and Development of Rare Disease Drugs*. The Guidelines offers recommendations on how to apply DCT in the clinical research and development process of rare disease drugs, tailored to the unique characteristics of rare diseases, providing a reference for scientific and standardized DCT in the research and development of rare disease drugs. The guidelines stipulates that regardless of the adoption of DCT elements, the fundamental principles of Good Clinical Practice (GCP) must be adhered to, i.e., protecting the safety and rights of trial subjects, as well as ensuring the authenticity, reliability, and traceability of data. Among these, the safety and rights of the trial subjects take precedence over other considerations. The application of DCT elements in the clinical research and development of rare disease drugs should not increase the safety risks for the trial subjects.

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Public comments sought by the Department of Comprehensive Affairs, Planning and Finance Affairs of the National Medical Products Administration on *Announcement on the Promulgation of Requirements for Application Procedure and Application Materials of Domestically Manufactured Drug Re-registration*

The National Medical Products Administration has organized the formulation of *Announcement on the Promul-*

gation of Requirements for Application Procedure and Application Materials of Domestically Manufactured Drug Re-registration (Draft for Comment) to earnestly implement legal documents such as the newly revised Drug Administration Law, Vaccine Administration Law, Regulations for the Implementation of the Drug Administration Law, and Measures for the Administration of Drug Registration, fulfill the requirements for reform of the drug review and approval system, improve the drug registration system, strengthen the management of drug re-registration, and serve and promote the high-quality development of the pharmaceutical industry. Public comments are hereby solicited. The term of public comments is from May 13, 2024 to June 12, 2024.

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Public comments sought on *Technical Guidelines for Analysis and Handling of Suspected and Unexpected Serious Adverse Reactions (SUSAR) in Clinical Trials of Anticancer Drugs (Draft for Comment)*

On May 31, the Center for Drug Evaluation of the National Medical Products Administration sought public comments on *Technical Guidelines for Analysis and Handling of Suspected and Unexpected Serious Adverse Reactions (SUSAR) in Clinical Trials of Anticancer Drugs (Draft for Comment)*. The guidelines aims to provide ideas and suggestions for the rational collection and scientific analysis of SUSAR during the trial drug safety analysis and monitoring process of clinical trials for anticancer drugs, so as to assist in the discovery and identification of drug safety signals, thereby facilitating subsequent safety risk assessment of the trial drugs, as well as subsequent clinical research and development and risk management. The term of public comments is one month from the date of promulgation.

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The promulgation of *Technical Guidelines for Research on Improved New Traditional Chinese Medicine (For Trial Implementation)*

The Center for Drug Evaluation has organized the formulation of *Technical Guidelines for Research on Improved New Traditional Chinese Medicine (For Trial Implementation)* to further implement the encouragement of secondary development of traditional Chinese medicine, the promotion of high-quality development of the traditional Chinese medicine industry, etc. as required in *Opinions of Central Committee of CPC and State Council on Promotion of the Inheritance and Innovative Development of TCM*, *Implementation Opinions of the National Medical Products Administration on Promotion of the Inheritance and Innovative Development of TCM*, etc., and guide applicants in conducting research on improved new traditional Chinese medicine, thereby facilitating the inheritance of the essence of traditional Chinese medicine and to adhere to correct and innovative approaches. The guidelines is hereby promulgated and shall come into effect upon promulgation (May 13).

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The National Medical Products Administration and National Health Commission promulgated *Notice on Strengthening the Management of Dextromethorphan and Other Drugs*

Pursuant to *Announcement of the National Medical Products Administration, the Ministry of Public Security and the National Health Commission on Adjusting the Catalogue of Psychotropic Substances (no. 54, 2024)*, started from July 1, 2024, dextromethorphan (including salts, single-component preparations), nalfurafine (including salts, isomers, and single-component preparations), lorcaserin (including salts, isomers, and single-component preparations), and compound preparations containing diphenoxylate shall be included in the catalogue of Schedule II psychotropic substances; midazolam API (including salts, isomers) and injections are adjusted from

Schedule II to Schedule I psychotropic substances.

