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subject: Legal Fees Incurred by Drug Manufacturers Under the Hatch-Waxman Act

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ISSUES

1. If a drug manufacturer files an Abbreviated New Drug Application (ANDA) with ¶ IV certification, are the legal fees the drug manufacturer incurs to defend against a 35 U.S.C. § 271(e)(2) patent infringement suit required to be capitalized under § 263(a) of the Internal Revenue Code and § 1.263(a)-4 of the Income Tax Regulations?
2. If a drug manufacturer holds a patent on a drug for which an ANDA with ¶ IV certification is filed, are the legal fees incurred by the drug manufacturer to try to establish that the manufacture, use, or sale of the drug subject to the ANDA would infringe the drug manufacturer's patent required to be capitalized under § 1.263(a)-4(d)(9) of the regulations?

CONCLUSIONS

1. Where a drug manufacturer files an ANDA with ¶ IV certification, the legal fees the drug manufacturer incurs to defend against a 35 U.S.C. § 271(e)(2) patent

infringement suit are required to be capitalized under § 263(a) of the Code and §§ 1.263(a)-4(d)(5) and 1.263(a)-4(b)(1)(v) of the regulations.

2. Where a drug manufacturer holds a patent on a drug for which an ANDA with ¶ IV certification is filed, the legal fees incurred by the drug manufacturer to try to establish that the manufacture, use, or sale of the drug subject to the ANDA would infringe the drug manufacturer's patent generally are not required to be capitalized under § 1.263(a)-4(d)(9) of the regulations.

FACTS

The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301–399d, provides that Food and Drug Administration (FDA) approval must be obtained before a new drug can be legally marketed and sold in the United States. 21 U.S.C. § 355. A company seeking to market a drug that has never been approved before (also called an innovator drug) must submit a New Drug Application (NDA) to the FDA. The NDA is the vehicle through which a drug sponsor formally proposes that the FDA approve a new pharmaceutical for marketing and sale in the U.S.

With the stated purpose of expediting the availability of less costly generic drugs, the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417 (the Hatch-Waxman Act), established an “abbreviated” application process, known as an Abbreviated New Drug Application (ANDA), for the review and ultimate approval of generic equivalents of previously approved (post 1962) innovator drugs. Generic drug applications are termed “abbreviated” because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent (i.e., performs in the same manner as the innovator drug).

In addition to expediting review of the safety and bioequivalence of generic drug products prior to approval for marketing, the ANDA process is also designed to accelerate the resolution of any patent infringement issues that may arise from the manufacture, use, or sale of a generic equivalent of an innovator drug. Thus, an ANDA applicant is required to certify (1) whether a patent exists covering the innovator drug that is relevant to the generic equivalent, and, if so, (2) whether the patent has expired, (3) whether approval is being requested to begin marketing the generic drug after the relevant patent has expired, or (4) whether, although a relevant patent exists, the patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the application is submitted (this fourth certification is known as a paragraph IV patent certification or ¶ IV certification).

In the case of an ANDA with ¶ IV certification, the first successful applicant is generally entitled to a 180-day exclusivity period (beginning from the first commercial offering of its drug) during which the FDA is not authorized to issue approval to any other generic drug manufacturer.

A ¶ IV certification application allows for the testing and development of a generic drug prior to patent expiration because under 35 U.S.C. § 271(e)(1) it is not an act of infringement to make or use a patented invention (other than a new animal drug or veterinary biological product) solely for the purpose of filing for regulatory approval to manufacture and sell a generic drug.

While making or using a patented drug in order to complete an ANDA is not an act of patent infringement, the act of filing an ANDA with ¶ IV certification constitutes an act of patent infringement, providing courts with jurisdiction to resolve patent issues before actual sale of the generic drug. 35 U.S.C. §§ 271(e)(2), (4).

