

## RECENT DEVELOPMENTS IN FEDERAL INCOME TAXATION

We apologize to our readers. If we had more time, this outline would be much shorter.

By

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*This recent developments outline discusses, and provides context to understand the significance of, the most important judicial decisions and administrative rulings and regulations promulgated by the Internal Revenue Service and Treasury Department during the most recent twelve months — and sometimes a little farther back in time if we find the item particularly humorous or outrageous. Most Treasury Regulations, however, are so complex that they cannot be discussed in detail and, anyway, only a devout masochist would read them all the way through; just the basic topic and fundamental principles are highlighted – unless one of us decides to go nuts and spend several pages writing one up. This is the reason that the outline is getting to be as long as it is. Amendments to the Internal Revenue Code are discussed to the extent that (1) they are of major significance, (2) they have led to administrative rulings and regulations, (3) they have affected items previously covered in the outline, or (4) they provide an opportunity to mock our elected representatives; again, sometimes at least one of us goes nuts and writes up the most trivial of legislative changes. The outline focuses primarily on topics of broad general interest (to us, at least) – income tax accounting rules, determination of gross income, allowable deductions, treatment of capital gains and losses, corporate and partnership taxation, exempt organizations, and procedure and penalties. It deals summarily with qualified pension and profit-sharing plans, and generally does not deal with international taxation or specialized industries, such as banking, insurance, and financial services.*

In the last twelve months, there have been many significant federal income tax developments. The Treasury Department and the IRS provided an abundance of administrative guidance and the courts issued many significant judicial decisions. The [Inflation Reduction Act](#), Pub. L. No. 117-169, enacted on August 16, 2022, imposes a 15 percent alternative minimum tax on corporations with “applicable financial statement income” over \$1 billion, imposes an excise tax of 1 percent on redemptions of stock by publicly traded corporations, extends through 2025 certain favorable changes to the premium tax credit of § 36B, and extends through 2028 the § 461(l) disallowance of “excess business losses” for noncorporate taxpayers. The [Consolidated Appropriations Act, 2023](#), Pub. L. No. 117-328, enacted on December 29, 2022, includes the SECURE 2.0 Act of 2022, which increases the age at which required minimum distributions (RMDs) must begin to age 73, reduces the penalty for failure to take RMDs, modifies the rules for catch-up contributions to qualified retirement plans, and makes many other significant changes that affect retirement plans. This outline discusses the major administrative guidance issued in the last year, summarizes recent legislative changes that, in our judgment, are the most important, and examines significant judicial decisions rendered in the last twelve months.

<b>I.</b>	<b>ACCOUNTING</b> .....	4
	A. Accounting Methods .....	4
	B. Inventories.....	4
	C. Installment Method .....	4
	D. Year of Inclusion or Deduction.....	4
<b>II.</b>	<b>BUSINESS INCOME AND DEDUCTIONS</b> .....	4
	A. Income.....	4
	B. Deductible Expenses versus Capitalization .....	4
	C. Reasonable Compensation .....	6
	D. Miscellaneous Deductions .....	7
	E. Depreciation & Amortization .....	10
	F. Credits .....	13
	G. Natural Resources Deductions & Credits .....	14
	H. Loss Transactions, Bad Debts, and NOLs .....	14
	I. At-Risk and Passive Activity Losses .....	14
<b>III.</b>	<b>INVESTMENT GAIN AND INCOME</b> .....	14
	A. Gains and Losses.....	14
	B. Interest, Dividends, and Other Current Income .....	14
	C. Profit-Seeking Individual Deductions.....	14
	D. Section 121.....	14
	E. Section 1031.....	14
	F. Section 1033.....	14
	G. Section 1035.....	14
	H. Miscellaneous .....	14
<b>IV.</b>	<b>COMPENSATION ISSUES</b> .....	14
	A. Fringe Benefits.....	14
	B. Qualified Deferred Compensation Plans .....	15
	C. Nonqualified Deferred Compensation, Section 83, and Stock Options.....	24
	D. Individual Retirement Accounts .....	24
<b>V.</b>	<b>PERSONAL INCOME AND DEDUCTIONS</b> .....	27
	A. Rates.....	29
	B. Miscellaneous Income .....	29
	C. Hobby Losses and § 280A Home Office and Vacation Homes.....	29
	D. Deductions and Credits for Personal Expenses .....	30
	E. Divorce Tax Issues.....	34
	F. Education .....	36
	G. Alternative Minimum Tax .....	36
<b>VI.</b>	<b>CORPORATIONS</b> .....	36
	A. Entity and Formation .....	36
	B. Distributions and Redemptions.....	36
	C. Liquidations .....	40
	D. S Corporations .....	40
	E. Mergers, Acquisitions and Reorganizations .....	40
	F. Corporate Divisions .....	40
	G. Affiliated Corporations and Consolidated Returns.....	41
	H. Miscellaneous Corporate Issues.....	41