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The promulgation of *Annual Report of Clinical Trial Progress for New Drug Registration in China (2023)*

On May 20, the Center for Drug Evaluation of the National Medical Products Administration promulgated *Annual Report of Clinical Trial Progress for New Drug Registration in China (2023)*. The *Report* indicates that, in 2023, the total number of clinical trials registered on the drug clinical trial registration and information disclosure platform exceeded 4,000 for the first time. The efficiency of clinical trial implementation is further improved, with the initiation efficiency also seeing an enhancement. According to the *Report*, trials for Schedule 1 innovative drugs accounted for 69.1% of the total volume of new drug clinical trial registrations. Although Schedule 1 innovative drugs are generally still in the early stage of research and development, there has been a slight increase in the proportion of Phase II and III clinical trials compared to the previous year. The *Report* also reflects the positive impact of policies that encourage research and development: there is a significant upward trend in the number of clinical trials of drugs for specific populations, such as pediatric and rare disease patients; and the number of clinical trials of medical imaging and radiopharmaceuticals has maintained a slight increase. Research and development enterprises have strengthened their layout in new technical fields such as cell therapy and gene therapy. In 2023, a total of 81 clinical trials for cell and gene therapy products were registered, nearly doubling compared to 2022.

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National Medical Products Administration promulgated *Classification Catalogue of In Vitro Diagnostic Reagents*

In accordance with the provisions of *Administrative Measures on the Registration and Record-filing of In Vitro Diagnostic Reagents (Decree No.48 of the State Administration for Market Regulation)*, *Announcement of the NMPA on the Promulgation of Classification Catalogue of In Vitro Diagnostic Reagents (No. 29 Announcement of NMPA, 2021)*, etc., the National Medical Products Administration has organized the revision of *6840 In Vitro Diagnostics Reagents Classification Sub-catalog (2013)* to form *Classification Catalogue of In Vitro Diagnostic Reagents*, in order to implement the relevant requirements of *Regulation on the Supervision and Administration of Medical Devices (Decree No.739 of the State Council)* and further guide the classification of in vitro diagnostic reagents. The *Classification Catalogue of In Vitro Diagnostic Reagents* is hereby promulgated.

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National Medical Products Administration conducts management review of the vaccine quality management system

On May 11, the National Medical Products Administration conducted the 2023 annual management review of the Vaccine Quality Management System (Vaccine QMS). Li Li, Secretary of the Leading Party Group and Director of the NMPA, chaired the meeting and evaluated the suitability, adequacy, and effectiveness of the NMPA organ's vaccine quality management system. During the management review, the Policy and Law Department, as the leading department for the construction of the NMPA organ's Vaccine QMS, reported on the overall situation of the construction and operation of the Vaccine QMS in 2023, and reported on identified issues, rectification and reform, and suggestions for system improvement. In the meeting, the annual system operation of various system constituent departments, such as Department of Comprehensive Affairs, Planning, and

Finance Affairs, Department of Policies and Regulations, Department of Drug Registration, Department of Drug Regulation, Department of Human Resources, etc., are deliberated.

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National Health Commission and Seven Other Departments issue *Guiding Opinions on Strengthening the Construction of Critical Medical Service Capacity*

On May 6, the National Health Commission, along with seven other departments, issued *Guiding Opinions on Strengthening the Construction of Critical Medical Service Capacity*. The opinions propose that, by the end of 2025, the national capacity for critical care medical beds (including comprehensive ICU beds and specialty ICU beds, the same below) will reach 15 per 100,000 people, with convertible critical care medical beds reaching 10 per 100,000 people, and the ratio of comprehensive ICU beds to physicians in relevant medical institutions will reach 1:0.8, with a bed-to-nurse ratio of 1:3. By the end of 2027, the national capacity for critical care medical beds is expected to reach 18 per 100,000 people, with convertible critical care medical beds reaching 12 per 100,000 people, effectively expanding the resources for critical medical service and achieving a more balanced regional layout with significantly enhanced specialty service capabilities.

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Notice of National Medical Products Administration on relevant matters concerning optimizing the application for the marketing registration of overseas-manufactured drugs that have been marketed in China and are transferred to be manufactured in China

For the purposes of further optimizing the foreign investment environment, promoting the high-quality development of the pharmaceutical industry, improving the accessibility of drugs, and satisfying the people's needs for drugs, the application procedure for the marketing registration of the overseas-manufactured drugs that have been marketed in China and are transferred to be manufactured in China is hereby optimized in accordance with *Opinions of the State Council on Further Optimizing the Foreign Investment Environment and Increasing Efforts to Attract Foreign Investment (No. 11 [2023], State Council)* and *Announcement of the NMPA on Promulgation of the Administrative Measures for Drug Post-marketing Changes (for Trial Implementation) (No. 8 [2021], State Council)*. The relevant matters are hereby announced as follows:

I. Where any overseas-manufactured drug that has been marketed in China is transferred to be manufactured in China, a domestic applicant shall file an application in accordance with the requirements and procedures of application for registration of drug marketing.

