Blue J Predicts

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In this article, Alarie and Condon use machine-learning models to evaluate the strength of the IRS's argument that the Tax Court in *Mylan* erred in holding that a generic drug manufacturer is not required to capitalize litigation expenses incurred in defending against patent infringement suits and instead may deduct them as ordinary and necessary business expenses.

Introduction

This month in our Blue J Predicts column we examine the deduction of legal and litigation expenses in the context of the generic drug industry. We use the IRS's appeal from the Tax Court to the Third Circuit in *Mylan*[1] to explore whether legal and litigation expenses related to intellectual property are considered "ordinary and necessary" under section 162(a). We also unpack the circumstances in which litigation expenses incurred in patent infringement litigation must be capitalized under the relevant regulations. Finally, using commercially available software, we demonstrate how Blue J's machine-learning models can help to predict the likely outcome of whether a particular business expense is deductible.[2]

The Tax Court in *Mylan* rejected the IRS's position that expenses incurred in litigating patent disputes under the relevant specialized IP regime were capital expenditures. The IRS now seeks to have the decision remanded with instructions to disallow the deductions. As we will show, the IRS's position on appeal is aggressive. Our algorithms predict with over 95 percent confidence that the legal expenses at issue in *Mylan* would have been treated by the courts in the past as ordinary and necessary business expenses and, further, that the expenditures are unlikely to be treated as capital expenditures on appeal.

Background

The ability to deduct ordinary and necessary business expenses from taxable income is one of the most powerful ways to mitigate tax liability under the IRC. Unlike capital expenditures, which are typically required to be amortized over the useful life of the asset, ordinary and necessary business expenses can be deducted in their entirety in the year in which they are incurred. Distinguishing expenses that are clearly deductible from those that will be resisted by the IRS can challenge the most experienced tax planners. If a tax dispute arises, determining the

[1] *Mylan v. Commissioner*, 156 T.C. 137 (2021).

[2] Visit bluej.com for more information.

strength of a position can depend on the ability to navigate the code, the complex web of relevant regulations, revenue rulings, and other administrative guidance, as well as judicial doctrine.

Many things must align for a business expense to be deductible in the current tax year. The expense must typically be ordinary and necessary and not a capital expenditure. Further, the expense cannot be one that is explicitly disallowed by the regulations. The eagerness of taxpayers to deduct business expenses and the difficulty of applying the ordinary and necessary standard to messy and complicated facts and circumstances, not to mention the complexity of the relevant regs, make those deductions a frequent target for the IRS. Indeed, as shown in *Mylan*, taxpayers may find that even business expenses that have been uncontestedly deducted from income for many years may be retrospectively targeted if, for example, the IRS determines that those expenses ought to have been capitalized instead of deducted.

The primary code provision governing deductibility of business expenses is section 162(a). It allows taxpayers to deduct "all the ordinary and necessary expenses paid or incurred during the taxable year in carrying on any trade or business." This is only the beginning of the analysis, of course. Section 263(a) says that "no deduction shall be allowed for" a capital expenditure. Thus, a business expense will only be deductible if it is determined to be a noncapital expenditure, in addition to being ordinary and necessary.

The regulations set out many intricate rules outlining categories of expenditures that are considered to be capital in nature. For example, reg. section 1.263(a)-4 classifies amounts that are paid to acquire or create intangible assets as capital expenditures. This is the crux of the dispute in *Mylan*. Careful attention must be paid to the language of the regulations to determine whether an expenditure is ordinary and necessary or whether it is attributable to capital.

Facts of *Mylan*

Mylan concerns the deductibility of legal expenses incurred under what the Tax Court described as a "highly reticulated statutory and regulatory scheme"[3] governing the marketing and sale of generic drugs. This scheme arose from Congress's attempt to reconcile various competing interests — including those of innovators and inventors, brand-name pharmaceutical companies, the makers of generic drugs, and consumers.

Under this regulatory regime, drug companies seeking approval from the Food and Drug Administration to sell a generic version of an already authorized brand-name drug can submit an abbreviated new drug application (ANDA). This is a simplified process of obtaining FDA approval by piggybacking on the approval of an existing brand-name drug. As long as the application can show that the generic version is biologically equivalent to and contains the same active ingredients as an approved brand-name drug, generic manufacturers can avoid the testing requirements to prove that a new drug is safe and effective.

