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IRS Provides Insight Into Treatment of Transferable Incentives

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In providing its views regarding a pharmaceutical company's costs to purchase a "front of the line" FDA voucher, the IRS Chief Counsel's Office provided insights into the treatment of other non-tax government incentives as well, say Connie Cunningham and James Atkinson of BDO USA.

In an internal advice on the tax treatment of a pharmaceutical company's incurred costs in purchasing from a third party a voucher to get expedited review of a new product, the IRS Chief Counsel's Office provides insight into the treatment of transferable incentives generally.

CCA 202304009 addresses whether a pharmaceutical or biotechnology company (herein a "pharma") must capitalize costs incurred in a purchase of a priority review voucher (PRV) that was issued to a third party by the U.S. Food & Drug Administration (FDA). As the name indicates, a PRV is a voucher entitling its holder to prioritized FDA review of a new medical treatment that an applicant seeks to offer to the public. Without such priority, the CCA explains, the process by which the FDA certifies that a proposed drug meets the prescribed scientific standards ensuring it is safe and effective — a New Drug Application (NDA) — typically takes 10 months or longer to complete. But by submitting the NDA with a PRV, the applicant can obtain FDA approval within six months, effectively moving to the "front of the line." While the PRV does not increase the likelihood the FDA will approve the NDA, pharmas treat PRVs as valuable assets because the quickened time frame in bringing a new drug to market helps them beat competitors to potentially enormous commercial rewards.

In this article, we will discuss how the IRS's analysis, based on well-established principles, generally aligns with analogous situations involving other transferable incentives. This discussion does not address the treatment of incentives created by the Inflation Reduction Act of 2022, which Treasury and the IRS addressed in REG-101610-23, stating that I.R.C. §6418 provides specific tax accounting rules for amounts paid or received for "eligible credits" as defined in that section, superseding the general federal income tax principles discussed herein.

Big Money at Stake

The FDA issues PRVs upon its approval of new treatments for certain neglected and rare diseases (targeted conditions). The PRV can be used by its holder for use with a future NDA, sold without restriction to another company, or simply held until the pharma decides how to use it. PRVs have no expiration date and can be transferred an unlimited number of times before eventually being redeemed with the FDA, as the Government Accountability Office notes in *Drug Development: FDA's Priority Review Voucher Programs* (Jan. 31, 2020).

The CCA notes as an example that a pharma might receive a PRV for developing a treatment for a rare disease. The original pharma could sell that PRV to an unrelated pharma that intends to redeem it with the FDA (either immediately or at some point in the future) to expedite the NDA process for a new treatment for a more common disease, giving that second treatment a broader consumer demand. The PRV presumably would have a greater commercial value in the hands of the second pharma for that reason. As a result, PRVs often are sold for tens or hundreds of millions of dollars (*see* Zachary Brennan, *Priority Review Voucher Updates, Who's Won PRVs, Who's Bought Them, and How Much They're Selling For*, EndpointsNews (online) (Nov. 13, 2023)).

Intended Use Is Key

Acquisition Costs

In concluding that a pharma must capitalize costs incurred to purchase a PRV, the Chief Counsel's Office applied the so-called "INDOPCO regulations" of Reg. §1.263(a)-4. Those regulations govern the treatment of costs incurred to create or acquire intangible assets, including transaction costs incurred in doing so.

For pharmas purchasing a PRV to use in connection with the purchaser's own NDA, the CCA viewed costs of obtaining expedited review of that filing as a transaction cost incurred to facilitate obtaining a "franchise right" — governmental consent to bring the new treatment to mar-

ket. As such, the CCA required adding the cost of obtaining expedited review to the tax basis of that intangible asset in accordance with §1.263(a)-4(g)(1) in the year the costs are paid or incurred. In other words, when acquired for the buyer's own use, the purchase price of the PRV is a transaction cost incurred in furtherance of a larger transaction.

