United States Court of Appeals for the Federal Circuit

ACTAVIS LABORATORIES FL, INC.,
Plaintiff-Appellee

v.

UNITED STATES,
Defendant-Appellant

2023-1320

Appeal from the United States Court of Federal Claims in No. 1:19-cv-00798-RTH, Judge Ryan T. Holte.

Decided: March 21, 2025

KEVIN P. MARTIN, Goodwin Procter LLP, Boston, MA, argued for plaintiff-appellee. Also represented by JESSE LEMPEL.

CLINT CARPENTER, Tax Division, United States Department of Justice, Washington, DC, argued for defendant-appellant. Also represented by ARTHUR THOMAS CATTERALL, DAVID A. HUBBERT.

Before CHEN, CUNNINGHAM, and STARK, *Circuit Judges*.

STARK, *Circuit Judge*.

Actavis Laboratories FL, Inc. ("Actavis") filed Abbreviated New Drug Applications ("ANDAs") with the United States Food and Drug Administration ("FDA"), seeking FDA approval to market and sell generic versions of branded drug products already being sold in the United States. In response to Actavis' ANDA filings, the manufacturers of those branded drugs – who already hold New Drug Applications ("NDAs") for their products, and also own patents covering those products – sued Actavis for patent infringement. These suits were filed pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly known as the "Hatch-Waxman Act." Under the Hatch-Waxman Act, the submission of an ANDA is considered an act of patent infringement when, as is the case here, the ANDA filer (Actavis) seeks FDA approval that would be effective prior to the expiration of patents covering the related, branded drug product. In such circumstances, as long as the NDA holder files suit claiming infringement within 45 days after receiving the statutorily-required notice from the ANDA filer, the Hatch-Waxman Act generally mandates that a district court stay the FDA's approval of the ANDA for 30 months, during which time the parties engage in litigation over infringement and invalidity of any pertinent patents. 21 U.S.C. § 355(j)(5)(B)(iii).

While some background explanation of pharmaceutical patent litigation is necessary to understand this appeal, this is not actually a patent case. It is, instead, a tax case.

Actavis treated the litigation expenses it incurred in defending itself in various Hatch-Waxman suits as ordinary and necessary business expenses and, therefore, deducted them on its tax returns in the years the expenses were incurred. The Commissioner of the Internal Revenue Service ("Commissioner," "IRS," or "government"), however, considered these expenses as capital expenditures. In his view they are incurred in pursuit of an intangible capital asset: namely, FDA approval to lawfully market a

generic drug product in this country. Actavis eventually paid its tax liabilities as calculated by the IRS – that is, without deducting its Hatch-Waxman litigation expenses – and then sued the Commissioner in the Court of Federal Claims to recover what Actavis contended was an overpayment. The Court of Federal Claims sided with Actavis and held that the litigation expenses are deductible and need not be capitalized.

The Commissioner appeals. We affirm.

I

This case arises at the intersection of the FDA's regulatory review process for approving new drugs, the Hatch-Waxman Act framework for resolving patent disputes relating to generic versions of branded drugs, and the provisions of Title 26 of the U.S. Code, which constitute the Internal Revenue Code ("IRC" or "Tax Code"), guiding the decisions of the IRS.

In the complex circumstances we confront, even keeping the terminology straight is somewhat tricky; each of the participants in these multi-faceted procedures plays several roles. We will refer to Actavis – and any similarly-situated party in a Hatch-Waxman suit, who is seeking to market a generic version of a branded drug – as the ANDA filer (its identity in the FDA process), the Hatch-Waxman defendant (its identity in the patent litigation), the Taxpayer (its identity vis-à-vis the Commissioner), and the generic drug manufacturer (the position it hopes to obtain at the conclusion of the process), interchangeably. We will refer to the manufacturer of the branded drug which the ANDA filer is seeking to sell a generic version of, as, interchangeably, the NDA holder (its identity in the FDA process), the Hatch-Waxman plaintiff or patent owner (its identity in the patent litigation), and the branded drug manufacturer (its identity in the marketplace the ANDA filer is seeking to enter).

A brief recitation of certain FDA practices and regulations, the Hatch-Waxman Act, and Tax Code provisions is necessary to understanding, and resolving, the parties' dispute.

