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Internal Revenue Service (IRS) Capitalized Legal Fees Incurred by Pharmaceutical Company

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In a recently released Field Attorney Advice, the Internal Revenue Service (IRS) Office of Chief Counsel concluded that a pharmaceutical company must capitalize legal fees incurred to obtain Food and Drug Administration approval for marketing and selling generic drugs and to prevent the marketing and sale of a competing generic drug. The IRS Office of Chief Counsel also concluded that it could impose an adjustment on audit to capitalize legal fees that the taxpayer expensed in prior years, including years closed by statute of limitations.

In a recently published Internal Revenue Service (IRS) Field Attorney Advice (FAA 20131001F, March 8, 2013), the IRS Office of Chief Counsel concluded that a pharmaceutical company must capitalize legal fees incurred to obtain U.S. Food and Drug Administration (FDA) approval for marketing and selling new generic drugs and to prevent the marketing and sale of a competing generic drug. The IRS also concluded that the Commissioner could change the taxpayer's method of accounting for the legal fees and impose an adjustment on audit to capitalize legal fees that the taxpayer expensed in prior years, including years closed by the statute of limitations.

NDA and ANDA

In order to market or sell a new drug in the United States, a New Drug Application (NDA) must be submitted to and approved by the FDA. An NDA consists of clinical and nonclinical data on the drug's safety and effectiveness, as well as a full description of the methods, facilities and quality controls employed during manufacturing and packaging. An NDA also must disclose all the patents that cover the drug.

To market or sell a generic version of an existing FDA-approved drug, the maker of the generic drug must submit an Abbreviated New Drug Application (ANDA) for FDA approval. An ANDA generally is not required to include preclinical and clinical trial data to establish safety and effectiveness. Instead, an ANDA applicant must show that its generic drug is bioequivalent to an existing drug. In addition, an ANDA applicant is required to provide certification that the ANDA will not infringe on the patent rights of a third party. Specifically, if an applicant seeks approval prior to the expiration of patents listed by the NDA holder, then a "paragraph IV certification" must be submitted by the applicant to certify that it believes its product or the use of its product does not infringe on the third party's patents, or that such patents are not valid or enforceable. The first generic drug applicant that files

an ANDA containing a paragraph IV certification is granted, upon approval, 180 days of marketing exclusivity.

For an ANDA with a paragraph IV certification, the applicant must send notices to the NDA holder for the referenced drug and to all patentees of record for the listed patents within 20 days of FDA notification that the ANDA is accepted for filing. If neither the NDA holder nor the patent holders bring an infringement lawsuit against the ANDA applicant within 45 days, the FDA may approve the ANDA. If the NDA holder or the patent holders file a patent infringement lawsuit against the ANDA applicant within 45 days, a stay prevents the FDA from approving the ANDA for up to 30 months. If, however, the patent infringement litigation is still ongoing after the 30 months, the FDA may approve the ANDA.

The Facts

The taxpayer is a pharmaceutical company engaged in developing, manufacturing, marketing, selling and distributing generic and brand name drugs. In the process of filing ANDAs with a paragraph IV certification, the taxpayer incurred legal fees in lawsuits filed by patent and NDA holders for patent infringement. In addition, the taxpayer as an NDA holder incurred legal fees in a lawsuit it filed against an ANDA applicant with a paragraph IV certification to protect its right to sell its branded drug until all patents expired. The taxpayer sought to deduct its legal fees as ordinary and necessary business expenses.

The IRS Analysis

Legal Fees Incurred in the Process of Obtaining FDA Approval of ANDAs

The IRS concluded that the legal fees incurred by the taxpayer as an ANDA applicant to defend actions for patent infringement in the process of filing the ANDA with paragraph IV certification must be capitalized under Treas. Reg. § 1.263(a)-4. The IRS characterized the fees as incurred to facilitate the taxpayer obtaining the FDA-approved ANDAs with paragraph IV certification, which granted the applicant the right to market and sell a generic drug before the expiration of the patents covering the branded drugs, and by filing early, potentially with a 180-day exclusivity period. As such, the IRS concluded, the fees are required to be capitalized as amounts paid to create or facilitate the creation of an intangible under Treas. Reg. § 1.263(a)-4(d)(5). In so concluding, the IRS rejected the taxpayer's argument that its fees did not facilitate obtaining FDA-approved ANDAs because it could have commercialized its generic drugs after the 30-month stay expired regardless of the outcome of the lawsuits. The IRS reasoned that the filing of the ANDAs with paragraph IV certification and the defense of the patent infringement lawsuit were a part of a series of steps undertaken in pursuit of a single plan to create an intangible.

