

# CLIENT ALERT

## Patent litigation fees deductible, Tax Court Rules

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In good news for generic drug manufacturers, the U.S. Tax Court recently ruled that they can deduct legal fees associated with patent infringement lawsuits, even when the legal fees are triggered by an FDA application, which will reduce their federal tax liabilities in the year in which those fees are incurred. In addition to deducting these fees going forward on their federal tax returns, drug manufacturers should consider whether this Tax Court decision entitles them to tax refund for prior years. Moreover, any companies that incur legal fees associated with creating intangibles (e.g., patents, rights to sell generic drugs, trademarks) will want to consider whether this ruling impacts them.

### Background

In *Mylan v. Commissioner*, 156 T.C. No. 10 (April 27, 2021), Mylan sought FDA approval to manufacture generic versions of existing FDA-approved drugs. As part of that process, Mylan had to notify the patent holder that Mylan applied to manufacture a generic version of its drug. The patent holder had 45 days to bring a patent infringement lawsuit. If a patent holder filed suit, the FDA was prohibited from granting “effective” approval to the generic drug for 30 months while the parties litigate the patent validity or infringement, although the FDA could grant tentative approval – which means the application is allowable except for the patent issue that needs to be resolved.

On its tax returns, Mylan deducted: (1) the legal fees associated with notifying the patent holders and (2) the legal expenses incurred in defending against the patent infringement lawsuits triggered by its FDA applications.

The IRS took the position that both costs had to be capitalized and amortized over fifteen years, instead of being deducted in the year they were incurred.

### Patent infringement legal fees: deductible expenses

The IRS argued Mylan had to capitalize the patent infringement legal fees because it incurred the legal fees as part of the process to obtain FDA approval to produce and market the generic drug. The Tax Court disagreed. The court stated that, although the application process “triggers the opportunity for patent litigation as well as the FDA review process, this statutory design does not transform patent litigation into a step in the [ ] approval process.” The Tax Court emphasized that the patent litigation has no bearing on the FDA’s safety and bioequivalence review and a generic drug manufacturer could win the patent litigation but still not receive FDA approval. Accordingly, Mylan won the issue and the Tax Court held the legal expenses associated with the patent litigation were deductible.

### Notice legal fees: capitalized expenses

The Tax Court ruled against Mylan with respect to the legal fees associated with notifying patent holders of its generic drug application. Mylan argued that the notice served to facilitate the patent litigation so the legal fees associated with the notice

should be deductible. The Tax Court rejected this argument. Unlike the patent infringement litigation, the Tax Court found that the notice was a prerequisite to obtaining FDA approval, and was therefore a part of the creation of the intangible asset. Accordingly, the expenses Mylan incurred to prepare, assemble, and send the notice letters had to be capitalized.

### **What this means for generic pharmaceutical taxpayers**

Overall, this is a taxpayer-favorable ruling. The IRS has 90 days to appeal the decision to the Third Circuit, and it might do so. Alternatively, the Tax Court's decision focused on Third Circuit caselaw, so it is possible the IRS could concede the issue in the Third Circuit but continue to litigate it elsewhere.

In the meantime, generic drug manufacturers should consider whether this ruling impacts prior tax years (*i.e.*, whether the manufacturer is entitled to a refund because it did not deduct these types of legal fees in prior tax returns). Obtaining such a refund may require the manufacturer to obtain the consent of the IRS to change its method of accounting. Also, their general counsel's offices will want to ensure that litigation and patent legal fees are tracked separately (*i.e.*, separate billing codes), from legal fees associated with notice procedures and other tasks associated with creation of the intangible asset.

Beyond generic drug manufacturers, companies that incur costs in creating intangibles (*e.g.*, trademarks, royalties, patents) should audit their legal expenses to identify expenses that are potentially deductible under this new ruling. As with generic drug manufacturers, these taxpayers may need to obtain the consent of the IRS to change their method of accounting if they are not already following the method of deducting them.

The Crowell Tax Team will continue to monitor this developing situation and provide additional updates when necessary. In addition, the Crowell Tax Team stands ready to answer any questions on what the *Mylan* decision means for created intangibles legal fees or how to account for legal fees to ensure they are deductible.

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