The Tax Court Offers a Mixed Bag in the *Mylan* Case

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In *Mylan, Inc. & Subsidiaries v. Commissioner*, 156 T.C. No. 10 (April 27, 2021), the Tax Court held that legal expenses incurred by a manufacturer of generic pharmaceutical drugs for the preparation, assembly and transmittal of notices required by the filing of an Abbreviated New Drug Application (ANDA) were required to be capitalized pursuant to section 263(a) of the Internal Revenue Code (the Code). However, the Tax Court also held that litigation expenses incurred to defend against patent infringement suits that arose in connection with the ANDA process were not required to be capitalized, but instead were deductible as ordinary and necessary business expenses pursuant to section 162(a). The decision provides some clarity on how generic drug manufacturers must treat legal expenses related to government approvals, and the part of the decision upholding deductions for patent litigation-related legal fees is likely to be welcome news to such manufacturers.

Background

Prior to marketing and selling a drug in the United States, a pharmaceutical manufacturer must obtain approval from the Food & Drug Administration (FDA). For the approval of generic drugs, the law provides an expedited process or application — the ANDA. The FDA will approve an ANDA if the generic drug manufacturer demonstrates that the generic drug has the same active ingredients as, and is technically equivalent to, an already approved brand name drug. However, the FDA's approval is only effective after certain other procedural requirements are satisfied. First, the ANDA process at issue in *Mylan* required the filing of a statement (known as a paragraph IV certification) certifying that any brand drug patent is invalid or will not be infringed by the manufacture, use or sale of the generic version of the drug. According to the court, this paragraph IV certification automatically counts as a patent infringement that often provokes a patent litigation suit. Further, the paragraph IV certification process requires the applicant to send notifications to brand drug patent holders that it had filed an ANDA with a paragraph IV certification. The brand drug patent holder then may bring a suit in the U.S. District Court to delay the effective date of the ANDA approval to no earlier than the date of the expiration of the patent. Additionally, if suit is brought within 45 days of the notification, a 30-month stay is triggered during which the FDA is prohibited from granting effective approval.

Prior to the District Court providing a decision in the patent infringement suit, the FDA may issue a temporary approval letter to the generic manufacturer, but this temporary approval does not provide the generic manufacturer with final or *effective* approval. Rather, if the District Court decides the infringement matter within the 30-month period, the FDA must follow the District Court's decision. However, if the District Court fails to issue a decision within the 30-month period, a generic manufacturer may sell the generic drug "at risk," meaning that if the ongoing court proceeding determines that the brand drug patent is valid and infringed, the generic manufacturer will be liable for the brand manufacturer's lost profits despite the FDA's temporary approval. The ANDA process rewards a successful ANDA applicant that is granted an effective ANDA approval with a 180-day exclusivity period during which the successful applicant has the right to sell the generic drug without competition from other generic manufacturers.

During the years at issue in the case, Mylan regularly filed numerous ANDAs with paragraph IV certifications. As a result, Mylan incurred legal fees both: (i) for the preparation, assembly and transmittal of formal notification letters as required by the ANDA process; and (ii) to defend itself against patent infringement suits brought in response to the ANDA paragraph IV certifications. Mylan deducted both types of legal expenses as ordinary

and necessary business expenses under section 162(a) on its tax returns. The IRS in its notice of deficiency determined that Mylan was required to capitalize both types of legal expenses pursuant to section 263(a) as costs that "facilitate" the creation of a capital asset (*i.e.*, FDA approval).

The IRS argued that all of the legal expenses incurred by Mylan facilitated the approval of the ANDAs (and therefore had to be capitalized) because both the notice requirement and the infringement litigation were part of the statutory process for making and securing approval of an ANDA. In contrast, Mylan argued that acquisition of an FDA-approved ANDA with a paragraph IV certification occurs when the FDA completes a scientific and technical review that results in the FDA issuing either a tentative or final approval letter. Mylan further argued that costs it incurred for the notices required by the paragraph IV certification facilitated patent litigation suits. Unlike costs incurred to defend or perfect title to intangible property, the section 263(a) regulations do not require a taxpayer to capitalize amounts paid to defend against patent infringement suits. Rather, such expenses are generally deducted as ordinary and necessary business expenses. See *Urquhart v. Commissioner*, 215 F.2d 17 (3d Cir. 1954) and statements made in the preambles to both the proposed and final section 263(a) regulations, 67 Fed. Reg. 77705 (Dec. 19, 2002) and T.D. 9107, 2004-1 C.B. 447, 450. Therefore Mylan argued that the legal expenses it incurred for the notices and the patent infringement suits are not required to be capitalized pursuant to section 263(a), but instead should be deducted.

The Tax Court's Holding

The Tax Court disagreed with Mylan's assertion that an FDA-approved ANDA with a paragraph IV certification occurs when the FDA provides either a tentative or final approval letter. Rather, the Tax Court found that the acquisition of an FDA-approved ANDA with a paragraph IV certification only occurs when the applicant receives an *effective* approval. The Tax Court further held that because the notice required for paragraph IV certification is a required step to secure the FDA's effective approval of an ANDA, legal costs incurred for the preparation, assembly and transmittal of the notices "facilitated" the FDA approval and thus were required to be capitalized under section 263(a).

However, the Tax Court disagreed with the IRS with respect to the litigation expenses incurred by Mylan, finding that the fact that patent litigation arises from the paragraph IV certification that is provided by the ANDA statute does not change the character of that litigation as an infringement suit. The court found that as a brand name drug patent holder is under no obligation to initiate an infringement suit in response to an ANDA with a paragraph IV certification, an infringement suit arising from such certification is not a step in obtaining an effective FDA approval. Instead the court found that a patent infringement suit filed in the paragraph IV certification process serves the same purpose as a normal patent infringement suit — allowing a patent holder the opportunity to defend its intellectual property rights. Accordingly, the court held that patent litigation costs incurred in the context of the paragraph IV certification process are not subject to capitalization pursuant to section 263(a), but instead should be deducted as ordinary and necessary business expenses.

The Tax Court's *Mylan* decision may not resolve the long-standing controversy surrounding the tax treatment of ANDA-related expenses incurred by Paragraph IV applicants. Both the IRS and Mylan have the right to appeal the portion of the decision adverse to them. Further, litigation may arise in the future involving other Paragraph IV applicants. Different facts and/or different judicial venues could conceivably yield different outcomes from that in *Mylan*. The *Mylan* decision, however, is certainly of interest to all generic drug manufacturers that apply for ANDAs using Paragraph IV certifications.