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subject: Capitalization and Recovery of Amounts Paid by Taxpayers to Acquire Priority Review Vouchers under §§ 263(a), 167, and 197 of the Internal Revenue Code

This Chief Counsel Advice responds to your request for assistance in determining the tax treatment of Priority Review Vouchers (PRVs) used in the pharmaceutical industry. Specifically, you have asked whether a pharmaceutical company (PC) must capitalize its costs of acquiring a PRV from a third-party PC, pursuant to § 263 of the Internal Revenue Code (Code), and—if so—whether those costs may be recovered under § 167 or § 197 of the Code.

ISSUES

(1) Whether amounts paid or incurred by a PC to acquire a PRV from a third-party PC must be capitalized as the cost of acquiring, creating, or facilitating the acquisition or creation of an intangible asset under § 263(a) of the Code?

(2) If the costs of acquiring, creating, or facilitating the acquisition or creation of a PRV must be capitalized, may these costs be recovered under § 167 or § 197, and if so, when does the useful life or amortization period, as applicable for these expenditures, begin?

CONCLUSIONS

(1) If the PC's intent is to use the PRV to expedite a New Drug Application (NDA), the PRV costs are properly treated as amounts incurred to facilitate the creation of a franchise right from the Federal Drug Administration (FDA), and therefore, must be capitalized under § 263(a) and the Income Tax Regulations (Regulations) thereunder. If the PC can demonstrate that it acquired the PRV with the intent to hold the PRV for sale, then the acquisition costs are properly treated as amounts paid for the acquisition of a separate intangible asset in a purchase or similar transaction, and therefore, must be capitalized under § 263(a) and the Regulations thereunder.

(2) If the PC uses the PRV to expedite the processing of an NDA filed with the FDA, the PC may amortize the amounts paid for the PRV under § 197 and the Regulations thereunder over the 15-year period beginning in the month that the NDA is approved by the FDA. If the PC utilizes the PRV for the NDA process, but is not awarded an NDA, the PC may recognize a loss under § 165 of the Code in the taxable year such loss is sustained. Further, if the PC resells the PRV to a third-party PC, it may not amortize the PRV costs under either § 167 or § 197 but may recover its basis through the recognition of gain or loss, whichever is appropriate, at the time such PRV is sold.

FACTS

Generally, a PC must obtain FDA approval of an NDA to market and sell any new drug in the United States. To incentivize PCs to develop new treatments for certain neglected and rare diseases (targeted conditions) and to accelerate the approval and market availability of these potentially important therapies, Congress created the Priority Review Voucher Program.[1] Under this program, the FDA may award a PRV to any PC that applies for and receives approval of an NDA for a new drug that treats certain targeted conditions.

A PRV entitles its holder to an expedited review by the FDA of any future NDA of the PC's choosing. Expedited review, in this context, means that the FDA will complete its review of an NDA within 6 months, rather than the 10 or more months that it generally takes for the FDA to review and approve an NDA. Although the use of a PRV does not ensure that the NDA will be approved, PCs treat PRVs as valuable assets because the use of a PRV in the NDA process can significantly reduce the time that it would take a PC to bring a desirable new drug to market.

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[1] Statutory authority for the PRV program is provided by 21 USC §§ 360n (tropical diseases), 360ff (rare pediatric diseases) and 360bbb-4a (agents that present national security threats).

In addition, a PRV awarded to a PC does not expire[2] and is freely transferable to a related or unrelated party. For example, a PC might receive a PRV for developing a drug for a neglected disease and sell that PRV to another PC, who will redeem it with the FDA to expedite the NDA process for a drug that could treat a more prevalent disease, and thus, is likely to be more profitable to that second PC.[3] As a result, PRVs are often transferred from one PC to another for significant cash market value. Once the PRV is transferred, the purchasing PC may use the PRV to accelerate the NDA process for a new drug immediately, it may hold the PRV to use later, or it may resell the PRV to another PC. There is no limit on the number of times a PRV may be transferred before it is remitted to the FDA. Thus, although a PRV is typically purchased by a PC with the intent to use it to expedite review of a specific NDA, a PC may also purchase a PRV with the intent to hold it for a future NDA, or with the intent to hold the PRV for sale.

When a PC decides that there is a benefit to expediting the review and approval of a particular drug, it redeems the PRV with the FDA as part of its NDA. Because this expedited review diverts the FDA's resources from the review of other pending NDAs, the FDA also requires the PC to pay a user fee at the time of redemption.[4]

LAW

A. Capitalization of Intangible Property

Section 162 of the Code allows taxpayers a deduction for all the ordinary and necessary expenses paid or incurred during the taxable year in carrying on any trade or business.

