

Paper Title: Fighting Poison with Poison?: The Chinese Experience with Pharmaceutical Patent Linkage

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Abstract

U.S. trade negotiators have renewed their push for mandatory regulatory patent linkage, which requires governments to deny market approval to certain generics drugs in favor of the company that originally invented the drug. The recently concluded South Korea-United States Free Trade Agreement (KORUS) dramatically raised the bar for generics approval there. For its next major trade effort, the United States proposed numerous intellectual property provisions into the Trans-Pacific Strategic Economic Partnership Agreement (TPP) which, if adopted, would introduce a robust patent linkage system into Australia, Brunei, Chile, Japan, Malaysia, New Zealand, Peru, Singapore and Vietnam.

At the center of this brewing storm sits China, which curiously took up patent linkage without any treaty obligations 10 years ago. China appears to be the proverbial missing link between the patent linkage standards around the Pacific—Its experience with patent linkage is both the source of the TPP patent linkage proposal as well as its intended target. And yet accounts of the pharmaceutical IP regulatory framework in China remain few, conflicting and incomplete.

This study examines each component of the Chinese patent linkage system in detail, including the new-drug/generics-drug divide, the drug-patent list, the patent-linked approval process, dispute resolution, the post-registration cancellation process, and the patent challenge incentive system. The analysis references actual legal disputes and highlights analogies and differences with the practice in the U.S., where patent linkage originated. It then explores several scenarios where patent linkage fails to keep infringing drugs off the market. Contrary to the conventional and grand discourse that situates a country's resistance to patent linkage within its desire to protect domestic interest, the study shows more mundane and ad hoc reasons of failure: the Chinese regulation promised more IP protection than what even the United States FDA is capable of deliver and the SFDA faced institutional weakness that undermines its effort in all areas of oversight. In short, it shows what can go wrong when patent linkage is hoisted upon a country in the absence of a professional administration, a realistic legal design and a palatable message.

The SFDA's experience with patent linkage also serves as a cautionary tale to the United States that more legal requirements may actually hinder enforcement. Historically, patent linkage emerged in the United States as a part of a statutory regime that is aimed to promote generics drugs by provoking patent challenges and making clinical data available for generics companies. But from the get-go, the U.S. expects China to adopt an anti-generics vision of patent linkage that the U.S. itself had rejected. This quest for more IP protection may have destabilized the

administrative system and led to reduced protection in actuality. As for U.S. trading partners around the Pacific, this account demonstrates the institutional forces that shape regulatory globalization and localization. Details of the Chinese experience can help potential PPT member countries identify concerns during trade negotiation and, in the case of South Korea, implement the actual patent linkage regime after the negotiation.