A

We begin with FDA regulatory review. In an opinion presenting the identical issue before us today, the United States Court of Appeals for the Third Circuit identified the most pertinent features of the FDA's process for evaluating applications to market new drugs in this country. *See Mylan Inc. v. Comm'r of Internal Revenue*, 76 F.4th 230, 233-38 (3d Cir. 2023). The Third Circuit explained:

> Drug manufacturers must obtain FDA approval to market any new pharmaceutical in the United States. Typically, a manufacturer submits a New Drug Application ("NDA") to the agency . . . .
>
> [G]eneric manufacturers [may] file an Abbreviated New Drug Application ("ANDA"). Instead of the time-consuming and costly testing requirements of an NDA, an ANDA requires the simpler showing that a generic drug has the same active ingredients as, and is biologically equivalent to, [the already approved] brand-name drug.
>
> . . .
>
> Once a generic manufacturer has obtained FDA approval for its ANDA, it must wait for the approval to become effective, which occurs upon resolution of the [Hatch-Waxman] litigation in its favor . . . or, if litigation is still pending, upon the expiration of the 30-month stay.

Id. at 233-34, 237 (internal quotation marks and citations omitted; fourth alteration in original).

B

The Hatch-Waxman Act established a new, expedited process for obtaining FDA approval to market and sell generic versions of previously-approved pharmaceutical drug products (often referred to as "branded," "brand-name," or "reference" drugs). Under the Hatch-Waxman Act, an ANDA submitted to the FDA must address any patents covering the approved reference drug; these patents are listed by the NDA holder in the FDA's "Orange Book." *See* 21 U.S.C. § 355(b)(1)(A)(viii). For any of the listed patents (that have not yet expired) the ANDA filer must submit one of two certifications. *See id.* at § 355(j)(2)(A)(vii). The first is a "Paragraph III" certification, which requests that the FDA make any approval to market the generic drug effective only upon the expiration of the listed patent(s). *See id.* at § 355(j)(2)(A)(vii)(III). Filing a Paragraph III certification allows the ANDA filer to avoid the risk of infringing the NDA holder's patents, but at the cost of having to delay launching its generic drug product until those patents expire. Filing a Paragraph III certification does not constitute an act of patent infringement.

Alternatively, the ANDA filer may submit a "Paragraph IV" certification, by which it is representing to the FDA that any patent covering the NDA holder's drug product "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the [ANDA] is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). By filing a Paragraph IV certification, it is possible that the ANDA filer will obtain effective FDA approval, allowing immediate sale of its proposed generic drug product, before the expiration of the NDA holder's patents.

Making a Paragraph IV certification, thus, has several consequences. First, submitting a Paragraph IV certification to the FDA triggers a requirement that the ANDA filer send a notification letter ("Paragraph IV Notice") to the patent owner within 20 days, setting out the factual and legal

bases for its contention that any pertinent patent listed in the Orange Book is invalid or will not be infringed by the proposed generic drug product. *See* 21 U.S.C. § 355(j)(2)(B).

Second, filing an ANDA with a Paragraph IV certification is, under the Hatch-Waxman Act, an act of patent infringement. *See* 35 U.S.C. § 271(e)(2) ("It shall be an act of infringement to submit . . . an [ANDA] . . . for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."). This gives the patent owner a cause of action against the ANDA filer ("Section 271(e) Claim"). The patentee can then file a patent infringement suit, in particular a Section 271(e) Claim, against the ANDA filer.

Third, this process gives the NDA holder-patentee the ability to prevent the FDA from giving final, effective approval to the ANDA for up to 30 months. It can accomplish this by filing a Section 271(e) Claim against the ANDA filer within 45 days of receiving the Paragraph IV Notice. *See* 21 U.S.C. § 355(j)(5)(B)(iii).[1] If the patentee prevails in this Hatch-Waxman lawsuit, any FDA approval of the ANDA will be "tentative," meaning that it will not be effective (and, therefore, will not permit sale of the generic drug) until the last of the infringed, valid patents covering the NDA

---

[1] The district court handling the Hatch-Waxman lawsuit has discretion to shorten or lengthen the 30-month stay based on the parties' cooperation with the court in its efforts to complete the case within 30 months. *See* 21 U.S.C. §§ 355(c)(3)(C), (j)(5)(B)(iii). Neither party to the appeal we are considering suggests that this discretion has any relevance to their tax dispute.