The analysis differs for pharmas purchasing PRVs to be held for resale. In that situation, the Chief Counsel's Office concluded that "[t]he common practice of buying and selling PRVs within the pharmaceutical industry demonstrates that the value of the PRV is measurable, and the possession and control of a PRV is capable of sale or transfer separate and apart from the seller [pharma's] trade or business." Therefore, costs incurred to acquire a PRV for resale must be capitalized as the cost of purchasing a "separate and distinct intangible asset." In other words, when purchased for resale or investment, the PRV is treated as a stand-alone intangible asset, rather than as a cost of facilitating the speedier acquisition of a separate intangible.

The CCA's focus upon the purchaser's intended use of the voucher in determining the appropriate tax treatment of acquisition costs aligns with other situations in which tax treatment is a function of the purchaser's intended use of the property. The treatment of costs to acquire two otherwise identical vehicles, for example, differs if one is purchased to be sold to customers and the other for use in the company's own trade or business, as courts held in the precedent cases of *Duval Motor Co. v. Commissioner* (1959) and *Latimer-Looney Chevrolet v. Commissioner* (1952), and the IRS ruled in Rev. Rul. 75-538.

The IRS has addressed similar issues in the context of the "rent-to-own" industry (in Rev. Rul. 95-52 and Rev. Proc. 95-38) as well as heavy equipment dealers that hold items for either sale or rental (in CCA 201025049 and TAM 9811004), each time concluding that the tax treatment of the purchased property was determined by the taxpayer's intended use. While these other scenarios are irrelevant to the pharma's facts in CCA 202304009, they underscore that in resting its application of the INDOPCO regulations upon the purchaser's intended use of the PRV, the Chief Counsel's Office was acting consistently with well-established principles.

Cost Recovery

The PRV purchaser's intended use of the voucher also determines when and how the pharma recovers any capitalized costs. Initially, the Chief Counsel's Office concluded that PRVs themselves are not amortizable under §197 (regardless of the PRV's intended use). The CCA explains that "section 197 intangibles" exclude rights to receive services from a governmental unit unless that right is acquired in conjunction with the purchase of a trade or business, citing §197(e)(4)(B) and Reg. §1.197-2(c)(6). In the IRS's view, because the PRV is an intangible right to receive services from the government — expedited NDA review by the FDA — it falls within this exclusion and cannot be amortized under §197. Likewise, because the PRV has an indefinite life, it cannot be amortized under §167. (Reg. §1.167(a)-3.) As a result, the CCA concludes that no cost recovery is permissible immediately upon acquiring the PRV. Presumably the PRV would be ineligible for the 15-year amortization safe harbor for intangibles under Reg. §1.167(a)-3(b), although this is not addressed in the CCA. That safe harbor is inapplicable to intangibles acquired from another person or to create financial interests.

The analysis changes when consideration goes to the taxpayer's intended use. If it is to hold the voucher for expeditious FDA review of the pharma's own NDA, the costs of the voucher become part of the transaction costs incurred in pursuing FDA approval to bring a new product to market. If the FDA approves the drug, any capitalized transaction costs — including the costs of the PRV — become part of the amortizable basis of the "franchise right" received from the FDA (i.e., governmental consent to market the new drug to the public), recovered over 15 years under §197.

Conversely, if the FDA rejects the application, the transaction costs — including the cost of a PRV used to expedite the ultimately unsuccessful FDA review — become deductible as a loss under §165 in the taxable year the pharma abandons the NDA process.

If, on the other hand, the pharma acquires the PRV to hold for resale or investment, the acquisition costs are capitalized into the tax basis of the acquired intangible asset and eventually recovered in computing taxable gain or loss on the sale or exchange of the PRV to a third party.

This difference in cost recovery based on the pharma's intended use of the voucher likewise reflects well-established principles. Otherwise-identical assets might be included in the taxpayer's inventory and their costs recovered as cost of goods sold if held for sale to customers, or alternatively recovered through depreciation if held for use in the taxpayer's own business operations or held for rental or lease to customers rather than for sale (see *Duval* and *Latimer-Looney*). The CCA's differing treatment of costs of acquiring PRVs reflects this principle.

Intangibles Acquired Directly From Government

By its terms, the CCA addresses only the tax consequences of purchasing a PRV from a third party and includes no discussion of the tax considerations arising from the receipt of the voucher directly from the FDA. Earlier authorities may provide some guideposts, however.