Under the ANDA process, the applicant must provide notice to the drug patent holder that an ANDA ¶ IV certification has been filed. The drug patent holder may file an infringement suit against the ANDA applicant within 45 days of the date of notification that an ANDA ¶ IV certification was filed (ANDA ¶ IV notice), in which case the FDA is prohibited from approving the ANDA for 40 months (40-month stay). If prior to expiration of the 40-month stay the court determines that the patent is not valid or is not infringed, FDA approval shall be made effective on the date that the court enters judgment. If prior to expiration of the 40-month stay the court determines that the patent has been infringed, then FDA approval shall be made effective on the infringed patent expiration date. If the drug patent holder does not bring an infringement suit within 45 days from the date on which the ANDA ¶ IV notice was received, FDA approval of the ANDA shall be made effective immediately, pending completion of the FDA's safety and effectiveness review. See 35 U.S.C. §§ 271(e)(4), 355(j)(5)(B)(iii). However, FDA approval may be withdrawn or altered if a patent infringement suit is filed after the 45-day period and a court determines that the patent has been infringed. See *Mylan Labs. v. Thompson*, 389 F.3d 1272 (D.C. Cir. 2004). If FDA approval of the ANDA becomes effective while the patent infringement suit is still pending, the ANDA applicant may choose to wait for a final ruling from the court before commercializing the approved drug, or may decide to commercialize the drug "at risk" of being sued for lost profits if the patent is later found to be valid and infringed.

LAW AND ANALYSIS

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

Section 263(a) generally requires capitalization of amounts paid for permanent improvements or betterments made to increase the value of any property or estate.

Section 1.263(a)-4 of the regulations provides rules for applying § 263(a) to amount paid to acquire or create intangibles.

Under § 1.263(a)-4(b)(1)(ii), a taxpayer must capitalize an amount paid to create an intangible described in § 1.263(a)-4(d).

Under §1.263(a)-4(d)(5)(i), 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.

Under § 1.263(a)-4(e)(1)(i), a taxpayer must capitalize an amount paid to facilitate the acquisition or creation of an intangible described in § 1.263(a)-4(d) 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 the facts and circumstances. In determining whether an amount is paid to facilitate a transaction, the fact that the amount would (or would not) have been paid but for the transaction is relevant, but is not determinative.

Under § 1.263(a)-4(e)(3), the term “transaction” means all of the factual elements comprising an acquisition or creation of an intangible and includes a series of steps carried out as part of a single plan.

Section 1.263(a)-4(d)(9)(i) requires a taxpayer to capitalize amounts paid to another party to defend or perfect title to intangible property if that other party challenges the taxpayer’s title to the intangible property.

The origin of the claim litigated test established in *United States v. Gilmore*, 372 U.S. 39 (1963), generally determines whether an amount incurred in litigation that may affect a taxpayer’s title to property is currently deductible under § 162(a). See also *Woodward v. Commissioner*, 397 U.S. 572 (1970); *United States v. Hilton Hotels Corp.*, 397 U.S. 580 (1970). In *Gilmore*, the Court held that “the origin and character of the claim with respect to which an expense was incurred, rather than its potential consequences upon the fortunes of the taxpayer, is the controlling basic test of whether the expense [is] ‘business’ or ‘personal’ and hence whether it is deductible or not...”. *Gilmore* at 49.

In applying the origin of the claim test, the taxpayer’s purpose in undertaking or defending a particular piece of litigation is not relevant. See *Woodward* at 578. The origin of the claim test is an objective inquiry to determine the origin and character of the claim, taking into account all of the facts and circumstances; it is not a test dependent on the formal titles to pleadings or subjective motives. Thus, while legal fees paid by a business in connection with business-related litigation generally are deductible as ordinary and necessary expenses under § 162, litigation fees with their origin in a capital transaction are required to be capitalized under the origin of the claim test.

ANDA Applicant

Where a drug manufacturer seeks FDA approval of an ANDA with ¶ IV certification, the question is whether the costs of defending a patent infringement claim brought following ANDA ¶ IV notice must be capitalized as part of the costs to obtain FDA approval to market and sell a generic drug.

In general, costs to defend against a claim of patent infringement are deductible on the theory that the taxpayer is protecting or maintaining its income-generating business. However, the law has long recognized that otherwise deductible costs, when incurred in a capital transaction, must be capitalized. *Commissioner v. Idaho Power Co.*, 418 U.S. 1 (1974).

It is uncontested that direct costs incurred to obtain approval to market and sell a generic drug must be capitalized. Under § 1.263(a)-4(d)(5)(i), a taxpayer must capitalize amounts paid to a governmental agency to obtain, renew, renegotiate, or upgrade its rights under a license, permit, franchise, or other similar right granted by that governmental agency. A generic drug manufacturer must obtain FDA approval to market and sell its generic drug and must file an ANDA (or NDA) in order to obtain such approval. FDA approval of an ANDA creates for the applicant an intangible identified in § 1.263(a)-4(d)(5)(i). Thus, the application fees incurred in pursuit of FDA approval for an ANDA must be capitalized as part of the acquisition costs for the approval to market and sell a generic drug.