To encourage pharmaceutical companies to bring generic versions of drugs to market as quickly as possible and to compensate for the risk of litigation from existing patent holders, the legislative scheme provides for a 180-day exclusivity period for the first company to obtain FDA approval of an ANDA drug. During this time the generic drug company may sell its drug without competition from any other generic manufacturer. It has been noted that this exclusivity period is valuable to generic drug manufacturers and can potentially be worth several hundred million dollars.[4]

Mylan Inc. is a manufacturer of pharmaceutical products, including brand-name and generic drugs. Mylan submitted many ANDA applications over the tax years 2012, 2013, and 2014. As part of some of its applications, Mylan made what is referred to as a Paragraph IV certification, stating that any patents covering the brand-name version of the drug were invalid or would not be infringed by the manufacture, use, or sale of its generic version. Mylan was required to notify patent holders of this certification and would then defend itself against any resulting

[3] *Mylan*, 156 T.C. 137, at 3.

[4] *Mylan v. Commissioner*, No. 22-1193 (3d Cir. 2022), appellant's brief at 13.

infringement suits. By proceeding under Paragraph IV, Mylan was able to obtain FDA approval to market and sell generic versions of drugs even before the patents on those drugs expired.

A Paragraph IV certification is deemed to be a form of patent infringement. In response to that notice, patent holders are entitled to bring suit in federal district court under 35 U.S.C. section 271(e)(2). Litigation under this section starts the clock on a 30-month period during which any FDA approval of the generic drug is ineffective while the suit is litigated. Expenses incurred by Mylan while defending against section 271(e)(2) lawsuits are the main point of controversy in the IRS's appeal.

On its returns for the relevant years, Mylan deducted amounts for legal fees paid to prepare Paragraph IV notice letters and litigation expenses incurred in defending itself against patent infringement suits resulting from those letters. The amounts deducted were significant: $47 million in 2012, $39.7 million in 2013, and $44.1 million in 2014. Mylan claimed that these legal fees and litigation expenses were deductible as ordinary and necessary business expenses. The IRS disallowed almost all of the deductions, taking the position that the expenses were incurred to facilitate the creation of intangible assets and were therefore capital expenditures that would be required to be amortized over 15 years. After an audit, the IRS determined that Mylan's tax deficiencies totaled $50 million.

Most of the facts at trial were stipulated by the parties. The Tax Court's analysis turned largely on the correct interpretation of the language of the regulations. Siding with the IRS in part, the Tax Court held that expenses incurred to prepare Paragraph IV notice letters were required to be capitalized because they were incurred to facilitate the acquisition of a right from a government agency. However, these expenses accounted for less than 5 percent of the asserted deficiencies. The remainder was attributable to deductions claimed for expenses incurred defending section 271(e)(2) lawsuits. Regarding these litigation expenses, the Tax Court reached a different conclusion, holding that the expenses were not attributable to capital and could properly be deducted.

The Tax Court began by noting that its inquiry must be construed as contextual and fact-specific and that the fact that similar deductions have been allowed in the past does not mean that similar expenses will be deductible in other cases. Discussing the principles of capitalization as they apply to intangible assets, the court explained that expenses must be capitalized when they create or enhance a separate and distinct asset, or when they otherwise generate significant benefits for the taxpayer extending beyond the current tax year. Because this standard is difficult to administer, the "exclusive scope of the significant future benefit test" is set out in the regulations, which identify specific categories of intangible assets for which capitalization is required. These include amounts paid to create specific types of intangible assets, including rights obtained from a government agency.[5] Further, taxpayers are required to capitalize amounts "paid to facilitate . . . an acquisition or creation of an intangible," including rights obtained from a government agency.[6]

The scope of "facilitate" for the purpose of acquiring or creating an intangible is described in the relevant regulation as follows:

> Except as otherwise provided in this section, an amount is paid to facilitate the acquisition or creation of an intangible (the transaction) if the amount is paid in the process of investigating or otherwise pursuing the transaction. Whether an amount is paid in the process of investigating or otherwise pursuing the transaction is determined based on all of the facts and circumstances.[7]

The Tax Court accepted the IRS's definition of the "transaction" (that is, the acquisition of the right), as the acquisition of effective government approval of an ANDA with a Paragraph IV certification, noting that the FDA's approval does not confer any rights on the applicant until it becomes effective. It is only after any outstanding patent issues have been addressed that the applicant can introduce a generic drug into

[5] Reg. section 1.263(a)-4(d)(5).

[6] Reg. section 1.263(a)-4(b)(1)(v).

[7] Reg. section 1.263(a)-4(e)(1)(i).

interstate commerce. The court also agreed with the IRS that the preparation of Paragraph IV notice letters was a prerequisite for government approval of an ANDA and that any of the legal expenses incurred to prepare and serve those letters were amounts incurred to facilitate the creation of an intangible asset and were therefore not deductible under the regulation.

