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U.S. Tax Court: Legal expenses for FDA approvals capitalized, but those for defending patent infringement suits are deductible

The U.S. Tax Court today issued an opinion holding that legal expenses that were necessary in obtaining FDA approval of the taxpayer's production of generic drugs must be capitalized, but that the legal expenses incurred by the taxpayer in defending patent infringement suits were deductible.

The case is: *Mylan, Inc. v. Commissioner*, 156 T.C. No. 10 (April 27, 2021). Read the Tax Court's [opinion](#) [PDF 162 KB]

Summary

The Tax Court summarized the facts in this case as follows:

- The taxpayer (a U.S. manufacturer of brand name and generic pharmaceutical drugs) incurred legal expenses in connection with applications submitted to the Food and Drug Administration (FDA) for approval to market and sell generic versions of brand name drugs.
- As part of the application process, the taxpayer was required to provide a certification regarding the status of any patents that had been listed by the FDA as covering the respective brand name drug.
- On some applications, the taxpayer certified that listed patents covering the brand name drugs were invalid or would not be infringed by the taxpayer's manufacture of generic drugs. When it made such a certification, the taxpayer was required to send notice letters to the brand name drug manufacturer and any patentees stating that the taxpayer had made such a certification.
- Certification also constituted an act of patent infringement giving the brand-name manufacturer and patentees the right to bring a patent infringement suit against the taxpayer.

- At issue in this case were the legal expenses incurred to prepare notice letters and legal expenses incurred in defending against these patent infringement suits.
- On its 2012, 2013, and 2014 federal income tax returns, the taxpayer deducted its legal expenses as ordinary and necessary business expenditures.
- The IRS, on examination, determined that these expenses were nondeductible capital expenditures that were required to be capitalized and thus disallowed the taxpayer's claimed deductions for the expenses at issue. Notices of deficiency were issued for each year for amounts ranging from about \$12.6 million to almost \$21 million. The taxpayer disagreed with the deficiency assessments and eventually initiated this action in the Tax Court.

The Tax Court today held that the taxpayer had to capitalize the legal expenses incurred to prepare notice letters because these expenses were necessary to obtain FDA approval of the taxpayer's generic drugs.

However, the legal expenses incurred to defend patent infringement suits were deductible as ordinary and necessary business expenses because the patent litigation was distinct from the FDA approval process.

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