<b>VII. PARTNERSHIPS</b> .....	41
A. Formation and Taxable Years .....	42
B. Allocations of Distributive Share, Partnership Debt, and Outside Basis.....	42
C. Distributions and Transactions Between the Partnership and Partners .....	42
D. Sales of Partnership Interests, Liquidations and Mergers.....	42
E. Inside Basis Adjustments .....	42
F. Partnership Audit Rules .....	43
G. Miscellaneous .....	43
<b>VIII. TAX SHELTERS</b> .....	45
A. Tax Shelter Cases and Rulings .....	47
B. Identified “tax avoidance transactions” .....	47
C. Disclosure and Settlement.....	47
D. Tax Shelter Penalties.....	47
<b>IX. EXEMPT ORGANIZATIONS AND CHARITABLE GIVING</b> .....	47
A. Exempt Organizations.....	47
B. Charitable Giving.....	47
<b>X. TAX PROCEDURE</b> .....	48
A. Interest, Penalties, and Prosecutions .....	50
B. Discovery: Summonses and FOIA.....	55
C. Litigation Costs.....	59
D. Statutory Notice of Deficiency .....	60
E. Statute of Limitations.....	60
F. Liens and Collections.....	68
G. Innocent Spouse .....	68
H. Miscellaneous .....	68
<b>XI. WITHHOLDING AND EXCISE TAXES</b> .....	77
A. Employment Taxes .....	83
B. Self-employment Taxes .....	83
C. Excise Taxes .....	83
<b>XII. TAX LEGISLATION</b> .....	84
A. Enacted.....	84
<b>XIII. TRUSTS, ESTATES &amp; GIFTS</b> .....	84
A. Gross Estate .....	84
B. Deductions .....	86
C. Gifts.....	86
D. Trusts.....	86

## I. ACCOUNTING

### A. Accounting Methods

### B. Inventories

### C. Installment Method

### D. Year of Inclusion or Deduction

## II. BUSINESS INCOME AND DEDUCTIONS

### A. Income

### B. Deductible Expenses versus Capitalization

1. **Legal expenses incurred related to the preparation of applications to the FDA for approval of generic drugs are capital expenditures while legal expenses incurred to defend patent infringement suits are currently deductible.** [Mylan, Inc. v. Commissioner](#), 156 T.C. 137 (4/27/21). The taxpayer, Mylan, Inc., and its subsidiaries manufacture both brand-name and generic pharmaceutical drugs. Mylan incurred substantial legal expenses in two categories. First, Mylan incurred legal expenses in connection with its applications to the FDA seeking approval of generic drugs. To obtain this approval, Mylan submitted abbreviated new drug applications (ANDAs). The FDA's application process for generic drugs includes a requirement that the applicant certify the status of any patents covering the respective brand name drug previously approved by the FDA (referred to as a "paragraph IV certification"). One option available to the applicant is to certify that the relevant patent is invalid or will not be infringed by the sale or use of the generic version of the drug. An applicant making this certification is required to send notice letters to the holders of the patents informing them of the certification. Such a certification is treated by statute as patent infringement and the holder of the patent is entitled to bring suit in federal district court. Mylan incurred substantial legal expenses to prepare the notice letters it sent in connection with its FDA applications. Second, Mylan incurred substantial legal expenses in defending patent infringement lawsuits brought by the name-brand drug manufacturers against Mylan in response to the notice letters that Mylan sent. Mylan claimed deductions for both categories of legal expenses. The IRS, however, determined that all of Mylan's expenses were capital expenditures under § 263(a). The Tax Court (Judge Urda) held that the legal expenses incurred by Mylan to prepare notice letters were capital expenditures but the legal expenses Mylan incurred to defend patent infringement suits were currently deductible business expenses.

*FDA applications for generic drugs and notice letter costs.* The court first addressed the issue of whether the costs Mylan incurred to prepare the notice letters it sent in connection with its ANDAs should be capitalized under § 263. The court's analysis focused in large part on the regulations under § 263 regarding intangibles. These regulations require a taxpayer to capitalize both amounts paid to *create* an intangible and amounts paid to *facilitate* an acquisition or creation of an intangible. Reg. § 1.263(a)-4(b)(1)(ii), (v). With respect to creation of an intangible, Reg. § 1.263(a)-4(d)(5)(I) provides:

A taxpayer must capitalize amounts paid to a governmental agency to obtain, renew, renegotiate, or upgrade its rights under a trademark, trade name, copyright, license, permit, franchise, or other similar right granted by that governmental agency.