The court disagreed with the IRS, however, regarding the proper characterization of section 271(e)(2) litigation expenses. These expenses constituted the bulk of the deductions at issue. The Tax Court reasoned that patent litigation following a Paragraph IV certification is not a step in obtaining effective FDA approval of an ANDA. The court also found nothing to distinguish section 271(e)(2) suits from other types of patent infringement litigation — the expenses associated with which are widely understood to be deductible.

The Tax Court also considered the judicially created origin-of-the-claim test, finding that under this analysis, section 271(e)(2) litigation expenses should be treated as deductible ordinary and necessary business expenses. Under this test, legal expenses are deductible as long as they are directly connected with (or pertaining to) the taxpayer's trade or business. Whereas in patent law, expenses to defend title are considered to involve the disposition or acquisition of a capital asset, defending patent infringement litigation relates to tort law. As the Tax Court noted:

> It thus does not appear that Section 271(e)(2) litigation relates to the acquisition or enhancement of any right of a generic drug manufacturer, such that the expenses incurred in that litigation must be capitalized. This litigation instead gives the brand name drug manufacturer a chance to protect its intellectual property. In this circumstance, the origin of the claim test suggests that Mylan's litigation expenses are deductible.[8]

The court concluded that expenses incurred to litigate section 271(e)(2) were deductible under section 162(a).

IRS's Position on Appeal

In its brief on appeal, the IRS takes the position that the dispositive question is not whether the section 271(e)(2) litigation is a step in the ANDA process. Rather, the inquiry should be "whether Mylan's legal fees were incurred to 'facilitate' the acquisition of effective FDA approvals of ANDAs with paragraph IV certifications," which depends on whether fees were paid "in the process of investigating or otherwise pursuing" those acquisitions.[9] According to the IRS, the only reason an applicant would ever make a Paragraph IV certification is to obtain effective FDA approval before the expiration of the brand-name patents. Therefore "a paragraph IV applicant that incurs section 271(e)(2) litigation expenses *necessarily* does so in the process of pursuing effective FDA approval."[10]

The IRS concedes that "expenses incurred in patent litigation may well be deductible costs of doing business in most contexts."[11] But it asserts that this is irrelevant because, in this case, the infringement suits were litigated to facilitate the taxpayer's acquisition of an intangible asset. The Tax Court erred, according to the IRS, when it framed the question as whether litigation is a step in the approval process. This framing is too narrow, according to the IRS. Instead, the issue is whether the expenses were incurred in the process of pursuing FDA approval. The IRS's position is that they were so incurred and that section 271(e)(2) litigation expenses are "by definition, incurred to facilitate the acquisition of an intangible."[12] Moreover, "as a result, they are not deductible as ordinary and necessary business expenses, but rather are capital expenditures that must be capitalized."[13]

The IRS takes the position that because the expenses were incurred in the broader context of acquiring an intangible asset, the language of the regulation is conclusive. Therefore, case law holding patent infringement litigation to generally be a deductible expense is not

[8] *Mylan*, 156 T.C. 137, at 44-45.

[9] Appellant's brief, *supra* note 4, at 21.

[10] *Id*.

[11] *Id*. at 23.

[12] *Id*. at 40, citing reg. section 1.263(a)-4(e)(1).

[13] *Id*. at 40.

applicable in this context. By this reasoning, since the regulation is controlling, the judicially created origin-of-the-claim doctrine does not apply, in the IRS's opinion.[14] If it did apply, the IRS argues, the Tax Court reached the wrong conclusion by not accounting for the importance of the context in which the expenses were incurred. This, rather than reliance on case law suggesting that patent litigation expenses are always deductible, is the correct approach, according to the IRS. However, despite this position, in its brief the IRS understandably tends to focus its analytical attention on the language of the regulations and the question of capital versus noncapital.