Section 263(a), however, prohibits current deductions for capital expenditures. Section 263(a) and § 1.263(a)-1(a) provide that no deduction is allowed for any amount paid out

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[2] The PRV program for neglected tropical diseases (enacted in 2007) does not sunset. However, the program for rare, pediatric diseases will expire in September 2024, although a drug designated as a rare pediatric treatment can still receive a voucher if the drug is approved by September 2026. See 21 USC § 360ff(b)(5); see also 21 USC § 360bbb-4a(g) (providing October 2023 sunset of national security threats PRV program). These programs can be renewed, and Congress has renewed the program several times already, most recently in § 321 of Title III of Subdivision BB of the Consolidated Appropriations Act, 2021, P.L. 116-260.

[3] Several factors influence whether a PC that is awarded a PRV will keep the PRV for future use or will sell the PRV to another PC, including consideration of potential profits from drugs in its development pipeline, the market value of a PRV, and the revenue that might be generated from its sale.

[4] Although the user fee is not the subject of this Chief Counsel Advice, these amounts must generally be capitalized under § 1.263(a)-4(d)(5)(i) as amounts paid to the government to obtain a franchise right from the government.

for permanent improvements or betterments made to increase the value of any property or estate.

Section 1.263(a)-4 provides rules for applying § 263 to amounts paid to acquire or create intangible property. Section 1.263(a)-4(b)(1) provides that except as otherwise provided in § 1.263(a)-4, a taxpayer must capitalize an amount paid to (i) acquire an intangible (see § 1.263(a)-4(c)); (ii) create an intangible described in § 1.263(a)-4(d); (iii) create or enhance a "separate and distinct intangible asset" within the meaning of § 1.263(a)-4(b)(3); (iv) create or enhance a future benefit identified in the Federal Register or the Internal Revenue Bulletin as an intangible for which capitalization is required; and (v) facilitate (as defined in § 1.263(a)-4(e)(1)) the acquisition or creation of an intangible.

Section 1.263(a)-4(b)(3)(i) provides that the term "separate and distinct intangible asset" means a property interest of ascertainable and measurable value in money's worth that is subject to protection under applicable State, Federal or foreign law, and the possession and control of which is intrinsically capable of being sold, transferred, or pledged (ignoring any restrictions imposed on assignability) separate and apart from a taxpayer's trade or business.

Section 1.263(a)-4(c)(1) provides that a taxpayer must capitalize amounts paid to another party to acquire any intangible from that party in a purchase or similar transaction. Section 1.263(a)-4(c)(1)(i)-(xv) provides a non-exclusive list of examples of the types of intangibles that are within the scope of this paragraph. Section 1.263(a)-4(c)(1)(viii), specifically, includes a franchise, trademark, or tradename (as defined in § 1.197-2(b)(10)).

Section 1.263(a)-4(d)(5)(i) provides that 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 intangible right granted by that governmental agency.

Section 1.263(a)-4(e) addresses transaction costs that must be capitalized because they facilitate the acquisition or creation of intangible property. Generally, § 1.263(a)-4(e)(1)(i) provides that an amount is paid to facilitate the acquisition or creation of an intangible if it is paid in the process of investigating or otherwise pursuing the transaction. Section 1.263-4(e)(3) provides that the term "transaction" means all of the factual elements comprising the acquisition or creation of an intangible and includes a series of steps carried out as part of a single plan to do so. Thus, § 1.263-4(e)(3) provides that a transaction can involve more than one invoice or more than one intangible.

B. Amortization, Depreciation, and Recovery of Intangible Property

Section 165 allows a deduction for any loss sustained during the taxable year and not compensated for by insurance or otherwise. Section 1.165-1(d)(1) provides that a loss is treated as sustained during the taxable year in which the loss occurs, as shown by a closed and completed transaction, and as fixed by an identifiable event occurring in such taxable year.

Section 167(a) provides that a reasonable allowance for the exhaustion, wear and tear, and obsolescence of property used in the trade or business or of property held by the taxpayer for the production of income shall be allowed as a depreciation deduction.

Section 1.167(a)-3 provides that if an intangible asset is known from experience or other factors to be of use in the business or in the production of income for only a limited period, the length of which can be estimated with reasonable accuracy, such an intangible asset may be the subject of a depreciation allowance. Examples are patents and copyrights. An intangible asset, the useful life of which is not limited, is not subject to the allowance for depreciation. No allowance will be permitted merely because, in the unsupported opinion of the taxpayer, the intangible asset has a limited useful life.

Section 197(a) provides that a taxpayer shall be entitled to an amortization deduction with respect to any amortizable § 197 intangible. The amount of the deduction under § 197 is determined by amortizing the adjusted basis of such an intangible ratably over the 15-year period beginning with the month in which the intangible was acquired. Section 197(b) provides that no other depreciation or amortization deduction shall be allowable with respect to any amortizable § 197 intangible.

