Patent Term Extension and Data Exclusivity
A Brief Comparison of China and the United States

It typically takes over a decade of research and development and tremendous investment to bring a new drug from laboratories to patients. To encourage innovative pharmaceutical research, certain countries provide special protective measures for the pharmaceutical industry to at least partially recoup its investment cost. For example, the United States provides patent term extensions for pharmaceutical patents to remedy patent term losses due to regulatory approval delays. The U.S. also provides certain protection of the safety and efficacy data that the innovative pharmaceutical companies generated and submitted for regulatory approval from being referenced in generic drug applications. As the U.S. and China are two of the largest pharmaceutical markets in the world, we provide a brief comparison of the general legal framework and practices in the United States and China in terms of patent term extension (PTE) and data exclusivity.

Patent Term Extension
In the United States, obtaining regulatory approval of a new drug may be a long process. To remedy the loss of certain patent term due to regulatory delays, the U.S. Patent Law provides patent term extension for a patent that claims a product, a method of making a product, or a method of using a product that has been subject to premarket regulatory review. 35 U.S.C. § 156(a). In general, the extension of the patent term equals one half of the testing period and the entire approval period of an approved drug, except that any time during which the New Drug Application (NDA) applicant did not act with due diligence during the regulatory review period is deducted from the testing or approval period. 35 U.S.C. § 156(c)&(g). The testing period starts from the date an Investigational New Drug Application becomes effective to the NDA filing date; the approval period starts from the NDA filing date to the NDA approval date. 35 U.S.C. § 156(g)(1)(B).

The testing and/or approval period in the U.S. can be protracted periods of time. PTE, however, cannot be unlimited. PTE is capped in two ways: (1) the remaining patent term after the drug approval as extended by PTE cannot exceed 14 years; and (2) the
period of patent term extension cannot exceed 5 years from the original expiration date of the patent. 35 U.S.C. § 156(c)(3)&(g)(6). In addition, only one PTE is granted for an approved drug product even if multiple patents cover the same approved product, and a patent can only be granted one PTE even if it covers more than one approved product.

In contrast, China currently does not provide any patent term extension even though the drug approval process there can be very long as well. As sales of many patented drugs peak after expiration of the relevant patents, innovative pharmaceutical companies are hoping that China would model the U.S. patent system and provide appropriate patent term extensions to remedy patent term losses due to regulatory approval delays. Despite the fast growth in innovative pharmaceutical research in China, however, the Chinese pharmaceutical industry is still predominantly generic, at least for the time being. The Chinese government is cautious towards laws, regulations, and policies that might burden the overall pharmaceutical industry and limit public access to affordable medicine.

Thus, strategies on patent application filing, prosecution, and management to strengthen and prolong protections of new drug products and methods of treatment and manufacture are critical to innovative pharmaceutical companies in China. For example, a company should carefully consider the timing for filing a patent application: filing too early relative to clinical testing may lead to a certain scenario where the patent expires before the drug receives approval and goes on the market; yet filing too late may jeopardize novelty of the claims. A company may also consider a tiered patenting strategy: first obtaining patent protections of the basic compound invention, and then filing applications to cover other aspects of the drug, such as salts, esters, hydrates, polymorphs, new formulations, new administration routes, and new indications as the data becomes available. Of course, these patent strategies can also be applied in the United States to achieve similar purposes, in addition to the statutory patent term extension.

Data Exclusivity

Sometimes, a patent covering a drug expires or is close to expiring before the drug is approved for market. Other times, a new drug may not be protected by a patent at all, for example, when the patent covering the drug is invalidated. To ensure innovative pharmaceutical companies to at least partially recover their investment, the United States provides certain protections of the safety and efficacy data generated and submitted for marketing approval. That is, a generic company cannot reference the safety and efficacy data generated and submitted by an NDA holder to seek approval of a generic drug until the appropriate data exclusivity periods have expired.