The Taxpayer's Position on Appeal

In its brief filed August 1, Mylan leans heavily on the reasoning in the Tax Court's decision. It emphasizes that "the capitalization regulations . . . are 'consistent with existing law'" according to the IRS.[15] And Mylan contends that patent infringement suits provoked by a Paragraph IV certification do not differ from other infringement suits except in terms of timing. Thus, Mylan asserts that there is no principled reason to depart from the general rule that costs incurred in defending patent infringement litigation are deductible.[16] Moreover, it observes that nothing in the regulations requires that departure.[17]

Mylan also relies on the rationale underlying the regulations to support its position. Specifically, Mylan asserts that its litigation defense costs do not produce significant future benefits.[18]

Finally, Mylan notes that the origin-of-the-claim test also supports the deductibility of patent litigation expenses,[19] pointing to long-standing precedent recognizing the deductibility of those costs.[20]

Predicting Business Expenses

Although the main focus of the IRS's position involves the proper application of the regulations regarding capital versus noncapital expenditures, judicial doctrine and policy considerations also factor into the analysis. It seems likely that one reason the IRS chose to focus its argument on the issue of textual interpretation is that this is a strategic position; the case for arguing the expenses are not "ordinary and necessary" is relatively weak. As we will show in this section, machine-learning algorithms can analyze data from judicial decisions to predict how a court might rule on questions of deductibility. This has the added benefit of streamlining legal analysis and enabling practitioners to focus their analysis on the arguments that have the greatest likelihood of success.

Blue J Tax has a predictor for deductibility of trade or business expenses that can analyze whether an expense reported on Schedule C of Form 1040 or Form 1120 is likely to meet the legal requirements of being ordinary and necessary. An ordinary expense is normal, usual, or customary in the taxpayer's business or that may be considered common in the industry. A necessary expense is appropriate and helpful to the development of the taxpayer's business. Capital expenditures are by definition not ordinary business expenses and typically must be amortized and deducted over the lifetime of the asset.

To generate a prediction using Blue J's machine-learning algorithm, a tax practitioner first completes a questionnaire to input the relevant facts into the software. The algorithm then performs its analysis in two steps. First, it determines whether an expense is a capital expenditure. Then a second analysis is applied to determine whether the item is ordinary and necessary.

Before an expense is predicted to be deductible, both constraints — that is, *not* capital, as well as ordinary and necessary — must be satisfied. The Tax Court did not directly address the ordinary and necessary constraint in its decision, noting only that expenses to defend against patent infringement are widely understood to be deductible business expenses. Still, this question is relevant to the analysis.

[14] *Id.* at 42.

[15] *Mylan*, No. 22-1193, appellee's brief at 9.

[16] *Id.* at 25.

[17] *Id.* at 27.

[18] *Id.* at 49.

[19] *Id.* at 52.

[20] *Id.* at 7.

Table 1. Sensitivity of Predictions to Key Facts

Scenario	2.2 Does the Expense Result in The Taxpayer Acquiring or Producing a New Intangible Asset?	2.3 Do the Benefits Extend Beyond the Tax Year for Which The Deduction Is Sought?	Blue J's Likelihood of Expenditures Being Treated as Capital
1	No	No	5%
2	Yes	No	8%
3	Yes	Yes	50%

When we run the facts and circumstances of *Mylan* through Blue J's algorithm, we can get a sense of the strength of Mylan's position. This prediction is based on the answers to 18 questions regarding the facts and circumstances that inform the outcome of these two machine-learning models.

The first model determines the outcome of the capital-versus-not-capital issue. Users answer several questions about the nature of the expense, including, "Has the expense increased the value of or otherwise enhanced a tangible or intangible asset?" and "Has the expense adapted a tangible asset to a new use?"

Of particular interest to the parties in *Mylan* is question 2.2, "Did the expense result in the taxpayer acquiring or producing a new intangible asset?" This is essentially the matter in dispute in *Mylan* — whether the regulations require that the taxpayer's litigation expenses be regarded as producing an intangible asset. As shown in Scenario 1 in Table 1, when this question is answered in the negative, assuming all the other facts of the case are constant, the algorithm predicts with 95 percent confidence that the expense is *not* a capital expenditure and an overall confidence of greater than 95 percent that the expense is a deductible business expense. Simply changing the answer to this question from a no to a yes as in Scenario 2 does not make much difference to the overall result. The algorithm still predicts with 92 percent confidence that the expense is not attributable to capital, even though the expenses are then characterized as resulting in the acquisition or production of a new intangible asset.

Consider Scenario 3, however. The predicted outcome becomes 50-50 when we answer yes to question 2.3, "Do the benefits accruing from the expense extend beyond the tax year for which the deduction is sought?" If we assume that the expenditures are indeed linked to acquiring a new intangible asset and that the benefits are considered to extend for longer than a year, then the algorithm predicts that it is equally likely that the expenses would be considered by a court to be capital or noncapital in nature.

Regarding Scenario 3 in Table 1, in its appellate brief, the IRS makes the case that requiring capitalization of Mylan's litigation expenses is consistent with the purpose of section 263 because the benefits accruing from FDA approval will extend well beyond the tax year. Indeed, it is true that once FDA approval is secured, Mylan will be able to market and sell its generic drugs for years to come.