Section 197(c)(1) provides that, except as otherwise provided in this section, the term "amortizable § 197 intangible" means any § 197 intangible which is (a) acquired by the taxpayer after August 10, 1993, and (b) held in connection with the conduct of a trade or business or an activity described in § 212.

Section 197(d)(1)(D) provides that a § 197 intangible includes any license, permit, or other right granted by a governmental unit or agency or instrumentality thereof. See also § 1.197-2(b)(8).

Section 197(d)(1)(F) provides that a § 197 intangible also includes any franchise, trademark, or trade name. See also § 1.197-2(b)(10).

Section 197(e)(4)(B) provides that § 197 intangibles do not include any right to receive tangible property or services under a contract or from a governmental unit if the right is not acquired as part of a purchase of a trade or business. See also § 1.197-2(c)(6).

Section 1.197-2(b)(10)(i) provides that the term "franchise" has the meaning given in § 1253(b)(1) and includes any agreement that provides one of the parties to the agreement with the right to distribute, sell, or provide goods, services, or facilities, within a specified area.

ANALYSIS

The proper tax treatment of a PC's costs to acquire a PRV is determined by examining the facts and circumstances surrounding that acquisition. Specifically, an inquiry must be made of whether a PC acquired the PRV with the intent to redeem the PRV with the FDA to expedite the NDA process, presently or in the future, or with the intent to hold the PRV for resale to others. The foregoing discussion details the legal analysis under both these circumstances by addressing each step of the PRV transactions – i.e., the PC's acquisition of the PRV from a third-party PC, the PC's use of the PRV in the NDA process, the PC's amortization and recovery of PRV costs, and the PC's disposition of the PRV in a sale or exchange.

A. PRV used to obtain an expedited NDA

1. Capitalization under § 263(a)

If the PC incurs costs for a PRV with the intent to utilize it to expedite an NDA--the process by which a PC obtains from the FDA the franchise right to market and sell a new drug in the United States--then the treatment of PC's costs is governed by § 1.263(a)-4(b)(1)(v). This section requires a taxpayer to capitalize amounts incurred to facilitate the creation of an intangible described in § 1.263(a)-4(d). Specifically, under § 1.263(a)-4(d)(5)(i), a taxpayer must capitalize amounts paid to a government agency to obtain rights under a trademark, trade name, copyright, license, permit, franchise or other similar right granted by a government agency.

Generally, amounts paid directly to a government agency to obtain the right to market and sell a product have been treated as costs of obtaining a franchise from the government. See Jefferson-Pilot Corp. v. Commissioner, 98 T.C. 435, 443 (1992), aff'd, 995 F.2d 530 (4th Cir. 1993) ("franchise" is sufficiently broad to include FCC licenses between government and licensee for right to broadcast within a specified area). Thus, for example, application fees paid to a government agency to obtain a franchise or other similar right from that agency must be capitalized under § 1.263(a)-4(d)(5)(i).

In addition, where a taxpayer pays a party other than the government amounts to facilitate the creation of a right from a government agency, the courts have required those amounts to be capitalized as costs that facilitate the acquisition of such right under §§ 1.263(a)-4(b)(1) and 1.263(a)-4(e). See Mylan, Inc. v. Commissioner, 156 T.C. No. 10 (Apr. 27, 2021) (holding, in part, that legal fees paid by a PC to prepare notices to patent owners, which were required to obtain approval of an abbreviated NDA from the FDA ("ANDA"), must be capitalized under § 263(a) as costs that facilitate the creation of the rights obtained from the government).

Because amounts paid for a PRV are incurred to expedite the NDA process in the pursuit of a franchise, these costs are properly characterized as transaction costs, that is, costs incurred to facilitate, or pursue, the creation of that franchise under §§ 1.263(a)-4(b)(1)(v), 1.263(a)-4(d)(5)(i), and 1.263(a)-4(e). Further, § 1.263(a)-4(e)(3) provides that the term "transaction" is meant to encapsulate all the factual elements comprising the creation of an intangible and includes a series of steps carried out as part of a single plan to do so. In this circumstance, then, the purchase of the PRV is one step in the PC's plan to obtain a franchise right from the FDA in an expedited manner. Therefore, amounts paid for a PRV are properly characterized as costs incurred to facilitate the creation of an intangible—the franchise—and must be capitalized and added to the basis of the that franchise under § 263(a) and § 1.263(a)-4(g)(1) in the taxable year that the costs are paid or incurred.