Tax Management Memorandum

ISSN 0148-8295

In Rev. Rul. 92-16, the IRS concluded that electricity-generating companies do not realize gross income under §61 upon the receipt of sulfur dioxide emission allowances from the Environmental Protection Agency. Because the receipt was not a taxable event to the recipient, the recipient also had no cost basis in the emission allowance.

As the Joint Committee on Taxation noted in a 2009 report on the tax considerations in climate change legislation, Rev. Rul. 92-16 provides no analysis regarding its conclusion that the receipt of a readily marketable intangible asset is not an "accession to wealth" currently taxable to the recipient. Nonetheless, courts as well as the IRS have reached the same conclusion in analyzing the tax treatment of various transferable state incentives in the form of state tax credits.

In *Tempel v. Commissioner*, for example, the Tax Court concluded that a taxpayer did not realize an accession to wealth upon its receipt of transferable conservation easement tax credits from the State of Colorado. The court and the parties agreed that the receipt of a state tax credit is not an accession to wealth that results in income under §61. Instead, the credits represent only the right to reduce a taxpayer's state tax liability, and a reduction in a tax liability is not an accession to wealth.

The IRS reached the same conclusion in CCA 201147024 regarding several types of state incentives issued by the Commonwealth of Massachusetts in the form of tax credits. These incentives included environmental cleanup credits, motion picture credits, low-income housing credits, and medical device credits.

As had the Tax Court in *Tempel*, the IRS concluded that the original recipient did not realize income for federal tax purposes. Instead, mirroring language in *Tempel*, the IRS said "the fact that a state tax credit is transferable does not cause it to lose its character as a reduction or potential reduction in liability in the hands of the taxpayer who originally qualified for the credit."

Citing a litany of earlier authorities, the Tax Court in *Tempel* agreed with the IRS (albeit for different reasons) that the taxpayer realized capital gain rather than ordinary income upon sale of the state tax credits to a third party. The court stated at page 350, citing *Caboara v. Commissioner* (1977), "courts and the Commissioner's rulings frequently treat government-granted rights as capital assets." The court noted that §197 may have the effect of characterizing certain intangibles used in a trade or business as §1231 assets, citing to §197(f)(7) and Reg. §1.197-2(g)(8). (See also *Curtis v. United States*, Rev. Rul. 72-384, Rev. Rul. 70-248, and Rev. Rul. 66-58.)

The Tax Court and the IRS likewise agreed that the original recipient of the state tax credit lacked a tax basis in the state tax credit at the time of its sale, as the credits had not been "purchased" from the issuing state, but instead "it was the State's unilateral decision to grant petitioners the State tax credits as a consequence of their compliance with certain State statutes" (*Tempel* at 353).

Because of the inherently different rights embodied in a state tax credit versus the FDA vouchers at issue in CCA 202304009, the two situations are readily distinguishable. Nonetheless, viewing the treatment of transferable state tax credits in conjunction with the IRS's consistent treatment of transferable EPA emission allowances in Rev. Rul. 92-16 casts at least some light on the potential tax treatment of a pharma's receipt of a PRV from the FDA.

While certainty awaits further guidance from Treasury and the IRS, they would be acting consistently with *Tempel* and earlier IRS pronouncements if they concluded that the pharma does not realize taxable income upon receiving a PRV from the FDA but does realize capital gain, with no basis offset, upon selling or exchanging the PRV in a transaction within the scope of §1001. If the pharma instead uses the PRV in connection with another of its own NDAs, CCA 202304009 suggests the PRV would be viewed as a component of that larger transaction (acquiring a new "franchise"). However, because the PRV likely would have no tax basis under the reasoning of Rev. Rul. 92-16, there would be no costs to include in the amortizable basis of the intangible received upon FDA approval of the NDA or to expense under §165 if the FDA denied the application.

Conclusion

While CCA 202304009 provides the pharmaceutical industry with guidance on the narrow topic of costs incurred to move to the front of the line at the FDA, the insights gleaned from that document, when combined with other IRS guidance in unrelated contexts, might help forecast the tax accounting treatment of various other non-tax government incentives as well.

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ISSN 0148-8295