ACTION ON DECISION

Subject: *Mylan, Inc. v. Commissioner*, 76 F.4th 230 (3d Cir. 2023), *aff'g* 156 T.C. 137 (2021).

Issue: Whether the legal expenses a generic drug manufacturer (Generic) incurs in defending patent infringement suits (ANDA Suits) brought under 35 U.S.C. § 271(e)(2) during the pendency of a Generic's abbreviated new drug application (ANDA) with the Food and Drug Administration (FDA) are required to be capitalized under I.R.C. § 263 or are deductible under I.R.C. § 162 as ordinary and necessary business expenses.

Discussion: In *Mylan, Inc. v. Commissioner*, 76 F.4th 230 (3d Cir. 2023), *aff'g* 156 T.C. 137 (2021), and *Actavis Laboratories, FL, Inc. v. The United States*, 131 F.4th 1345 (Fed. Cir. 2025), *aff'g* 161 Fed. Cl. 334 (2022), the taxpayers filed ANDAs with the FDA, seeking FDA approval to market generic drug products in the United States. In response to the taxpayers' ANDA filings, the patent holders of those branded drugs sued the taxpayers for patent infringement. As a result, the taxpayers incurred and deducted legal expenses as defendants in the ANDA Suits. The Internal Revenue Service, asserting that the expenses should be capitalized, disallowed the deductions and issued notices of deficiency. The United States Tax Court and the United States Court of Federal Claims, however, held that the legal expenses are deductible. On appeal, both the United States Court of Appeals for the Third Circuit and the United States Court of Appeals for the Federal Circuit affirmed their respective lower courts.

When obtaining approval from the FDA to market their drugs, Generics are permitted to bypass the long and costly drug testing process if they show their drug has "the same active ingredients as, and is biologically equivalent to," a previously approved drug. The Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585. Generics' drug development and application preparation activities are not subject to patent infringement suits, but their FDA applications, if made with intention to commercially produce and market drugs, are not so protected. 35 U.S.C. § 271(e)(1), (2). As part of their ANDA application, Generics must notify the branded drugs' patent holders of their application (ANDA Notice). An ANDA Notice may be followed by an ANDA Suit. An ANDA Suit, if filed within 45 days of ANDA Notice receipt, stays the FDA approval's effective date, but not the approval process itself, for 30 months. 21 U.S.C. § 355(j)(5)(B)(iii). If the lawsuit is resolved before the 30-month stay expires and the Generic wins, the stay is lifted.

Taxpayers must capitalize amounts paid to create, or facilitate the creation of, certain intangibles, one of which is rights under a trademark, trade name, copyright license, permit, franchise, or other similar right granted by a governmental agency. Treas. Reg.

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§ 1.263(a)-4(b)(1)(ii), (v) & (d)(1), (5). Treas. Reg. § 1.263(a)-4(e)(1)(i) provides that the scope of "facilitative expenses" is broad and encompasses an amount that is paid to facilitate the acquisition or creation of an intangible (the transaction) if the amount is paid in the process of investigating or otherwise pursuing the transaction.

Parties to patent infringement cases are generally allowed to deduct their legal expenses. *See Schillinger v. United States*, 155 U.S. 163, 169 (1894); Treas. Reg. § 1.263(a)-4(e)(5), Example 6. However, both the section 263(a) regulations and the predecessor origin of the claim analysis require parties to capitalize their litigation expenses if "the origin of the claim litigated is in the process of acquisition itself." *Woodward v. Commissioner*, 397 U.S. 572, 577-78 (1970).

The Third Circuit in *Mylan* affirmed the Tax Court's conclusion that legal expenses incurred in litigating ANDA suits are deductible under both the "origin of the claim" test set forth in *Woodward*, 397 U.S. at 572, as well as Treas. Reg. § 1.263(a)-4. *Mylan*, 76 F.4th at 245-246. First, applying Treas. Reg. § 1.263(a)-4(b)(1)(v), which requires capitalization of "[a]n amount paid to facilitate an acquisition or creation of an intangible," the court determined that ANDA Suit costs are deductible on the basis that such litigation does not *facilitate* taxpayer's acquisition of the intangible asset (FDA approval). *Mylan*, 76 F.4th at 245. "Patent litigation, if it occurs at all after a Paragraph IV certification, does not facilitate the acquisition of an FDA-approved ANDA because the two processes are distinct and ultimately separate." *Id.* at 244-245. The Third Circuit reached the same conclusion applying the "origin of the claim" test by determining that the origin of the claim being litigated in an ANDA Suit originates in patent infringement and thus held that the legal costs are deductible. *Id.* at 246.

Similarly, the Federal Circuit in *Actavis* affirmed the Court of Federal Claims' conclusion that legal expenses incurred in litigating ANDA suits are deductible under both the "origin of the claim" test set forth in *Woodward*, 397 U.S. at 572, as well as under Treas. Reg. § 1.263(a)-4. *Actavis*, 131 F.4th at 1353. First, applying the "origin of the claim" test, the Federal Circuit determined that the origin of the claim being litigated in an ANDA Suit originates in patent infringement and thus held that the legal costs are deductible. *Actavis*, 131 F.4th at 1356. The Federal Circuit reached the same conclusion under Treas. Reg. § 1.263(a)-4(b)(1)(ii), (v), which requires capitalization of "[a]n amount paid to create an intangible" and of "an amount paid to facilitate…creation of [such] an intangible." The court held that ANDA Suit costs are deductible on the basis that such litigation does not *facilitate* taxpayer's acquisition of the intangible asset (FDA approval). *Id.* at 1358. "The District Court presiding over the related Hatch-Waxman

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lawsuit has no power to grant approval of an ANDA; its only ability to impact FDA approval is to delay its effectiveness[.]" *Id*.

The Service will follow the decisions of the Third Circuit and Federal Circuit. Accordingly, the Service will treat legal expenses incurred in defending ANDA Suits brought under 35 U.S.C. § 271(e)(2) during the pendency of a Generic's ANDA with the FDA as ordinary and necessary business expenses under section 162 that are not required to be capitalized under section 263.[1]

Recommendation: Acquiescence.

/s/
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[1] The Service will no longer assert the position taken in Generic Legal Advice Memorandum No. AM-2014-6 (concluding the legal fees incurred by a Generic to defend against an ANDA Suit must be capitalized as facilitating the creation of an intangible asset under section 1.263(a)-4(e)(1)).

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