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Federal Circuit Refuses to Rehear Case Involving Orange Book Listing of Device Patents

Late last year we reported on the United States Court of Appeals for the Federal Circuit decision holding that certain device patents should not have been listed in the FDA's Orange Book since the claims of the patents in question did not recite the active drug substance.

Following that decision, the brand company patent holder, Teva, filed a petition to request the Federal Circuit to rehear the case in front of all judges in the Circuit. Teva's position was supported by a number of brand pharmaceutical companies, as well as the Pharmaceutical Research and Manufacturers of America.

On Monday, March 3, 2025, the Federal Circuit entered an Order denying Teva's rehearing request. Teva may still attempt to appeal the December 2024 Federal Circuit decision to the United States Supreme Court, but there is no guarantee that the Supreme Court will agree to hear the case.

If left undisturbed by the Supreme Court or further legislative or regulatory actions, the Federal Circuit decision begins to provide some clarity regarding whether device patents can be listed in the Orange Book when they do not recite the active ingredient. Either way, further litigation involving Orange Book patent listings can be expected. It will be important for both brand and generic companies to carefully review the specific language of all patent claims that may be or are currently in the Orange Book for approved drugs where there are device components associated with the drug.

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