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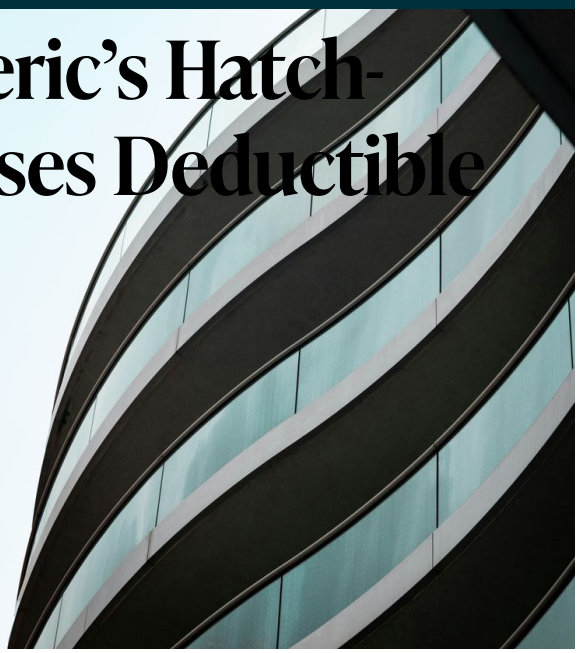
Federal Circuit Holds Generic's Hatch-Waxman Litigation Expenses Deductible



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A March 21 Federal Circuit decision in *Actavis Laboratories FL, Inc. v. United States*, No. 23-1320 (Fed. Cir. Mar. 21, 2025) marked a victory for generic drug developers, affirming that legal expenses incurred defending Hatch-Waxman suits are tax-deductible as ordinary and necessary business expenses. The Federal Circuit's ruling provides potentially significant tax benefits to Hatch-Waxman defendants and clarifies that they can deduct litigation expenses to the same extent as other patent infringement litigants.

This case relates to Actavis Laboratories FL, Inc.'s ~$12 million tax deductions between 2008 and 2009 for legal expenses it incurred defending itself in Hatch-Waxman litigations. Actavis deducted these costs under 26 U.S.C. § 162(a), which permits deductions for ordinary and necessary business expenses. But the IRS disagreed, determining that the expenses were non-deductible capital expenditures under an IRS regulation because they "facilitate[d]" Actavis's acquisition of "intangible assets"—here, FDA's approval of Actavis's generic drug applications ("ANDA"). Actavis paid the ~$12 million after the IRS sent notices of deficiency, but Actavis later filed amended returns for 2008 and 2009 requesting a refund of the legal expenses. When the IRS failed to timely act on Actavis's request, Actavis sued in the Court of Federal Claims, which sided with Actavis and held that the expenses were deductible.

On the IRS's appeal, the Federal Circuit analyzed the deductibility of Actavis's expenses under two tests, reaching the same result for both. First, under the Supreme Court's "origin of the

claim" test, the Federal Circuit considered "whether the origin of the claim litigated is in the process of acquisition" of FDA's approval of Actavis's ANDA. *Woodward v. Comm'r*, 397 U.S. 572, 577 (1970). The court found that the origin of the claim in Hatch-Waxman litigation is the plaintiff's allegation of infringement—not the defendant's pursuit of FDA approval. Judge Stark noted that "Hatch-Waxman litigation typically proceeds in parallel with the FDA's regulatory review, but the two lanes are distinct." He also found that adopting the IRS's position would treat Hatch-Waxman defendants unfairly because Hatch-Waxman plaintiffs (i.e., brand manufacturers) and parties to non-Hatch-Waxman patent litigation are permitted to deduct litigation expenses.

Second, the Federal Circuit addressed the IRS's approach under 26 C.F.R. § 1.263 and the "significant future benefit" test. The regulation requires that any expenses that facilitate the creation of an intangible asset be capitalized rather than deducted. Although the Federal Circuit again referenced the parallel nature of Hatch-Waxman litigation and FDA approval, it also found that the two operate on different pathways. While acknowledging that litigation could affect the timing of approval, the court noted that the district court overseeing a litigation has no power to approve an ANDA. Ultimately, the court held that Hatch-Waxman litigation expenses do not facilitate a generic's acquisition of FDA approval.

The Federal Circuit's decision aligns with the Third Circuit's previous holding in *Mylan Inc. v. Comm'r of Internal Revenue*, 76 F.4th 230 (3d Cir. 2023) and confirms that a generic manufacturer's Hatch-Waxman legal expenses are deductible in the year they are incurred. Based on the Federal Circuit's holding, generic manufacturers should consider deducting litigation expenses in planning their tax strategies.

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