Mylan, Inc. & Subsidiaries v. Commissioner, 156 T. C. No. 10 (2021)

In a significant ruling, the U. S. Tax Court determined that Mylan, a generic drug manufacturer, must capitalize legal fees for preparing FDA notice letters but can deduct costs for defending patent infringement suits. This decision impacts how pharmaceutical companies handle legal expenses related to FDA approvals and patent disputes, clarifying the tax treatment of such expenditures.

Parties

Mylan, Inc. & Subsidiaries (Petitioner), a U. S. corporation and manufacturer of generic and brand name pharmaceutical drugs, filed petitions against the Commissioner of Internal Revenue (Respondent) to challenge determinations of tax deficiencies for the years 2012, 2013, and 2014. The cases were consolidated in the U. S. Tax Court.

Facts

Mylan incurred significant legal expenses from 2012 to 2014 in two categories: (1) preparing notice letters to the FDA, brand name drug manufacturers, and patentees as part of the process for obtaining FDA approval for generic versions of drugs, and (2) defending against patent infringement lawsuits initiated by these manufacturers and patentees. These lawsuits were triggered by Mylan's submission of Abbreviated New Drug Applications (ANDAs) with paragraph IV certifications, asserting that certain patents listed in the FDA's Orange Book were invalid or not infringed by Mylan's generic drugs.

Procedural History

Mylan deducted its legal expenses as ordinary and necessary business expenditures on its 2012, 2013, and 2014 tax returns. Following an IRS examination, the Commissioner determined these expenses were capital expenditures required to be capitalized and disallowed Mylan's deductions, issuing notices of deficiency for tax deficiencies amounting to $16,430,947 for 2012, $12,618,695 for 2013, and $20,988,657 for 2014. Mylan filed timely petitions for redetermination with the U. S. Tax Court, which consolidated the cases and held a trial.

Issue(s)

Whether the legal expenses Mylan incurred for preparing notice letters required to be sent as part of the FDA approval process for generic drugs must be capitalized under section 263(a) of the Internal Revenue Code?

Whether the legal expenses Mylan incurred for defending against patent infringement lawsuits brought by brand name drug manufacturers and patentees are deductible as ordinary and necessary business expenses under section 162(a)?

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Rule(s) of Law

Section 162(a) of the Internal Revenue Code allows deductions for all ordinary and necessary expenses paid or incurred during the taxable year in carrying on any trade or business. Section 263(a) mandates capitalization of expenditures that create or enhance a separate and distinct asset or generate significant future benefits for the taxpayer. Section 1. 263(a)-4(b)(1)(v), Income Tax Regs. , requires capitalization of amounts paid to facilitate the acquisition or creation of certain intangibles, including rights obtained from a governmental agency.

Holding

The U. S. Tax Court held that the legal expenses Mylan incurred to prepare notice letters are required to be capitalized because they were necessary to obtain FDA approval of Mylan's generic drugs. Conversely, the legal expenses incurred to defend patent infringement suits are deductible as ordinary and necessary business expenses because the patent litigation was distinct from the FDA approval process.

Reasoning

The court's reasoning differentiated between the two types of legal expenses based on the origin and character of the claims and the applicable legal standards:

For the notice letter expenses, the court applied the regulation under section 1. 263(a)-4(b)(1)(v), which requires capitalization of expenses facilitating the creation of an intangible asset. The court found that the notice letters were a required step in securing FDA approval, thus facilitating the acquisition of an intangible asset (effective FDA approval).

For the litigation expenses, the court employed the "origin of the claim" test, focusing on whether the litigation arose from the acquisition, enhancement, or disposition of a capital asset. The court determined that the patent infringement suits were tort claims, not related to the acquisition or enhancement of Mylan's intangible assets. The court also considered the policy objectives of the Hatch-Waxman Act, which encourages the entry of generic drugs into the market while protecting brand name drug manufacturers' patent rights. The court found that the litigation was a mechanism for brand name manufacturers to protect their intellectual property rights, not a step in the FDA approval process for Mylan.

The court also analyzed relevant regulatory examples and the nature of patent infringement litigation, concluding that such litigation expenses are typically deductible as ordinary and necessary business expenses for companies engaged in the business of exploiting and licensing patents.

Disposition

The court sustained the IRS's determinations regarding the capitalization of

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expenses for preparing notice letters and ruled that the litigation expenses for defending patent infringement suits were deductible as ordinary and necessary business expenses. The court also upheld the IRS's determination that Mylan's capitalized expenses were subject to amortization over a 15-year period under section 197 of the Internal Revenue Code.

Significance/Impact

This case clarifies the tax treatment of legal expenses in the pharmaceutical industry, particularly for generic drug manufacturers. It establishes that expenses for preparing FDA-required notice letters are capital expenditures due to their role in facilitating FDA approval, whereas expenses for defending patent infringement suits are deductible as ordinary and necessary business expenses. This ruling impacts how pharmaceutical companies structure their legal strategies and manage their tax liabilities. It also underscores the distinction between expenses related to regulatory compliance and those arising from tort claims, which may influence how other industries categorize similar expenses for tax purposes. Subsequent courts and the IRS may refer to this decision when addressing similar issues, potentially affecting the tax treatment of legal expenses across various sectors.

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