With respect to facilitating the acquisition or creation of an intangible, Reg. § 1.263(a)-4(e)(1) provides:

[A]n 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.

Mylan and the IRS disputed whether Mylan's legal fees were incurred to "facilitate" the acquisition of a right obtained from a governmental agency and therefore were required to be capitalized. They agreed that the relevant "transaction" was the *acquisition* of an FDA-approved ANDA with a paragraph IV certification. But they disagreed on when this acquisition occurs. Mylan argued that the acquisition of an FDA-approved ANDA occurs when the FDA completes its scientific investigation and issues an approval letter. The IRS asserted that the acquisition of an FDA-approved ANDA with a paragraph IV certification occurs only when the approval letter issued by the FDA becomes effective. The distinction is that the FDA may issue an approval letter but the approval does not grant any rights to the applicant until it becomes effective. Only when the approval becomes effective does the applicant have the right to begin delivery of a generic drug. *See* 21 U.S.C. § 355(a). With respect to Mylan's legal fees incurred in preparing the notice letters relating to the filing of its ANDAs with paragraph IV certifications, the court concluded that these costs were capital expenditures. The notice is a required step in securing FDA approval of an ANDA. According to the court, because the notice requirement was a prerequisite to securing FDA approval, "the legal expenses Mylan incurred to prepare, assemble, and transmit such notice letters constitute amounts incurred 'investigating or otherwise pursuing' the transaction of creating FDA-approved ANDAs ... and must be capitalized."

*Litigation expenses.* The court reached a different conclusion regarding Mylan's litigation expenses, holding that they were currently deductible. The IRS argued that a patent infringement suit is a step in obtaining FDA approval of an ANDA. The court disagreed, however, and reasoned that the outcome of a patent litigation action has no effect on the FDA's review of a generic drug application. The FDA continues its review process during the course of a patent infringement action and may issue a tentative or final approval of an application before the infringement action is finally decided. A successful patent dispute does not guarantee that a generic drug manufacturer will obtain FDA approval of an ANDA. While it is true that a successful challenge by a patent holder will result in a prohibition of the marketing of a generic drug found to infringe, the court reasoned that the coordination of the FDA approval process with the outcome of related patent litigation does not insert the patent litigation into the FDA's ANDA approval process. A patent on a name-brand drug does not prevent FDA approval of a generic version of the drug and patent litigation on the part of the patent holder is not a step in the FDA's approval process for a generic drug. In reaching its conclusion that the litigation expenses incurred by Mylan were currently deductible as ordinary and necessary expenses, the court also applied the "origin of the claim" test, which inquires as to "whether the origin of the claim litigated is in the process of acquisition", enhancement, or other disposition of a capital asset." *Woodward v. Commissioner*, 397 U.S. 572, 577 (1970); see also *Santa Fe Pac. Gold Co. v. Commissioner*, 132 T.C. 240, 264-265 (2009). Here, the court reasoned, Mylan's legal expenses arose from legal actions initiated by patent holders in an effort to protect their patents. The court followed the decision of the U.S. Court of Appeals for the Third Circuit in *Urquhart v. Commissioner*, 215 F.2d 17 (3d Cir. 1954), which held that patent litigation arises out of the exploitation of the invention embodied in the patent and, therefore, costs incurred to defend a patent infringement suit are not capital expenditures because they are not costs incurred to defend or protect title but rather are expenses incurred to protect business profits. Because Mylan's legal expenses arose out of the patent infringement claims initiated by the patent holders, the court held, they were currently deductible.

**a. Legal expenses incurred to defend patent infringement suits are currently deductible.** [Actavis Laboratories, FL, Inc. v. United States](#), 161 Fed. Cl. 334 (8/19/22). The plaintiff in this case, Actavis Laboratories Florida, Inc. (Actavis), was the substitute agent for Watson Pharmaceuticals, Inc. (Watson). Watson manufactured both brand-name and generic pharmaceutical drugs. To obtain approval of generic drugs, Watson submitted to the Food and Drug Administration abbreviated new drug applications (ANDAs). The ANDA application process for generic drugs includes a requirement that the applicant certify the status of any patents covering the respective brand name drug previously approved by the FDA (referred to as a "paragraph IV certification"). One option available to the applicant is to certify that the relevant patent is invalid or will not be infringed by the sale or use of the generic version of the drug. An

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