Bloomberg Tax

Tax Management Memorandum™

Pharma Wins Again on Deducting Patent Dispute Costs for Generics

By James Atkinson
BDO USA

An appellate court affirmed that the legal fees a maker of a new generic drug pays in defending against patent infringement claims arising from its application to the FDA don't facilitate approval and need not be treated as a cost of obtaining an intangible asset, BDO's James Atkinson reports.

The pharmaceutical industry has prevailed once again in establishing the right to deduct legal fees paid in defending against patent infringement claims arising from a company's application to market a new generic drug. Because the most recent victory was secured in the US Court of Appeals for the Third Circuit—the home of many members of the industry—that court's July 27 decision in *Mylan, Inc. & Subsidiaries v. Commissioner* (3d Cir.) hopefully will be particularly beneficial in strengthening the industry's position.

Although the facts at issue in *Mylan* center upon the rules for governmental review and approval of pharmaceutical products by the Food and Drug Administration (FDA), the basic legal question before the court was straight-forward: whether expenses incurred in litigating a patent dispute resulting from the taxpayer's application for FDA approval to market a new drug ''facilitated'' obtaining that approval and must be treated as a cost of obtaining an intangible asset.

Affirming the Tax Court's 2021 decision (156 T.C. 137) in *Mylan*, the Third Circuit agreed with the taxpayer that the FDA's scientific review of the new drug and a district court's adjudication of a related patent dispute were independent albeit coordinated proceedings and, as such, the costs of one need not be treated as a cost of the other.

ANDAs and Hatch-Waxman

FDA approval must be obtained before any branded pharmaceutical product may be marketed or sold to the public. It is a ''long, comprehensive, and costly testing process'' that begins with the pharmaceutical manufacturer's submission of a New Drug Application (NDA) (3d Cir. at *1; T.C. at 139). (Descriptions of the FDA processes and the Hatch-Waxman Act herein are drawn from discussions in either or both of the courts' *Mylan* opinions. The Supreme Court offers a description as well in a non-tax opinion.) The FDA's review and approval process ensures that the new drug is safe and effective. If successful, the pharmaceutical manufacturer will receive the FDA's ''effective approval'' to offer the new drug for sale to the public.

Separately, the pharmaceutical company may seek protection for the intellectual property associated with its new product under the federal patent and trademark laws, administered by the US Patent and Trademark Office (USPTO). The USPTO is a separate organization within the federal government, having no jurisdictional or organizational overlap with the FDA. The USPTO is a component of the Commerce Department whereas the FDA is part of the Department of Health and Human Services. The two agencies' regulatory roles and areas of expertise are distinct, and they function independently.

The FDA's approval process applies to manufacturers of generic as well as branded products. However, Congress has provided a ''shortcut'' to FDA approval for manufacturers hoping to develop and market generic copies of brand-name drugs that have already successfully completed the full FDA approval gauntlet. Under the Drug Price Competition and Patent Term Restoration Act of 1984 (''Hatch-Waxman Act''), companies seeking FDA approval for a generic drug must submit an Abbreviated New Drug Application (ANDA). The ANDA essentially builds upon the extensive testing that the FDA performed in approving the brand-name drug upon which the proposed generic version is based. The ANDA applicant must demonstrate that its proposed generic drug has the same active ingredients as, is biologically equivalent to, and would preserve the identity, strength, quality, and purity of, its brand-name counterpart.

Because the proposed generic drug is in effect ''piggybacking'' on a brand-name product already on

the market, the Hatch-Waxman Act also includes provisions protecting the intellectual property rights of the developer of the branded drug. Specifically, as part of the ANDA process, the applicant must indicate whether the branded product is protected by a currently valid patent. The *Mylan* opinions indicate that in most cases, the ANDA applicant chooses ''paragraph IV certification,'' asserting that any patent for the brand-name product ''is invalid or will not be infringed by the manufacture, use, or sale'' (T.C. at 142) of the generic version. The FDA does not review the accuracy of that certification or consult with the USPTO in processing the ANDA.

The ANDA process also requires the applicant to notify holders of patents for the brand-name version of the drug within 20 days of the applicant's paragraph IV certification. Under the Hatch-Waxman Act, the paragraph IV certification creates a deemed infringement of the original patent, even though no actual infringement has occurred, since the generic drug has not been approved for sale by the FDA. The deemed infringement is a legal fiction creating a jurisdictional vehicle for the patentee to file a protective lawsuit against the ANDA applicant before the generic version is released and any actual damages arise. Patentees are not required to assert patent infringement against the ANDA applicant, and the Third Circuit cites (at n.8) testimony from Mylan's general counsel that patentees do so approximately 75% of the time.