product expires. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd). If, however, (i) the litigation concludes in favor of the ANDA filer before the end of the 30-month period; (ii) the 30-month period expires while the litigation is still pending; or (iii) the patentee fails to file suit within 45 days of receipt of the Paragraph IV Notice, then the FDA may grant final, effective approval without delay and the generic drug can enter the market.[2] *See id.* at § 355(j)(5)(B)(iii). These scenarios incentivize generic drug manufacturers to file ANDAs with Paragraph IV certifications. As a further incentive, the Hatch-Waxman Act provides a 180-day period of exclusivity to the first ANDA filer with a Paragraph IV certification to obtain effective approval from the FDA. *Id.* at § 355(j)(5)(B)(iv)(I).

In *Mylan*, the Third Circuit pointed out some particularly pertinent details of the Hatch-Waxman litigation process:

> [B]rand-name manufacturers do not always file a lawsuit in response to a Paragraph IV certification. Therefore, an ANDA accompanied by a Paragraph IV certification could receive effective approval and go to market without any attendant patent litigation.
>
> . . .
>
> A brand-name drug manufacturer's decision to engage in or abstain from patent infringement litigation plays no role in the FDA's review of an ANDA. Whether the application is approved or rejected turns on scientific and technical issues . . . . And, while a[] [Hatch-Waxman] suit may affect the

---

[2] If the patentee eventually prevails on its Section 271(e) Claim after the 30-month stay expires, the FDA's effective approval of the ANDA will be converted to tentative approval.

> timing of the FDA's effective approval of a[n] [ANDA], litigation does not control the timing of the FDA's review.

76 F.4th at 237-38 (internal quotation marks, footnote, and citations omitted). In short, while Hatch-Waxman litigation very frequently follows the filing of an ANDA accompanied by a Paragraph IV certification, and will often affect the timing of effective FDA approval of an ANDA, it does not affect the FDA's review of the ANDA on the merits.

C

Several tax statutes and regulations are directly at issue in this appeal. First, 26 U.S.C. § 162(a) ("Section 162") authorizes taxpayers to deduct "ordinary and necessary expenses paid or incurred during the taxable year in carrying on any trade or business." Second, 26 U.S.C. § 263(a) ("Section 263") prohibits such deductions for "capital expenditures." Capital expenditures are "costs incurred in the acquisition or disposition of a capital asset;" generally, a capital asset is "property having a useful life substantially beyond the taxable year." *Woodward v. Comm'r*, 397 U.S. 572, 575 (1970) (internal quotation marks omitted). Capital assets may be tangible, such as an oil well, or may be intangible, such as a license to operate an oil well. *See* 26 U.S.C. § 263(c). IRS regulations give examples of capital expenditures, including "[a]n amount paid to acquire or produce a unit of real or personal tangible property," "[a]n amount paid to improve a unit of real or personal tangible property," and "[a]n amount paid to acquire or create intangibles." 26 C.F.R. § 1.263(a)-1(d) ("C.F.R. § 1.263").

Generally, a taxpayer prefers to treat an expenditure as an ordinary and necessary business expense, rather than as a capital expenditure, because the Tax Code permits deduction of ordinary expenses immediately, rather than requiring gradually writing off (i.e., amortization) of the costs over a period of years. "The primary effect of characterizing a payment as either a business expense or a

capital expenditure concerns the timing of the taxpayer's cost recovery: While business expenses are . . . deductible [at the time of the expense], a capital expenditure usually is amortized and depreciated over the life of the relevant asset." *INDOPCO, Inc. v. Comm'r*, 503 U.S. 79, 83-84 (1992); *see also Mylan*, 76 F.4th at 238 ("The practical difference in tax treatment between deductions and capital expenditures is the timeline of cost recovery: deductions may be claimed during the year incurred while capital expenditures are either depreciated (for tangible assets) or amortized (for intangible assets) over the life of an asset."). If a particular payment might qualify as both an ordinary and necessary business expense, which can be deducted, and also a capital expenditure, which cannot, the Tax Code requires that Section 263 take precedent, meaning that such a payment must be treated as a capital expenditure and not deducted. *See* 26 U.S.C. § 161 ("Section 161"); *Comm'r v. Idaho Power Co.*, 418 U.S. 1, 17 (1974). In this regard, then, a deduction in the year an expense is incurred is an "exception[] to the norm of capitalization." *INDOPCO*, 503 U.S. at 84.

