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U.S. – China Trade Agreement: China Agrees to Make Changes That Could Benefit U.S. Drug Companies Doing Business in China

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Most notably, China agreed to take steps to implement a patent resolution procedure, similar to that provided in the Hatch-Waxman Act, to resolve patent disputes before generic drugs enter the Chinese market. The Agreement leaves it to China to develop and implement the precise details for this patent resolution procedure consistent with its legal system. However, the Agreement requires that the procedure include a notification system whereby patent holders, licensees or parties who previously submitted safety and efficacy information to secure marketing approval are informed when another party seeks approval based on the same information. The procedure must also provide for a system to adjudicate patent rights and expeditious remedies, which will possibly include preliminary injunctive relief or equivalent measures.

China also agreed to allow pharmaceutical patent applicants to rely on supplemental data (for example, test results) to satisfy the requirements for patentability during patent examination, patent review and judicial proceedings. Implementing this provision will provide applicants and patent owners in China similar opportunities to present helpful supporting data as applicants and patent owners in the United States have enjoyed.

Finally, the Agreement provides that China will establish mechanisms to modify a patent's term similar to those provided in 35 U.S.C. §§ 154, 156. Specifically, the Agreement allows term extensions for patents whose issuance is unreasonably delayed during examination for reasons not attributable to the applicant. The Agreement also provides that the terms of patents covering new pharmaceutical products (or methods of making or using such

products) can be extended to compensate for unreasonable delays in receiving Chinese marketing approval. However, China may limit such adjustments to no more than five years, and may limit the resulting effective patent term to no more than 14 years from the date of marketing approval in China.

The Agreement provides China with 30 working days to promulgate an Action Plan identifying the measures it will take to implement its obligations related to intellectual property reform and the date by which the measures will go into effect. However, the ultimate impact of the Agreement will depend largely on when and how these provisions are implemented and on the strength of the protections ultimately provided. But at least on their face, the provisions of Chapter 1 of the Agreement represent a commitment from China to take steps to improve protections for innovative pharmaceutical companies.

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