The FDA's scientific review and any patent dispute between the parties are coordinated, yet independent.

Upon the filing of an ANDA, the FDA begins its formal review process, which continues without regard to a patent dispute. The FDA does not consider pending patent disputes in conducting its scientific review of the generic drug. Although the FDA may decline to approve the generic drug for many technical reasons listed in the governing food and drug laws, none of the listed grounds for rejection of an ANDA relates to patent issues.

If the patentee files a patent infringement lawsuit within 45 days of receiving notice of the applicant's paragraph IV certification, however, the Hatch-Waxman Act creates an automatic 30-month stay during which the FDA may not grant ''effective'' (or final) approval to market and sell the generic drug. If the FDA approves the ANDA during the 30-month stay, it may grant only ''tentative'' approval for the sale of the generic drug (with no marketing or sales actually permitted yet). If the patent dispute continues once the 30-month stay expires, the FDA can issue final approval, allowing the applicant to market and sell the generic drug (''at risk'' for damages if it ultimately loses the patent dispute), despite the ongoing litigation. If the district court rules in favor of the patentee during the 30-month stay, the FDA will follow that determination and make its approval of the ANDA effective only upon expiration of the existing patent.

In other words, if the FDA ultimately approves the drug as being safe and effective, the patent dispute affects that approval only as to when it enters into force and marketing and sales can begin. As such, while a patent dispute might delay the FDA approval start date, it cannot affect *whether* the taxpayer receives the approval.

Facilitative Costs?

For the years at issue, Mylan incurred tens of millions of dollars in legal fees to defend against patentee claims that generic drugs for which it was seeking FDA approval violated the patentee's intellectual property rights. Because Mylan was seeking a valuable intangible right from the FDA—governmental approval to sell a new pharmaceutical—the IRS took the position that the legal fees arising from the patent litigation ''facilitated'' Mylan's ability to obtain that intangible asset and, as such, had to be treated as part of its acquisition cost.

The parties' dispute arose under the so-called ''INDOPCO regulations'' of Treas. Reg. §1.263(a)-4. In the broadest terms, the INDOPCO regulations require taxpayers to capitalize costs incurred to acquire any intangible asset or to create any of nine specifically listed intangible assets, including rights obtained from a governmental agency (*id*. at -4(d)(5)(i)). (For a full discussion of the INDOPCO regulations, see Atkinson, 509 T.M., *Principles of Capitalization*.)

The INDOPCO regulations at -4(d)(9) also require taxpayers to capitalize costs incurred to ''defend or perfect title to intangible property.'' As both the Third Circuit and the Tax Court note, the preamble to the regulations explains that this requirement is consistent with the long-standing rules distinguishing between costs incurred to defend the taxpayer's ownership of property (the costs of which must be capitalized) and costs incurred to defend against infringements on the use of the taxpayer's property by another (the costs of which are deductible).

In addition to direct costs, the INDOPCO regulations require capitalizing indirect or transactional costs incurred to ''facilitate'' the acquisition or creation of intangible assets. Facilitative costs are separate from the cost of the asset itself, and instead are ancillary costs incurred in ''investigating or otherwise pursuing the transaction.'' Importantly, as the *Mylan* courts note, the regulations specifically provide, ''[t]he fact that the amount would (or would not) have been paid but for the transaction is relevant, but is not determinative'' (3d Cir. at n.22; T.C. at 161).

As the courts note, the parties' dispute also implicates the ''origin of the claim'' test, under which the

ISSN 0148-8295

treatment of litigation costs generally will be determined by reference to the underlying claim being adjudicated. Claims arising in tort—such as patent infringement claims—typically support current deductions for litigation costs because they are not viewed as having a sufficient nexus to future income producing activities, but instead typically are viewed as remedying past damages.

One Has No Bearing on the Other

With these basic legal standards in mind, the Tax Court and the Third Circuit each held that an ANDA applicant's defense against patent infringement lawsuits was independent of the FDA approval process, with one having no bearing upon the outcome of the other. Because the costs of the patent dispute did not ''facilitate'' the FDA's approval of the generic drug, they need not be capitalized under the INDOPCO regulations as a cost incurred in obtaining a right from a governmental agency, and instead could be deducted in the year incurred.