The IRS further concluded that the cost recovery of the capitalized legal fees incurred to obtain the FDA-approved ANDAs must be suspended until the FDA approves the ANDAs, and the capitalized fees must be amortized on a straight-line basis over 15 years as section 197 intangibles.

Legal Fees Incurred to Protect Its Right Against Other ANDA Applicants with Paragraph IV Certification

With respect to the legal fees incurred by the taxpayer as an NDA holder in the litigation against another ANDA applicant, the IRS characterized the fees incurred to defend the validity of the patents owned by the taxpayer as amounts paid to defend or perfect title to intangible property that are

required to be capitalized under Treas. Reg. § 1.263(a)-4(d)(9). In contrast, the fees incurred by the taxpayer in the litigation relating to determining whether valid patents have been infringed are not required to be capitalized under Treas. Reg. § 1.263(a)-4(d)(9).

The IRS further concluded that the capitalized fees incurred to protect the patents and the FDA-approved NDA must be added to the basis of the patents to be depreciated under section 167. The cost recovery begins in the months in which the legal fees were incurred and is allocated over the remaining useful lives of the patents.

In characterizing the legal fees incurred by the taxpayer in defending the validity of its patents as costs of defending or perfecting title to intangible property, the IRS distinguished the legal fees at issue from the litigation expenses incurred by the taxpayers in defending a claim that their patents were invalid in *Urquhart v. Comm'r*, 215 F.2d 17 (3rd Cir. 1954). In *Urquhart*, the taxpayers were participants in a joint venture that was engaged in the business of inventing and licensing patents. The taxpayers obtained two patents involving fire-fighting equipment and, after threatening litigation against Pyrene Manufacturing Company, brought an infringement suit against a customer of Pyrene, seeking an injunction and recovery of profits and damages. The case was dismissed, and Pyrene subsequently commenced an action against the taxpayers seeking a judgment that the taxpayers' patents were invalid and that its own apparatus and methods did not infringe the patents. A counterclaim was filed for an injunction against infringement, and an accounting for profits and damages. Pyrene did not raise any questions as to title to, or ownership of, the patents and was successful in the lawsuit. The patents held by the taxpayers were found to be invalid. In holding that the legal fees incurred by the taxpayer were deductible as ordinary and necessary business expenses, the U.S. Court of Appeals for the Third Circuit rejected the IRS's contention that the litigation was for the defense or protection of title.

Distinguishing the FAA from *Urquhart*, the IRS focused on the fact that the taxpayers in *Urquhart* were professional inventors engaged in the business of exploiting and licensing patents, and that *Urquhart* involved the taxpayers' claims for recovering lost profits. By emphasizing that Pyrene did not raise any issue as to title to the patents in *Urquhart*, the IRS seemed to ignore the fact that, like the taxpayer in the FAA, Pyrene sought a judgment on the validity of the taxpayers' patents and that the outcome of the litigation in *Urquhart* also focused on the validity of the patents.

Change of Accounting Method for Legal Fees Incurred by the Taxpayer

The IRS also concluded that the taxpayer's treatment of its legal fess associated with each ANDA or patent as either deductible or capitalizable is a method of accounting that the Commissioner can change on an ANDA-by-ANDA or patent-by-patent basis. The consequence of this conclusion, if valid, is that the IRS can impose on audit an adjustment to capitalize legal fees that the taxpayer deducted in prior years, including years closed by the statute of limitations. For example, the IRS can include in the taxpayer's gross income for the earliest year under examination an adjustment equal to the amount of the legal fees the taxpayer previously deducted, less the amount of amortization that the taxpayer properly could have taken had the taxpayer capitalized the legal fees.

A taxpayer that voluntarily changes its method of accounting, however, receives more favorable terms and conditions than a taxpayer that has its method of accounting changed by the IRS on examination. For example, a taxpayer that changes its method of accounting voluntarily can spread the adjustment resulting from the change over four taxable years, and the first year of the adjustment is the current taxable year as opposed to the earliest open taxable year.

The publication of this FAA likely will bring the attention of examining agents to this issue. Therefore, if a taxpayer believes it is using an improper method of accounting for legal fees (or any other item), it should carefully consider whether to voluntarily change its method of accounting before the IRS proposes to change the taxpayer's method of accounting on examination.

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