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Federal Circuit: "Hatch-Waxman" litigation expenses not capital expenses and may be deducted in year incurred

The U.S. Court of Appeals for the Federal Circuit today affirmed a decision of the Court of Federal Claims that the taxpayer's "Hatch-Waxman" litigation expenses were not capital expenses, and thus the taxpayer was entitled to deduct the expenses as ordinary business expenses in the years they were incurred.

The case is: *Actavis Laboratories FL, Inc. v. United States,* No. 23-1320 (Fed. Cir. March 21, 2025). Read the Federal Circuit's **decision**

Summary

The taxpayer filed abbreviated new drug applications (ANDAs) with the U.S. Food and Drug Administration (FDA), seeking FDA approval to market and sell generic versions of branded drug products already being sold in the United States. In response to the taxpayer's ANDA filings, the manufacturers of those branded drugs—who already held new drug applications (NDAs) for their products and also owned patents covering those products—sued the taxpayer for patent infringement under the Hatch-Waxman Act.

The taxpayer treated the litigation expenses it incurred in defending itself in those various suits as ordinary and necessary business expenses and, therefore, deducted them on its tax returns in the years the expenses were incurred. The IRS, however, considered the expenses to be capital expenditures because they were incurred in pursuit of an intangible capital asset (i.e., FDA approval to lawfully market a generic drug product in the United States). The Court of Federal Claims held that the litigation expenses were deductible and need not be capitalized, and the Federal Circuit affirmed.

The Federal Circuit concluded that under either the "origin of the claim" test set forth in *Woodward v. Commissioner,* 397 U.S. 572 (1970) and *United States v. Gilmore*, 372 U.S. 39 (1963), or the "significant future benefit" methodology set out in *INDOPCO, Inc. v. Commissioner*, 503 U.S. 79 (1992) and embodied in Treas. Reg. § 1.263(a)- 4, the taxpayer's Hatch-Waxman litigation expenses were deductible ordinary business expenses, and not capital expenditures. Regarding the origin of claim test, the court concluded that the claim being litigated in a Hatch-Waxman lawsuit originates in patent infringement, not the acquisition of

FDA approval of an ANDA. Similarly, regarding the significant future benefit test, the court concluded that Hatch-Waxman litigation is not part of the "process of . . . pursuing" approval of an ANDA.

The court noted that its analysis was consistent with that of the Third Circuit in *Mylan Inc. v. Commissioner*, 76 F.4th 230 (3rd Cir. 2023), and it rejected the government's arguments that *Mylan* was wrongly decided.

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