Patent infringement defense costs incurred in the ANDA process are not amounts paid directly to the FDA to obtain a right to market and sell. If they are capitalizable, it is because they are “transaction costs” that facilitate the acquisition or creation of a right to market or sell under § 1.263(a)-4(d)(5)(i). The facilitation standard under § 1.263(a)-4(e)(1)(i) is intentionally broad in scope (all costs paid in the process of investigating or otherwise pursuing the transaction), as is the definition of “transaction” (all of the factual elements comprising an acquisition or creation of an intangible, including a series of steps carried out as part of a single plan). Pursuit of a transaction does not require the successful completion of a transaction; it merely requires a taxpayer to attempt to gain or accomplish the transaction.

Under the statutory scheme established by the Hatch-Waxman Act, resolution of the patent claims is an integral step in the process of pursuing FDA approval of an ANDA with ¶ IV certification. An applicant must certify not only that the generic drug is biologically equivalent to one or more drugs for which a patent exists, but that the patent is (or patents are) invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the application is submitted. As part of this certification process, the applicant must provide notice to the drug patent holder that an ANDA ¶ IV certification has been filed and, if the drug patent holder files an infringement suit against the ANDA applicant within 45 days of the ANDA ¶ IV notice, the FDA is prohibited from approving the ANDA for 40 months. Further, the effective date of FDA approval becomes dependent on how the patent infringement litigation is resolved and the nature of any court order. See 35 U.S.C. §§ 271(e)(4), 355(j)(5)(B)(iii). Even if a patent infringement suit is filed after the 45-day window has expired, the effective date of FDA approval may still be altered if the ANDA applicant loses the patent infringement case. See *Mylan Labs. v. Thompson*, 389 F.3d 1272 (D.C. Cir. 2004). The effective date of FDA approval is therefore dependent on the outcome of any patent infringement litigation that arises as a direct result of the filing of an ANDA with ¶ IV certification.

The infringement suit pursuant to an ANDA with ¶ IV certification is so integral to the process by which generic drug manufacturers obtain approval to market and sell a generic version of a drug that the litigation costs to defend the suit are incurred “in the process of pursuing” such approval. A patent infringement suit following an ANDA with ¶ IV certification is distinguishable from the typical non-ANDA patent infringement suits brought outside of the Hatch-Waxman framework. The deemed act of infringement created by filing an ANDA with ¶ IV certification is uniquely designed to permit patent issues to be resolved without actual acts of infringement (e.g., manufacturing, using, or selling) that are generally required in order for infringement to exist, and the outcome of that patent resolution can affect the rights the FDA will grant to the applicant (e.g., the date of FDA approval; a potential 180-day exclusivity period). Under the Hatch-Waxman Act, the two events, the filing of an ANDA with ¶ IV certification and the defense of the patent infringement suit, are elements of a unified statutory scheme for obtaining FDA approval to market and sell a generic drug.

We conclude that the patent defense litigation following an ANDA with ¶ IV certification originates in a capital transaction: the application for FDA approval to market and sell a generic drug, and that the costs of such litigation facilitate that transaction and must be capitalized under § 1.263(a)-4(e)(1).

Our conclusion is consistent with the underlying purpose of the capitalization rules, which attempt to match expenses with the income generated by those expenses. In filing an ANDA with ¶ IV certification, an applicant is seeking to obtain the right to market and sell a generic drug in advance of actually manufacturing and selling that drug. All costs the generic drug maker incurs in the process of seeking FDA approval are better matched against the income derived from future sales of a generic drug, sales that cannot commence until after FDA approval is received.

Patented Drug Manufacturer

In the case of a drug manufacturer that holds a patent on a drug for which an ANDA with ¶ IV certification is filed, the legal fees incurred by the drug manufacturer to try to establish that the manufacture, use, or sale of the drug subject to the ANDA would infringe the drug manufacturer’s patent are incurred to defend an existing intellectual property right, and not as part of the creation of a new intangible.