2. Amortization, Depreciation, and Recovery under §§ 167 and 197

Although they must be capitalized, amounts paid or incurred to acquire a PRV are not depreciable or amortizable at the time a PRV is acquired. Sections 197(c)(1) and (d)(1)(D) and § 1.197-2(b)(8) generally provide that licenses, permits, or other rights granted by a government unit will constitute an amortizable § 197 intangible. With respect to an acquired PRV, however, an exception applies. Specifically, § 197(e)(4)(B) and § 1.197-2(c)(6) provide that the definition of a § 197 intangible excludes any right to receive tangible property or services under a contract or from a governmental unit if the right is not acquired as part of a purchase of a trade or business. Accordingly, because a PRV provides the PC with expedited servicing of an NDA by the FDA, the amounts paid or incurred by a PC to acquire a PRV are not amortizable under § 197 at the time the PRV is acquired by the PC. Likewise, amounts paid or incurred to acquire a PRV are not depreciable under § 167 because PRVs do not expire, and assets with unlimited useful lives are excluded from the scope of § 167. See § 1.167(a)-3.

However, amounts paid or incurred for a PRV may be recovered later as a cost of facilitating the creation of a franchise right. Section 197(d)(1)(F) provides that a § 197 intangible also includes any franchise, trademark, or trade name. Because such franchise right is held in connection with the conduct of PC's trade or business, the costs of the PRV and any other costs incurred in the process of obtaining the franchise are properly treated as an amortizable § 197 intangible under §§ 197(c)(1)

and 197(d)(1)(F). See § 1.197-2(b)(10)(i). Accordingly, under § 197(a), the PC may recover these costs and any other costs related to the creation of the franchise right ratably over a 15-year period beginning on the first day of the month that the NDA is approved.

If no NDA is granted by the FDA, the PC would be permitted, subject to the loss disallowance rules in § 197(f)(1) and § 1.197-2(g), to deduct the costs of acquiring the PRV, and any application fees associated with the NDA, as a loss under § 165 in the taxable year the NDA process is abandoned by the PC. See § 1.165-1(d)(1).

B. PRV Acquired for Resale

1. Capitalization under § 263(a)

If a PC acquires the PRV with the intention to hold the PRV for resale or investment, the treatment of the PC's acquisition costs is governed by §§ 1.263(a)-4(b)(1)(i) and 1.263(a)-4(c)(1). Under these intangible property regulations, a taxpayer is required to capitalize amounts paid to another party to acquire an intangible from that party in a purchase or similar transaction. Section 1.263(a)-4(c)(1) provides examples of the types of intangibles that must be capitalized under this provision. However, these examples are not exclusive. In fact, § 1.263(a)-4(b)(3) provides a definition of separate and distinct intangible property for purposes of applying the intangible regulations. Specifically, § 1.263(a)-4(b)(3) states that a separate and distinct intangible asset includes a property interest of ascertainable and measurable value in money's worth that is subject to protection under applicable state, federal or foreign law and the possession and control of which is intrinsically capable of being sold, transferred, or pledged separate and apart from a trade or business.

Although amounts paid for a PRV are not listed in the specific examples of acquired intangibles under § 1.263(a)-4(c)(1), these amounts do fall within the definition of a separate and distinct intangible asset under § 1.263(a)-4(b)(3). Specifically, a PRV is a property interest that provides the bearer with the right to receive expedited regulatory review of an NDA by the FDA, and this interest is protected under statutes authorizing the FDA to grant PRVs and allowing such PRVs to be transferred. See § 1.263-4(b)(3). The common practice of buying and selling PRVs within the pharmaceutical industry demonstrates that the value of a PRV is measurable, and the possession and control of a PRV is capable of sale or transfer separate and apart from the seller PC's trade or business. Accordingly, in this context, a PRV is properly characterized as a separate and distinct intangible asset under § 1.263(a)-4(b)(3) and, as such, the acquisition cost of the PRV must be capitalized under § 263(a) and § 1.263(a)-4(c)(1) in the taxable year such costs are paid or incurred.

2. Amortization, Depreciation, and Recovery under §§ 167 and 197

As discussed above, amounts paid or incurred to acquire a PRV are not depreciable or amortizable at the time such PRV is acquired. This is because any right to receive services from a governmental unit is excepted from the definition of a § 197 intangible unless such right is acquired as part of a purchase of a trade or business. See § 197(e)(4)(B); § 1.197-2(c)(6). Further, assets with unlimited useful lives, such as PRVs that never expire, are not depreciable under § 167. See § 1.167(a)-3.

Thus, if a PC acquires a PRV with the intent to resell it or hold it for or investment, and such PRV is never used by the PC in an NDA application, the PC would not be permitted to amortize or depreciate the capitalized costs of the PRV. Instead, the PC's recovery of PRV costs would typically be limited to gain or loss upon the disposition of the intangible, which would likely occur when the PRV is transferred, sold, or exchanged to another PC in accordance with applicable provisions of the Code. See, e.g., §§ 1001, 1012.

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Please call (202) 317-5100 if you have any questions regarding § 263(a) or at 202-317-7005 if you have any questions regarding § 167 or § 197.