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China’s new Patent Term Extension: A Welcome Change for Innovators

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On December 21, 2023, the China National Intellectual Property Administration (CNIPA) issued the final version of the revised Implementing Rules for the Patent Law and the Guidelines for Patent Examination, which will become effective on January 20, 2024. These Regulations complete legislative efforts on changes to the Chinese patent system introduced by the 4th amendment to the Patent Law that was promulgated in June 2021. They also provide details on the much-anticipated Chinese patent term extension introduced by Art. 42(3) of the Patent Law back in 2021. The patent term extension (PTE) is to compensate for the loss of the effective patent term due to time spent on seeking marketing approval of new drugs.

PTEs are available for patents in China on certain **new drugs and improved new drugs**. Eligible patents are compound patents, formulation patents, crystal patents, method of manufacture patents and medical use patents (both first and second medical uses) but do not include intermediate patents. “New drug” refers to innovative drugs and specified improved new drugs according to the definition provisions of the related Laws and Regulations and in accordance with the National Medical Products Administration (NMPA)?provisions. However, according to the *Work Plan for the Reform of Chemical Drug Registration Classification* and its official interpretation implemented by the NMPA, “innovative drugs” refers to new drugs that have not been marketed in China or abroad. Therefore, according to the position of CNIPA, “innovative drugs” means Class 1 new drugs, which are “new globally,” not just “new in China.” Despite this, neither the Patent Law nor the Implementing Rules gives a specific definition for “new drugs.” There is therefore the possibility that CNIPA’s position on the interpretation of new drugs will be challenged in future litigation.

Another class of eligible drugs are “improved new drugs.” These are listed on the drug certificates issued by NMPA and fall into one of the following categories: 1) chemical drugs of class 2.1 that form esters or salts of known active ingredients; 2) chemical drugs of class 2.4 (i.e. drugs containing known active ingredients for new indications); 3) preventive biological products of class 2.2 that are vaccines improved against bacterial or viral strains; 4) therapeutic biological products of class 2.2 for new indications; 5) traditional Chinese medicine of class 2.3 (i.e., traditional Chinese medicines with increased functions and indications).

Other types of improved new drugs are not eligible. They are 1) drugs based on optical isomers of known active ingredients, or modified acid radicals, bases or metal elements of known salt active ingredients, or other non-covalent-bond-forming derivatives (such as complexes, chelates or

inclusion compounds); 2) new dosage forms (including new drug delivery systems) containing known active ingredients; new formulation processes, and new methods of administration; and 3) new combination formulations containing known active ingredients.

A PTE must be requested within 3-months from the date of marketing approval in China and meet the following requirements: 1) the issue date of the patent must be earlier than the approval date of the medicine in China; 2) the patent term must not have expired; 3) The patent must not have been previously granted a PTE; and 4) the new drug must fall within the scope of the patent. Moreover, if the drug is covered by multiple patents, a PTE is available for one patent only. If one patent covers multiple drugs, a PTE request can be based on one drug only. For patents that expire before January 20, 2024, a PTE is still available if the requirements for PTEs are met. But PTEs cannot be sought for drug-related patents where the relevant medicine was approved for marketing in China before June 1, 2021 (i.e., the effective date of the fourth amendment to the Chinese Patent Law).

The term extension calculation is similar to the European system, namely subtracting the period between patent filing and marketing approval by 5 years. The overall PTE duration is restricted to 5 years after normal patent expiry **and** 14 years after marketing approval (which is the same as the U.S., although the method of calculating term extension is different.).

If there is any disagreement regarding the eligibility or length of a term extension between a patentee and CNIPA, the patentee or interested parties can apply for administrative reconsideration by the CNIPA. Subsequent judicial review is available to parties dissatisfied with the reconsideration decision. They can file a lawsuit with a court within fifteen days from the date of receiving the reconsideration decision.

The introduction of PTEs in China is a win for pharmaceutical companies because it can provide additional years of protection which were not previously available. While it was modeled on the U.S. and European systems (i.e., SPC), it has some unique characteristics. For example, a Chinese PTE will be limited to the indication for which the PTE is applied, i.e., a PTE is indication-specific. This is rather different from the U.S. With this indication-specific PTE, generics and biosimilars can try to bypass the PTE with skinny labels and promote off-label use. While off-label use is largely illegal in China, combatting off-label use is not straightforward. Having said this, certain reimbursement is based on indication meaning that off-label use cannot obtain reimbursement if being dispensed for the patented use. There is also the option of launching patent infringement litigation against off-label use.

In short, the patent term extension provisions are a positive development for innovators. Innovative drug companies should be prepared to align their IP, regulatory, marketing and sales teams to ensure PTE eligibility for those drugs that are most important for the Chinese market. In particular, while pre-clinical trials and product registration testing can generally be carried out abroad, sponsors should consider conducting their clinical trials in China at a fairly early stage in order to support their Chinese marketing approval application. Specifically, as noted above, CNIPA ‘s position is that new PTEs apply only to new drugs and new indications submitted in China before they are approved in any other country. This could arguably change multinational pharmaceutical companies’ global regulatory strategy. Of course, global patent filing strategy will also need to be adjusted if the goal is to maximize Chinese PTEs.

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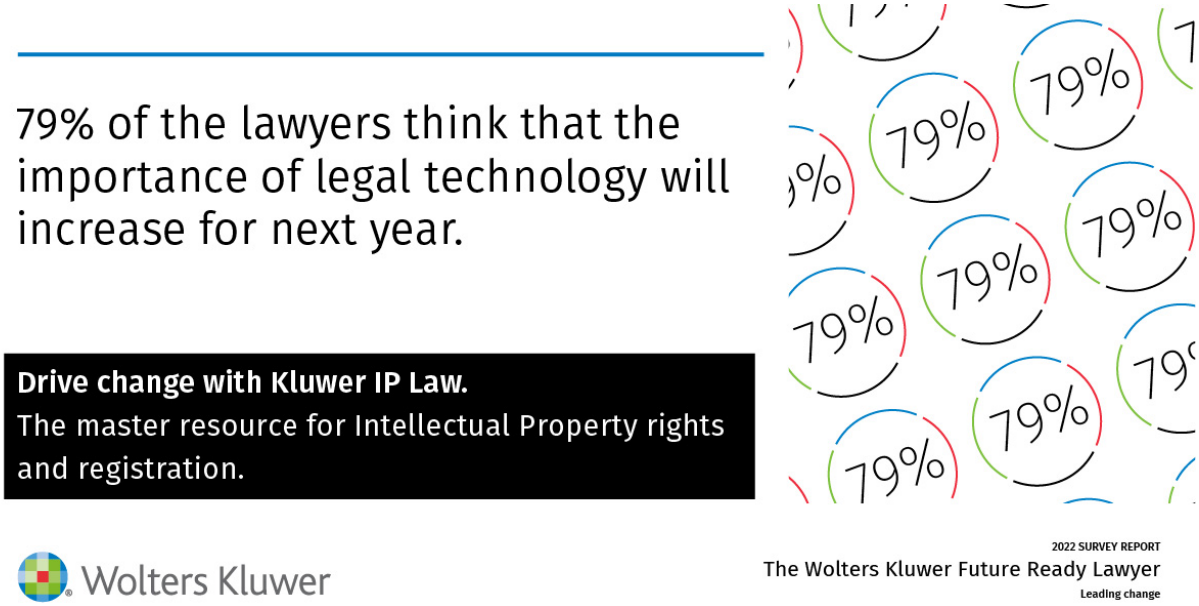

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