In general, there are four types of data exclusivity in the United States: (1) new chemical entity (NCE) exclusivity, (2) clinical investigation exclusivity, (3) pediatric exclusivity, and (4) orphan drug exclusivity. Under the NCE exclusivity, the first applicant to receive NDA approval for a drug product containing an active moiety that is a new chemical entity enjoys a 5-year period of data exclusivity. See 21 U.S.C. §§ 355(c)(3)(E)(ii), 355(j)(5)(F)(ii); 21 C.F.R. § 314.108. During this 5-year period, no other company can submit an NDA or an abbreviated new drug application (ANDA) seeking regulatory approval of a drug product containing the same active moiety. Id. One exception to this rule is that such an application may be submitted after 4 years if it
contains a certification of patent invalidity or noninfringement (the so-called paragraph IV certification). \textit{Id.} Thus, in practice, this 5-year exclusivity period may be extended to at least 6 to 7 years because typically it takes the U.S. Food and Drug Administration (FDA) one to two years to approve such an application.

Under the clinical investigation (CI) exclusivity, an applicant that submits a new or supplemental NDA, containing reports of new clinical investigations (other than bioavailability studies) essential to approval of the application, is entitled to 3-year data exclusivity. 21 U.S.C. §§ 355(c)(3)(E)(iii)\&(iv), 355(j)(5)(F)(iii)\&(iv); 21 C.F.R. § 314.108(b)(4)\&(5). A company may receive CI exclusivity for new clinical investigations on new formulations, salts, new indication, new dosage form, new dosage strength, or new route of administration of a previously approved drug product.

A company sponsoring a drug treating a rare disease or condition may be granted a 7-year orphan drug data exclusivity. 21 USC § 360cc; 21 C.F.R. § 316. During that 7-year period, the U.S. FDA will ordinarily not approve another company’s marketing application for the same drug for the same use or indication. 21 C.F.R. § 316.31. However, the U.S. FDA may approve the same drug for a different indication, or for the same orphan indication if the drug is clinically superior to the previously approved orphan drug. 21 C.F.R. § 316.34.

A company may also be granted a six-month pediatric exclusivity after submission of pediatric studies at the U.S. FDA’s request, regardless of whether the studies are successful or not. 21 USC § 355a(b). The 6-month pediatric exclusivity period does not stand alone and is attached to the end of any existing exclusivity and patents for any drug product containing the same active moiety as the drug studied. \textit{Id.} Compared to the United States, data protection in China is very weak. China provides some data protection for drugs containing new chemical ingredients, but does not provide any other type of data protection. “According to Article 35 of Implementation Regulation of the Pharmaceutical Administration Law, for a period of 6 years from the date of the original applicant’s approval, the Chinese FDA shall not approve a subsequent application that used, without the express consent of the original applicant, the undisclosed R&D data and other data generated by the original applicant for submission of application of manufacturing or marketing of a drug containing new chemical ingredients, unless the submitted data is generated by the subsequent applicant itself.” Article 20 of the Drug registration Regulation. That is, within 6 years from the date of the original applicant’s approval, a drug application using the original applicant’s undisclosed data without express consent will not be approved in China. Publicly disclosed data from the original applicant, however, can be used in another drug application within the data protection period.

In practice, this data protection mechanism in China may be easily circumvented. China requires only a limited set of data for market approval of a generic drug. A company may rely on its own data and apply for approval of a generic drug during the drug protection period. Thus, data protection in China is more of a literal sense, and is much narrower than the data exclusivities provided in the U.S. And the data protection laws and regulations in China are not well defined or clearly interpreted, resulting in confusion and conflicts in some cases.

This situation may be changed in the near future, however, as amending the Pharmaceutical Administration Law has been included in the current five-year
legislature plan of the Chinese National Standing Committee. The Chinese FDA is in the process of collecting comments regarding issues on the enforcement of the current Pharmaceutical Administration Law. See www.sda.gov.cn/WS01/CL0778/95775.html

Overall, compared to the U.S., the Chinese laws and regulations provide much weaker protections, and thus less incentive, for innovative pharmaceutical research. But as the Chinese pharmaceutical industry is transforming from generic to innovative, the pharmaceutical laws, regulations, and policies in China will likely change to promote and accommodate this trend in the coming years.

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