> Requiring Mylan to capitalize the litigation expenses it incurred to facilitate its acquisitions of effective FDA approvals of its paragraph IV ANDAs — approvals that entitle Mylan to market its generics for many years to come — does just that. The extreme position is Mylan's (and the Tax Court's) contention that Mylan is entitled to fully deduct its litigation expenses years before it will pay the taxes on the income that is attributable to those expenses.[21]

Note, however, that the lion's share of the benefits from bringing a generic drug to market are likely to be realized in the early months of the generic's availability, when the ANDA gives the exclusive right to market the generic for 180 days. This exclusivity period was designed by Congress to encourage applicants to proceed under Paragraph IV and thereby incur the risk of

[21] *Id*. at 49.

litigation. In fact, the Tax Court cites authority to the effect that the "vast majority of potential profits for a generic drug manufacturer materialize" during this period.[22] If the IRS is correct that the vast majority of the benefits of bringing a generic to market come from the 180-day exclusivity period, then this seems to be at least partly at odds with characterizing the benefits of the ANDA as extending for many years beyond the tax year in which the deduction is sought.

Trends in the Case Law

An additional benefit of using analytics to inform litigation strategy is that it can help litigants focus their arguments by identifying the issues that are most likely to be controversial and identifying which aspects of the case are likely to be more difficult to establish.

One way to analyze trends in the case law is to look at the overall pattern of outcomes. If we focus our attention on the business expense deductibility cases involving the question of whether expenses were ordinary and necessary, we find that the relevant expense was found to be deductible in 171 of 275 (62 percent) of the cases in Blue J's database.[23]

Table 2. Results in Case Law

	Outcome = Not Ordinary and Necessary	Outcome = Ordinary and Necessary
Total number of cases (out of 275)	104	171
Held to be capital expenditure[a]	39/104	0/171
Held to be *not* a capital expenditure[b]	64/104	169/171
Expense was incurred in defending civil or criminal proceedings and originated in activities strictly related to the business	6/104	19/171

[a]Excludes cases in which the court did not determine whether the expense was a capital expenditure.

[b]*Id.*

We can parse the data further to uncover additional trends. For instance, out of the entire case universe, the expense was found to be a capital expenditure in only 14 percent of the cases (39 of 275). Further, in cases in which the expense was *not* a capital expenditure, the court held that the expense was deductible as an ordinary and necessary business expense in 61 percent of the cases (169 of 275). In only 23 percent of the cases (64 of 275) did the court hold that a noncapital expenditure was not ordinary and necessary. Among cases that go to court, if an expense is found *not* to be a capital expense, it will be held to be a deductible business expense approximately 73 percent of the time (169 of 233 cases).

This demonstrates that the highest bar for a taxpayer to clear in establishing deductibility is showing that the expense is not attributable to capital. Once it is established that a particular expenditure is noncapital, the evidence suggests that it is comparatively easy, in most cases, to prove that the expense is ordinary and necessary.

The universe of cases concerning litigation expenses is smaller. However, out of 25 cases in which the expense was incurred in defending civil or criminal proceedings and originated in activities strictly related to the business, the expense was held to not be a deductible business expense in only six cases, yielding a taxpayer success rate of 76 percent (19 of 25 cases). This supports the Tax Court's observation that the overall trend in the case law supports the deductibility of litigation expenses. Of course, these high-level analytics are merely a good

[22]*Mylan*, 156 T.C. 137, at 13.

[23]Blue J's database includes all available court decisions on the deductibility of ordinary and necessary business expenses between 1933 and the present.

starting point for additional qualitative analysis. One of the advantages of using the Blue J platform is that the cases matching relevant criteria can be located immediately and accessed for deeper analysis and consideration.

Conclusion

The ability to deduct the entirety of an expense in the current year is a powerful tax incentive that has significant implications for taxpayers' business strategies. From the perspective of the IRS, this can make business deductions a tempting target for reassessment. Tax planners are well advised to pay close attention to the language of the regulations when classifying an expense. When it comes to both planning and litigation, tax practitioners can leverage machine-learning algorithms to solidify their positions and hone their arguments by quantifying the strength of their positions and highlighting the most salient factors. As noted, the IRS has taken an aggressive stance in appealing the Tax Court's decision on the deductibility of litigation expenses in its appeal of *Mylan*. We will see in the coming months whether this strategy is successful. It appears that the taxpayer has the stronger position in this dispute. However, a ruling for the IRS could pay off significantly in increased revenue for the treasury for many years to come. ■