II. Where any overseas-manufactured drug that has been marketed in China is transferred to be manufactured in China, the domestic applicant may submit the original registration application materials of the overseas-manufactured drug, and submit the relevant research materials on the transfer of the drug to domestic manufacturing in support of its application for registration of drug marketing. The specific requirements for application materials shall be separately formulated and promulgated by the Center for Drug Evaluation of the National Medical Products Administration.

III. For the application for marketing registration of RLD chemical drug and biological product that are transferred to be manufactured in China, the National Medical Products Administration shall incorporate it into the scope of application of priority review and approval.

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The promulgation of *National Drug Sampling Inspection Annual Report (2023)*

On March 26, the National Institutes for Food and Drug Control promulgated *National Drug Sampling Inspection Annual Report (2023)*. The Annual Report indicates that, in 2023, the national drug sampling inspection tasks involving a total of 18,762 batches of preparation products and traditional Chinese medicine slices across 132 varieties are completed, with samples sourced from 1,114 drug manufacturers, 2,528 operating enterprises, and 511 usage institutions. The inspection of samples was conducted by 47 testing organizations, including the National Institutes for Food and Drug Control, and 136 batches of non-compliant products were identified. The sampling inspection results demonstrate that the current drug safety situation in China is generally stable and controllable, with drug quality consistently maintained at a high level.

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The promulgation of *National Adverse Drug Reaction Monitoring Annual Report (2023)*

On March 26, the National Center for Adverse Drug Reaction Monitoring promulgated *National Adverse Drug* Reaction *Monitoring Annual Report (2023)*. The *Report* indicates that, in 2023, the national adverse drug reaction monitoring network received 2.419 million *Adverse Drug Reaction/Event Report Forms*, with an average of 1,716 reports per million population, and 98.5% of the county-level areas across the country reported adverse drug reactions/events.

The *Report* comprehensively reflects the overall situation and role of adverse drug reaction monitoring in China in 2023. It demonstrates that the National Center for Adverse Drug Reaction Monitoring effectively carried out various monitoring works throughout the year of 2023, e.g., collaborating on the revision of *Measures for the Reporting and Monitoring of Adverse Drug Reactions*, and advancing the informatization construction for the extraction of adverse drug reaction terminology of innovative drugs and drugs conditionally approved, which provides scientific and robust support for drug regulation and effectively protects and promotes public health.

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Industry Dynamics (China)

China to host AIPPI for the first time

China is set to host the AIPPI Congress for the first time, marking a significant milestone in the organization's 127-year history. The 2024 AIPPI Congress, hosted by the China Council for the Promotion of International Trade (CCPIT) and the International Association for the Protection of Intellectual Property (AIPPI), and organized by the People's Government of Hangzhou and the China Branch of AIPPI, will take place in Hangzhou, Zhejiang Province, from October 19th to 22nd.

Zhao Ping, spokeswoman for the CCPIT, said that the theme of the conference is "Balanced Protection and Innovative Development of Intellectual Property Rights", and it is expected that 1,500 guests from over 80 countries and regions will attend. "The first-time hosting of the AIPPI Congress in China reflects the international community's high regard for China's great focus on intellectual property protection, strengthening of the legal safeguard of intellectual property, and improvement of the intellectual property management system. It is of great significance for promoting exchanges and cooperation between Chinese and foreign intellectual property worlds, deepening China's participation in the formulation of international intellectual property rules, and promoting China's achievements in intellectual property protection to the world. This will become a milestone event in the history of China's work on intellectual property protection," she said.

Source: CCPIT

Novartis' innovative medicine Tabrecta® approved in China

On June 12, Novartis announced that its non-small cell lung cancer (NSCLC) treatment, Tabrecta ® (capmatinib hydrochloride tablets), has been approved by the National Medical Products Administration of China, and is indicated for adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) who have not received systematic treatment and carry a mesenchymal-epithelial transition factor (MET) exon 14 skipping (METex14).

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Bayer receives CDE Breakthrough Therapy designation for new targeted therapeutic drug for lung cancer

Recently, the Center for Drug Evaluation of the National Medical Products Administration (NMPA) of China has granted Breakthrough Therapy designation for BAY 2927088, a new targeted therapy for adult patients with unresectable or metastatic non-small cell lung cancer (NSCLC), whose tumors have activating HER2 mutations, and who have received a prior systemic therapy. BAY 2927088 is a tyrosine kinase inhibitor in development by Bayer. It is currently being evaluated as a potential new targeted treatment option for patients with NSCLC harboring HER2 activating mutations. In February 2024, the U.S. Food and Drug Administration (FDA) also grant-

ed BAY 2927088 Breakthrough Therapy designation.