A taxpayer must capitalize amounts paid to another party to defend or perfect title to intangible property if that other party challenges the taxpayer’s title to the intangible property. § 1.263(a)-4(d)(9)(i); *Safety Tube Corp. v. Commissioner*, 168 F.2d 787 (6th Cir. 1948) (legal fees required to be capitalized where controversy was over which party had title and ownership of the patent). This rule, however, is “not intended to require capitalization of amounts paid to protect property against infringement and to recover profits and damages as a result of an infringement, which are generally deductible as ordinary and necessary business expenses under § 162(a). See, e.g., *Urquhart v. Commissioner*, 215 F.2d 17 (3rd Cir. 1954) (expenditures made by a licensor of patents to protect against infringement and to recover profits and damages were made to

protect, conserve, and maintain business profits, and not to defend or perfect title to property). Whether an amount is paid to defend or perfect title, on the one hand, or to protect against infringement, on the other, is a factual matter.” Preamble to Prop. Regs. Guidance Regarding Deduction and Capitalization of Expenditures, 67 Fed. Reg. 77701-01 at 77705, 2003-1 C.B. 373.

The nature of costs incurred in a patent infringement suit is a factual matter, and the federal tax treatment of costs incurred in a patent infringement suit depends on the nature of the costs. Patent infringement costs are capital if incurred for the defense or perfection of title to the patent. On the other hand, patent infringement costs are deductible if incurred to protect against infringement of the patent. If the costs are incurred for both purposes, then a direct tracing, if possible, or a reasonable allocation of costs if a direct tracing is not possible, is necessary to determine the proper treatment of the patent infringement costs for federal tax purposes.

Section 1.263(a)-4(d)(9)(iii) provides a patent infringement example that contains defense of title costs in which one party is accused of having stolen from the first party the technology upon which the patent is based:

R corporation claims to own an exclusive patent on a particular technology. U corporation brings a lawsuit against R, claiming that U is the true owner of the patent and that R stole the technology from U. The sole issue in the suit involves the validity of R’s patent. R chooses to settle the suit by paying U \$100,000 in exchange for U’s release of all future claim to the patent. R’s payment to U is an amount paid to defend or perfect title to intangible property under paragraph (d)(9) of this section and must be capitalized.

In the example, title is at issue because U asserts that as the original developer of the technology it, and not R, is the true owner of the patent. Therefore the costs paid by R corporation in the patent infringement litigation are subject to capitalization under § 1.263(a)-4(d)(9)(i).

In the context of patent infringement suits arising from an ANDA with ¶ IV certification, however, costs incurred to defend against a claim that the patent holder does not have proper ownership of the patent are likely to be rare. Innovator drugs take years to gain FDA approval. The FDA application process is transparent and well documented. All approved drugs are publicly listed, and ownership of any associated patent or patents is well documented. Furthermore, ¶ IV certification does not challenge ownership of a patent but rather provides that the patent for the listed drug is not valid, or will not be infringed by the generic drug. Thus, while not out of the realm of possibility, raising a question about whether the notified patent holder of a listed drug is the true owner of the patent would be unusual in patent infringement litigation arising from an ANDA with ¶ IV certification.

On the other hand, certification that the patent for a drug is not valid, or will not be infringed by the generic drug, will generally raise questions regarding the validity of the patent itself, such as the extent of coverage afforded by the patent or whether the technology encompassed by the patent was unique when the patent was applied for. Although such challenges may raise questions regarding the protection afforded by the patent, or even whether the patent was properly issued by U.S. Patent and Trademark Office, these challenges do not raise the question of whether the patent holder is the true owner of the patent.

Defense of the scope and valid issuance of a patent protects the patent holder's rights against infringement. As noted, costs incurred to protect a patent holder's rights against infringement and to permit the patent holder to protect profits and avoid damages as a result of an infringement are generally deductible as ordinary and necessary business expenses under § 162(a).

In conclusion, where a drug manufacturer holds a patent on a drug for which an ANDA with ¶ IV certification is filed, the legal fees incurred by the drug manufacturer to try to establish that the manufacture, use, or sale of the drug subject to the ANDA would infringe the drug manufacturer's patent generally are not required to be capitalized under § 1.263(a)-4(d)(9). It would be highly unusual in the context of a patent infringement suit arising from an ANDA with ¶ IV certification for the ownership or title to the patent to be in question. However, if that were the case, § 1.263(a)-4(d)(9) may require capitalization of some portion of the drug manufacturer's legal fees.

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