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

In a significant ruling, the U. S. Tax Court held that Mylan, a pharmaceutical company, must capitalize legal fees for preparing FDA-required notice letters related to generic drug approvals, but can deduct expenses for defending patent infringement lawsuits. This decision clarifies the treatment of legal costs in the pharmaceutical sector, balancing the need for capitalization of costs directly related to FDA approval processes against the deductibility of litigation costs defending patent rights.

Parties

Mylan, Inc. & Subsidiaries, the petitioner, is a U. S. corporation involved in the manufacture of both brand name and generic pharmaceutical drugs. The respondent, the Commissioner of Internal Revenue, represents the Internal Revenue Service (IRS). The case was adjudicated in the U. S. Tax Court.

Facts

Mylan incurred legal fees from 2012 to 2014 in connection with applications submitted to the FDA for approval to market and sell generic versions of brand name drugs. As part of the application process, Mylan was required to certify the status of any patents listed in the FDA's Orange Book as covering the respective brand name drug. Mylan's certifications often stated that the listed patents were invalid or would not be infringed by their generic drugs, triggering the need to send notice letters to brand name drug manufacturers and patentees. Such certifications also constituted an act of patent infringement, giving the brand name manufacturers and patentees the right to sue Mylan for patent infringement. Mylan deducted these legal expenses on its tax returns as ordinary and necessary business expenditures, but the IRS disallowed these deductions, deeming them capital expenditures required to be capitalized.

Procedural History

The IRS, upon examination, determined that Mylan's legal expenses were nondeductible capital expenditures and issued notices of deficiency for the tax years 2012, 2013, and 2014, with deficiencies of $16,430,947, $12,618,695, and $20,988,657, respectively. Mylan filed timely petitions with the U. S. Tax Court for redetermination of these deficiencies. The cases were consolidated, and a trial was held in Washington, D. C.

Issue(s)

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

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Whether the legal expenses incurred by Mylan to defend against patent infringement suits under section 271(e)(2) of the U. S. Code are deductible as ordinary and necessary business expenses under section 162(a) of the Internal Revenue Code?

Rule(s) of Law

Section 162(a) of the Internal Revenue Code allows for the deduction of all ordinary and necessary expenses paid or incurred during the taxable year in carrying on any trade or business. Conversely, section 263(a) mandates that no deduction shall be allowed for capital expenditures, which are to be capitalized. Section 1. 263(a)-4(b)(1), Income Tax Regs. , requires the capitalization of amounts paid to acquire or create certain intangibles, including rights obtained from a governmental agency. Section 1. 263(a)-4(d)(5)(I), Income Tax Regs. , specifies that taxpayers must capitalize amounts paid to a governmental agency to obtain rights under licenses, permits, or similar rights. Section 1. 263(a)-4(e)(1)(I), Income Tax Regs. , further defines that an amount is paid to facilitate the acquisition or creation of an intangible if it is paid in the process of investigating or pursuing the transaction.

Holding

The U. S. Tax Court held that the legal expenses incurred by Mylan to prepare notice letters for FDA approval are required to be capitalized under section 263(a) of the Internal Revenue Code because they were necessary to obtain FDA approval of Mylan's generic drugs. Conversely, the legal expenses incurred to defend against patent infringement suits are deductible as ordinary and necessary business expenses under section 162(a) because the patent litigation was distinct from the FDA approval process.

Reasoning

The court's reasoning was based on the distinction between the legal fees for preparing notice letters, which were directly related to obtaining FDA approval, and the litigation expenses for defending patent infringement suits, which were separate from the FDA approval process. The court applied the 'origin of the claim' test to determine the nature of the legal expenses. The notice letters were a required step in securing an FDA-approved Abbreviated New Drug Application (ANDA), thus facilitating the acquisition of an intangible asset, i. e. , the right to market the generic drug upon effective FDA approval. Therefore, these expenses were capital in nature and subject to capitalization under section 263(a). In contrast, the patent infringement litigation arose out of the ordinary and necessary activities of Mylan's generic drug business and was not directly related to acquiring FDA approval. The court referenced the case of Urquhart v. Commissioner, which established that expenses incurred in defending against patent infringement are deductible as they relate to the protection of business profits rather than the acquisition of property rights. The court also considered the regulatory examples provided in the Income

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Tax Regulations, which supported the deductibility of litigation expenses separate from the broader project of obtaining FDA approval. The court rejected the Commissioner's argument that the litigation expenses facilitated the acquisition of FDA approval, emphasizing that such litigation was initiated by patent holders to protect their intellectual property rights and was not a necessary step in the FDA approval process. Furthermore, the court noted that the statutory coordination between patent litigation outcomes and FDA approval does not convert the litigation into a step in the FDA approval chain.

Disposition

The court sustained the IRS' determinations for the amounts incurred to prepare paragraph IV notice letters, affirming the requirement to capitalize these expenses. However, it ruled in favor of Mylan regarding the deductibility of the litigation expenses incurred to defend against patent infringement suits.

Significance/Impact

This decision has significant implications for the pharmaceutical industry, particularly for generic drug manufacturers. It clarifies the tax treatment of legal expenses related to the FDA approval process and patent litigation, establishing a clear distinction between costs that must be capitalized and those that can be deducted. The ruling impacts how generic drug manufacturers manage their tax liabilities and plan their legal strategies regarding patent disputes. It also underscores the importance of the 'origin of the claim' test in determining the nature of legal expenses, which could influence future cases involving the deductibility of legal fees across various industries. The decision may lead to increased scrutiny by the IRS on the categorization of legal expenses by pharmaceutical companies, potentially affecting their financial planning and reporting.

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