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Yunnan Baiyao's INR101 injection approved for clinical trial

On May 9, Yunnan Baiyao's wholly-owned subsidiary, Yunhe Pharmaceutical, received tacit approval from the Center for Drug Evaluation of the National Medical Products Administration for its INR101 injection. The INR101 injection is a Schedule 1 innovative drug in the field of radiodiagnosis developed by Yunhe Pharmaceutical, and is indicated for PET imaging of PSMA-positive lesions in patients with prostate cancer.

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Roche's MabThera® subcutaneous formulation approved in China

On April 8, Roche Pharma China announced that its product MabThera® (generic name: rituximab injection for subcutaneous use) has been officially approved by the National Medical Products Administration of China for:

- patients with CD20-positive Stage III-IV follicular non-Hodgkin's lymphoma, who have not received treatment, in combination with chemotherapy;
- patients with previously-treated follicular lymphoma, who are to receive alone-maintenance treatment after the disease is completely or partially alleviated by MabThera plus chemotherapy;
- relapsed or chemotherapy resistance follicular lymphoma;
- CD20-positive diffuse large B-cell lymphoma (DLBCL), in combination with the standard CHOP chemotherapy regimen (cyclophosphamide, doxorubicin, vincristine, prednisone) for 8 cycles.

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Cases

SPC case: Six-year patent dispute in the Sino-US medical field, awarding damages of RMB 20 million

In February 2024, SPC issued a second instance judgment in a patent infringement dispute between a US company (the plaintiff) and a Yueyang biotechnology company, among others (the defendants). The court held the defendants to pay economic damages of RMB 18.5 million and reasonable expenses of RMB 1.5 million.

On October 25, 2017, the plaintiff filed a patent infringement lawsuit in the Shanghai Intellectual Property Court (the first instance court), accusing the defendants of infringing its invention patent. On May 31, 2021, the court issued a first instance judgment, awarding damages of RMB 11 million. Both the plaintiff and the defendants appealed to SPC. SPC held that based on the evidence presented, not all the products claimed by the plaintiff shall be identified as infringing products. In addition, SPC, relying on the financial ledgers provided by the defendants for some product models, held that the defendants' minimum sales revenue during the period from May 2016 to March 2021 shall be RMB 197,910,204 (approximately RMB 200 million). The profit from infringement was at least RMB 23,749,224 (approximately RMB 23.75 million), which exceeded the amount of damages claimed by the plaintiff in this case. Therefore, SPC fully supported the plaintiff's claim for damages.

Source: SPC

SPC Case: Responding to biosequence patent infringement claims based on patent examination history

Recently, SPC concluded the case of patent infringement involving Amyris Biotechnologies (Plaintiff) and Hebei Kainali Biotechnology Co., Ltd. and Shanghai Xihao Trading Co., Ltd. (Defendants). This case relates to biosequence patent infringement. The court found that the patent involved a protease with a specific mutation sequence. During patent prosecution, both the first and second office actions clearly stated that the claims in the patent application documents were not supported by the specification. Plaintiff adopted these amendment suggestions, changing "including" to "existing" and making further amendments based on the third office action, ultimately being granted a patent. It can be inferred that during patent prosecution, Plaintiff gave up the possibility of other mutations beyond the seven validated mutation methods by amending the claims. However, in this infringement lawsuit, the plaintiff argued again that the scope of protection of claim 3 of the patent included the possibility of amino acid sequence mutations at other sites beyond the seven mutation methods, which lacks legal basis and is not supported. The evidence in the case does not prove that the infringing product has the same amino acid sequence as claim 4 of the patent, so it cannot be determined that the infringing product falls within the scope of protection of the patent. Plantiff's claim that Kainali's infringing product falls within the scope of protection of claims 3 and 4 of the patent lacks factual and legal basis, and the court does not support this.

Source: Shanghai Intellectual Property Court

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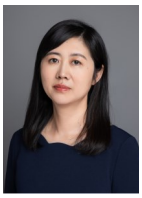

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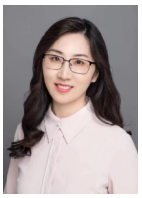

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