

News

BCLP PARTNER DAVID B. SCHWARTZ COMMENTS IN LAW360 ON FEDERAL CIRCUIT'S ORANGE BOOK RULING

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BCLP Partner David B. Schwartz commented in Law360 on the Federal Circuit's recent decision regarding the Orange Book, a key list maintained by the U.S. Food and Drug Administration (FDA) that includes patents associated with approved drug products. The former Lead Investigative Attorney at the U.S. Federal Trade Commission (FTC) noted, "This has been an issue the FTC's been concerned about for decades," and highlighted the potential for increased FTC action under the new administration, adding that there is value in "sending a message to the rest of the pharmaceutical industry that you should not be engaging in this kind of alleged misconduct."

The Federal Circuit's ruling in *Teva Branded Pharmaceutical Products R&D Inc. et al. v. Amneal Pharmaceuticals of New York LLC et al.* has significant implications for the pharmaceutical industry. By upholding that device-only patents cannot be listed in the Orange Book, the decision may pave the way for increased legal challenges to improperly listed patents. David observed that while the immediate impact may be limited, drug companies must carefully evaluate their Orange Book listings and prepare for potential antitrust scrutiny. Further litigation and regulatory developments will determine the full impact of this decision in the years to come.

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