As explained by the Tax Court, the FDA's scientific determination of whether the generic drug is safe and effective for public use is unrelated to and unaffected by a district court's legal determination regarding the intellectual property rights of the brand-name drug's patent holder. The FDA's approval process proceeds at its own pace, without regard to whether the patentee files a patent infringement lawsuit or the status of any such dispute. The FDA is not equipped to and does not consider the parties' legal positions in the patent litigation as part of its scientific review process.

Likewise, the district court adjudicating the patent dispute will not consider the scientific question of whether the generic version of the drug is safe and effective under the applicable food and drug laws. The only question before the court is whether there has been (or more accurately, would be) an infringement of the patentee's intellectual property rights under federal patent law by reason of the applicant's marketing of the generic version of the patentee's drug.

The Third Circuit points out that the patent litigation itself does not result in the ANDA applicant's acquisition or creation of an intangible asset within the contemplation of the INDOPCO regulations. The deemed-infringement under the Hatch-Waxman Act creates a legal fiction in favor of the patentee, permitting it to proactively defend its intellectual property rights—if it so chooses—before the actual marketing of the generic version and before any damages have occurred. The patentee's ability to proactively assert its legal right creates no entitlement on the part of the ANDA applicant, however, and resolution of the patent litigation creates no intangible asset for the ANDA applicant. Even if the applicant prevails in the patent dispute, the district court's determination would result neither in FDA approval for the generic drug nor in the creation of any intellectual property rights on the part of the ANDA applicant (that remains the role of the USPTO).

Both the Third Circuit and the Tax Court also point to the well-established principle that while costs incurred to defend one's ownership of property must be capitalized, challenging someone else's improper use of the taxpayer's property sounds in tort—a claim that the infringing party's usage has reduced the taxpayer's profits from its own assets—and the costs of doing so may be deducted. As the patentee's legal costs in the infringement litigation would be deductible under this principle, the ANDA applicant's costs of defending against such an assertion should be deductible as well.

The *Mylan* courts rejected the IRS's broad assertion that capitalizing the legal fees was required because the patent litigation arose directly from the taxpayer's seeking FDA approval for the generic drug. The IRS took the position that because the patent dispute would not have arisen but for the taxpayer's initiation of the ANDA process, the costs of resolving that dispute were incurred in pursuing FDA approval and, under the literal language of the INDOPCO regulations, ''facilitated'' the FDA's conferring a valuable right upon the applicant.

The IRS argued that Mylan made a choice to ''provoke litigation'' by selecting paragraph IV certification in preparing its ANDA. The IRS asserted that the company did so to obtain FDA approval as quickly as possible, to beat its competitors to market, and to obtain the lucrative economic benefits of doing so. The result of that decision—the patentee's lawsuit—was a direct consequence of the applicant's choice in how to pursue FDA approval, and the costs arising from those consequences therefore were incurred in pursuing FDA approval. The government pointed to the 30-month stay arising upon the patentee's filing suit in district court as proof of the linkage between the scientific and intellectual property elements of the overall process of bringing the generic drug to market. That position originated in three non-precedential Office of Chief Counsel memoranda (FAA 20114901F, FAA 20114703F, and AM-2014-006), the Third Circuit noted.

The Third Circuit bluntly disagreed (at *10) with the IRS's factual assertion, noting that patent litigation—if it occurs at all—does not facilitate the acquisition of FDA approval because ''the two processes are distinct and ultimately separate.'' The court emphasized that, if anything, a concurrent patent dispute can impact the ANDA process only negatively, by potentially delaying the effective date of final FDA approval, but can never accelerate that process.

In agreeing with the taxpayer, both courts also point to the INDOPCO regulations' guidance that whether a

ISSN 0148-8295

cost would have arisen ''but for'' a transaction is not determinative of whether the cost facilitates that transaction. Instead, the courts considered the ''balancing act'' that Congress sought to achieve through enactment of the Hatch-Waxman Act, simultaneously promoting the availability of lower-cost generic drugs while safeguarding the legal protections afforded to the original developers of the branded product and the staggering sums those companies invest in developing new pharmaceuticals.

Although both objectives are built into the structure of the Hatch-Waxman Act, and the two processes largely occur concurrently, the court rejected the notion that the patentee's decision to protect its legal rights in its intellectual property facilitates the applicant's securing FDA approval to sell the generic drug to the public. The Hatch-Waxman Act advances the patentee's interests through one element and advances the ANDA applicant's interests through the other. A decision in one has no bearing upon a decision in the other. The Tax Court held (at 159) that Congress's decision to coordinate the two processes in the interests of balancing the dual-objectives of the Hatch-Waxman Act ''does not convert such litigation into a link in the ANDA approval chain.''

