

**The Intersection of Patent Linkage and Competition Law:
False File Listing and Reverse Payments**

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Abstract

The Pharmaceutical Affairs Act introduced a chapter dedicated to the Patent Linkage of Drugs in 2019, leading to an increasing alignment of our country's regulatory framework with the patent linkage provisions found in the U.S.'s Hatch-Waxman Act. Over the several decades since this system was first implemented in the United States, two major competition law disputes have gradually emerged, either due to the allocation of institutional incentives or to the existence of legal loopholes. One of these concerns the abuse of the Orange Book listing system, and the other pertains to reverse payments. To address these two issues, the U.S. Congress has continuously been amending the regulations under the Federal Food, Drug, and Cosmetic Act (FD&C) since 2003, and related judicial interpretations have been evolving. While our country's new patent linkage system draws heavily from the latest U.S. legal norms, it has also inherited numerous competition law ambiguities associated with those systems. Nevertheless, this article still questions whether the current legal regulations are sufficient to completely prevent these competition law issues from occurring. Furthermore, it suggests that simply focusing on prevention may not be the optimal approach and that establishing a solid enforcement foundation for competition law should be a short-term goal. Based on this, the article contends that the first step should be to clarify the interpretation of the Fair Trade Act in various cases, followed by a review of system loopholes and attempts to rectify them through legislative changes. To delve deeper into these two major issues, by drawing on the U.S. legal experience, this article aims to elucidate the original purposes of each piece of legislation and the evolution of each dispute. On the one hand, it seeks to explore the potential strengths and weaknesses of the current system based on the U.S. experience. On the other hand, by analyzing the origins of these problems, it serves as a foundation for future discussions on interpretation.

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