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

In a landmark ruling, the U. S. Tax Court held that Mylan, a generic drug manufacturer, must capitalize legal expenses related to preparing FDA-required notice letters for generic drug applications, while expenses defending against patent infringement suits are deductible. This decision clarifies the tax treatment of legal costs incurred by generic drug companies in navigating the complex regulatory landscape of pharmaceutical patents, impacting how such costs are managed in the industry.

Parties

Mylan, Inc. & Subsidiaries, the petitioner, is a U. S. corporation engaged in the manufacture of both brand name and generic pharmaceutical drugs. The respondent, the Commissioner of Internal Revenue, represents the Internal Revenue Service (IRS). Mylan challenged the IRS's disallowance of deductions for legal expenses incurred during 2012, 2013, and 2014.

Facts

Mylan incurred significant legal expenses from 2012 to 2014 related to its efforts to bring generic versions of brand name drugs to market. The process involved submitting Abbreviated New Drug Applications (ANDAs) to the Food & Drug Administration (FDA), which required certifications regarding any patents listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) that covered the brand name drugs. Mylan often certified that these patents were invalid or would not be infringed by their generic drugs (paragraph IV certifications), triggering the need to send notice letters to the brand name drug manufacturers and patentees. These certifications also constituted an act of patent infringement, leading to lawsuits against Mylan under 35 U. S. C. § 271(e)(2). Mylan deducted the legal fees incurred for preparing notice letters and defending against these infringement suits as ordinary and necessary business expenses under Internal Revenue Code (IRC) § 162(a). The IRS, however, determined these were nondeductible capital expenditures under IRC § 263(a).

Procedural History

Upon examination of Mylan's 2012, 2013, and 2014 tax returns, the IRS disallowed the deductions for legal expenses, asserting they were capital expenditures to be amortized over 15 years under IRC § 197. The IRS issued notices of deficiency for each year, determining tax deficiencies of $16,430,947, $12,618,695, and $20,988,657, respectively. Mylan petitioned the U. S. Tax Court for redetermination, and the cases were consolidated for trial. The Tax Court's standard of review was de novo.

Issue(s)

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Whether the legal expenses incurred by Mylan to prepare notice letters required for FDA approval of generic drugs are required to be capitalized under IRC § 263(a)?

Whether the legal expenses incurred by Mylan to defend against patent infringement suits under 35 U. S. C. § 271(e)(2) are deductible as ordinary and necessary business expenses under IRC § 162(a)?

Rule(s) of Law

IRC § 162(a) allows a deduction for "all the ordinary and necessary expenses paid or incurred during the taxable year in carrying on any trade or business. " Conversely, IRC § 263(a) mandates the capitalization of expenditures that create or enhance a separate and distinct asset or generate significant future benefits. The regulations under IRC § 1. 263(a)-4(b)(1) require the capitalization of amounts paid to acquire or create certain intangibles, including rights obtained from a governmental agency. The origin of the claim test, established in cases such as Woodward v. Commissioner, 397 U. S. 572 (1970), is used to determine whether legal expenses are deductible or must be capitalized based on the nature of the underlying claim.

Holding

The Tax Court held that the legal expenses incurred by Mylan to prepare notice letters required for FDA approval are capital expenditures under IRC § 263(a) because they facilitate the acquisition of FDA approval, an intangible asset. Conversely, the legal expenses incurred by Mylan to defend against patent infringement suits under 35 U. S. C. § 271(e)(2) are deductible as ordinary and necessary business expenses under IRC § 162(a) because such litigation is distinct from the FDA approval process and arises from the protection of business profits.

Reasoning

The court's reasoning hinged on the distinction between the two types of legal expenses. For notice letter expenses, the court applied the rule that amounts paid to facilitate the acquisition of an intangible asset must be capitalized. The court found that the notice letters were a required step in securing FDA approval, thus facilitating the acquisition of the intangible right to market the generic drug. The court rejected Mylan's argument that these expenses were merely related to potential patent litigation, emphasizing that the notice was a statutory prerequisite for ANDA approval.

Regarding the litigation expenses, the court applied the origin of the claim test and found that these expenses arose out of patent infringement claims, which are torts aimed at protecting the patent holder's business profits. The court relied on precedents such as Urquhart v. Commissioner, 215 F. 2d 17 (3d Cir. 1954), which established that expenses incurred in defending patent infringement suits are deductible because they relate to the protection of business profits rather than the

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acquisition of property rights. The court distinguished these expenses from those incurred in defending title to intellectual property, which are capital expenditures.

The court also considered regulatory examples under IRC §§ 1. 263(a)-4 and 1. 263(a)-5, finding that the litigation expenses did not facilitate the acquisition of FDA approval but were instead related to resolving patent rights, thus supporting their deductibility.

Disposition

The court sustained the IRS's determination to capitalize the legal expenses incurred for preparing notice letters and upheld the disallowance of deductions for those expenses. Conversely, the court allowed deductions for the legal expenses incurred in defending patent infringement suits. The court's decisions will be entered under Rule 155 of the Tax Court Rules of Practice and Procedure.

Significance/Impact

This decision has significant implications for the pharmaceutical industry, particularly for generic drug manufacturers. It clarifies that legal expenses related to the regulatory process of obtaining FDA approval must be capitalized, affecting the timing of tax deductions for such costs. Conversely, it affirms the deductibility of expenses incurred in defending against patent infringement suits, providing clarity and potential tax benefits for companies engaged in such litigation. The ruling may influence how generic drug companies structure their legal strategies and manage their tax liabilities, potentially affecting the pace and cost of bringing generic drugs to market. The case also underscores the importance of the origin of the claim test in distinguishing between deductible and capital expenditures in the context of legal fees.

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