As such, the Third Circuit agreed with the Tax Court that Mylan was not required to treat the legal fees incurred in defending itself against a ''deemed infringement'' lawsuit as a cost facilitating the FDA's effective approval to market a generic drug.

In contrast, however, the Tax Court did require Mylan to capitalize the costs of notifying the relevant brand-name patent holders that it had filed with the FDA an ANDA with a paragraph IV certification (the letters which created the right of the patentees to sue for patent infringement). In the court's view, notifying the patentees that the ANDA applicant was certifying to the FDA that the patents either were invalid or were not being infringed upon was a requirement of the ANDA application process itself. As such, like the other direct and ancillary costs incurred in preparing the ANDA, the costs of those notification letters ''facilitated'' the applicant's eventual receipt of the FDA's effective approval to market the generic drug, a valuable intangible asset the costs of which had to be capitalized under the INDOPCO regulations.

Mylan did not appeal the Tax Court's holding on this issue nor its finding that the capitalized costs had to be amortized over 15 years pursuant to §197.

Going Forward

Although addressing transactions applicable to the pharmaceutical industry, the *Mylan* decisions are useful more broadly in understanding the scope of the ''facilitative'' costs that must be capitalized under the INDOPCO regulations in creating or acquiring intangible assets. Three courts—including the Court of Federal Claims in a case decided in 2022—now have rejected the IRS's broad interpretation of that standard.

Instead, the Tax Court, the Court of Federal Claims, and now the Third Circuit have made clear that otherwise independent proceedings or chains of events do not become ''facilitative'' of each other simply because they occur at the same time. Similarly, two independent transactions are not ''facilitative'' of each other simply because they arise from the same set of underlying facts.

As did the courts in *Mylan*, taxpayers considering the potential application of the INDOPCO regulations to transactional costs should begin by identifying the ''transaction'' under consideration. In other words, *what* is potentially being facilitated by the costs at issue? The Tax Court's conclusion in *Mylan* that the relevant transaction was the receipt of effective approval from the FDA was critical to its holding that the FDA approval process was not facilitated by costs incurred for a separate transaction—the legal dispute between the parties regarding application of patent law to the generic drug under scientific review by the FDA. Each arose from the same set of facts—Mylan's development and desire to market a generic version of a brand-name drug—but were independent transactions.

After isolating the transaction under consideration, the taxpayer should carefully identify the costs that facilitate that transaction—but *only* that transaction. As the courts in *Mylan* note, the INDOPCO regulations expressly reject a ''but for'' test. As such, the fact that certain transactional costs arise from a given set of facts does not automatically require capitalizing transactional costs of a different transaction arising from that same set of facts or occurring concurrently. If the two transactions have no bearing on each other, as in *Mylan*, one logically cannot facilitate the other. Instead, a broader review of the applicable facts and circumstances is required to explore the interrelationship, if any, between the transactions.

Mylan is of particular benefit to the pharmaceutical industry. The jurisprudence of the Third Circuit—covering the states of New Jersey, Delaware, Pennsylvania as well as the US Virgin Islands—governs disputes between the IRS and the many members of the pharmaceutical industry based in that region. Given that both the Tax Court and the Court of Federal Claims (a ''refund'' forum having national jurisdiction) likewise agree, hopefully the IRS Independent Office of Appeals will weigh the hazards of litigation heavily in favor of industry members in determining whether and how to resolve this and similar issues before it.

A broad cross-section of other industries may benefit from *Mylan* as well. Any industry that routinely

ISSN 0148-8295

obtains governmental approvals for business operations—particularly approval processes that result in separately identifiable costs that do not create an intangible asset—should carefully consider the case's impact to determine whether various transactional costs might have been capitalized unnecessarily.

More broadly, all taxpayers applying the INDOPCO regulations to costs incurred to acquire or create intangible assets should consider the *Mylan* courts' admonishment not to apply the INDOPCO regulations' ''facilitative'' standard as expansively as did the IRS.

This article does not necessarily reflect the opinion of Bloomberg Industry Group, Inc., the publisher of Bloomberg Law and Bloomberg Tax, or its owners.

Author Information

James Atkinson is a managing director at BDO USA, practicing in the area of federal income taxation, with a focus on federal tax accounting issues. He formerly served in senior executive positions with the IRS National Office. He is the author of 509 T.M., *Principles of Capitalization*.

ISSN 0148-8295