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Federal Circuit Decides Case Involving Orange Book Listing of Device Patents

Earlier this year we reported on the Federal Trade Commission's efforts taken against certain drug manufacturers when listing device patents in the FDA's Orange Book. We concluded that the efforts to date by the FTC had a minimal impact on a manufacturer's decision on whether to list a device patent. This past Friday, the United States Court of Appeals for the Federal Circuit weighed in on this issue by affirming the United States District Court for the District of New Jersey's decision that certain patents should not have been submitted for listing and, therefore, would be delisted. *Teva Branded Pharmaceutical Products R&D, Inc. et al. v. Amneal Pharmaceuticals of New York, LLC et al.*, (Fed. Cir Case 2024-1936, Dec. 20, 2024).

The Orange Book statutes set forth three types of patents that should be listed in the Orange Book. These are patents directed to the drug substance, the drug composition/formulation, and the approved methods of using the drug. Teva had listed nine patents in the Orange Book for its ProAir® HFA albuterol inhaler. Five of the patents were directed to a dose counter used for the delivery device or the canister used to store the active ingredient, albuterol sulfate. However, the claims of these patents did not recite the albuterol sulfate active ingredient. These five patents were asserted against Amneal in Hatch-Waxman Paragraph IV litigation.

Amneal contended that the five patents should not have been listed in the Orange Book because they were not directed to the types of patents that qualify for listing and requested that the patents be delisted from the Orange Book. In addition, Amneal counterclaimed for antitrust liability, arguing that the listing of these patents wrongfully delayed approval of their ANDA. The lower court agreed with Amneal and, on December 20, 2024, the Federal Circuit affirmed the decision because the claims in question did not include the active ingredient:

> . . . to qualify for listing, a patent must claim at least what made the product approvable as a drug in the first place – its active ingredient. In other words, Teva cannot list its patents just because they claim the dose-counter and canister parts of the ProAir® HFA.

The Court further explained that where a product includes both drug and device elements,

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it is what causes it to be a drug that is critical to whether a patent should be listed:

One touchstone of the distinction between drugs and devices is that the former are "composed of complex chemical compounds or biological substances" and the latter are "characterized more by their purely mechanical nature." . . . Put differently, "what distinguishes a drug from a device under the FDCA is that a device excludes a product that achieves its primary intended purposes through either chemical action or metabolism."

As the Teva patents did not claim the active ingredient, the Court determined that the only conclusion they could reach was:

To list a patent in the Orange Book, the patent must, among other things, claim the drug for which the applicant submitted the application and for which the application was approved. And to claim that drug, the patent must claim at least the active ingredient. Thus, patents claiming just the device components of the product approved in an NDA do not meet the listing requirement of claiming the drug for which the applicant submitted the application.

Finally, the Court determined that the drug/device combination nature of the product did not alter its reasoning:

. . . a combination product being approved with an NDA does not necessarily make every part of the NDA a drug. That is, a drug-device combination product being approved with an NDA does not make the device parts a drug. The fact that the combination product was approved with an NDA just means that the drug mode of action predominated. On the facts of this case, the drug for which the application was submitted and approved is thus not every component of Teva's ProAir® HFA. Instead, it is the part of the drug-device combination that made it regulatable as a drug in the first place. And that is the active ingredient.

Although this decision appears to put to bed the dispute over listing patents in the Orange Book that are directed solely to a delivery device, Teva may still file for a rehearing or rehearing *en banc* of the December 20 ruling with the Federal Circuit. In addition, it's possible that Teva could also file an appeal to the United States Supreme Court. But, this decision certainly highlights the importance for both brand and generic companies to fully evaluate the statutory patent listing criteria for each relevant patent. We can certainly expect more litigation involving Orange Book patent listings, but we now have some guidance from the Federal Circuit to consider.