The Commissioner has adopted regulations addressing the application of Section 263 to the acquisition or creation of capital assets, including intangibles. *See* 26 C.F.R. § 1.263(a)-4; Final Regulations, 69 Fed. Reg. 436 (Jan. 5, 2004). 26 C.F.R. § 1.263(a)-4 identifies a variety of payments that must be treated as capital expenditures, including "[a]n amount paid to create" "rights obtained from a governmental agency," such as a license. 26 C.F.R. § 1.263(a)-4(b)(1)(ii), (v); 26 C.F.R. § 1.263(a)-4(d)(5). The regulation further requires treatment as a capital expenditure of "an amount paid to *facilitate* . . . an acquisition or creation of an intangible." 26 C.F.R. § 1.263(a)-4(b)(1)(v) (emphasis added). "Facilitate," in turn, is broadly defined to cover "the process of investigating or otherwise pursuing the transaction." 26 C.F.R. § 1.263(a)-4(e)(1)(i). Finally, the regulation defines "transaction" to mean "all of the

factual elements comprising an acquisition or creation of an intangible." *Id.* § 1.263(a)-4(e)(3).

II

During 2008 and 2009, Actavis was a defendant in at least nine Hatch-Waxman lawsuits brought by NDA holders under § 271(e)(2), relating to seven different ANDAs Actavis filed with Paragraph IV certifications.[3] Actavis incurred substantial expenses in these Hatch-Waxman suits: $3,882,951 and $8,481,237 in 2008 and 2009, respectively. J.A. 6 (citing J.A. 66). Actavis deducted these litigation expenses as ordinary and necessary business expenses under Section 162. After reviewing Actavis' tax returns, the Commissioner determined that the expenditures were incurred in order to facilitate the creation of intangible assets, specifically FDA approvals of Actavis' ANDAs that would become effective prior to the expiration of NDA holders' patents. Hence, the IRS sent Actavis Notices of Deficiency, advising it that the legal expenditures were nondeductible and had to be capitalized under Section 263 and C.F.R.§ 1.263(a)-4. Eliminating these deductions resulted in tax deficiencies of $1,359,033 for 2008 and $2,968,433 for 2009, plus interest and late-payment penalties. After Actavis paid these amounts, it filed amended returns for 2008 and 2009, claiming refunds. The IRS failed to act on the amended returns.

Actavis filed suit against the United States in the Court of Federal Claims, seeking refunds for what Actavis alleged were tax overpayments for 2008 and 2009. Following discovery, the parties filed cross-motions for summary judgment.

---

[3] As a formal matter, the name of the entity that filed the tax returns was Watson Pharmaceuticals, Inc., which due to subsequent transactions can now fairly be referred to, for simplicity, as Actavis.

Before the Court of Federal Claims could address the motions, the United States Tax Court ruled in favor of Mylan. In *Mylan, Inc. v. Commissioner*, 156 T.C. 137, 161-62 (2021), the Tax Court held that expenses an ANDA filer "incurred in defending [Hatch-Waxman] suits were not 'paid to facilitate' the transaction and are not required to be capitalized." This is the judgment later appealed to, and affirmed by, the Third Circuit in *Mylan*.

While the *Mylan* appeal was pending, the Court of Federal Claims granted summary judgment to Actavis and denied the Commissioner's cross-motion for summary judgment. J.A. 3-37.[4] The Commissioner timely appealed.

During the pendency of our appeal, the Third Circuit affirmed the Tax Court's *Mylan* decision. *See Mylan*, 76 F.4th at 233. The Third Circuit agreed with the Tax Court that Mylan's expenses incurred in litigating Hatch-Waxman suits were not capital expenses and, therefore, could be deducted as ordinary business expenses. *See id.* at 242-44.

We have jurisdiction over the Commissioner's appeal under 28 U.S.C. § 1295(a)(3). We review the Court of Federal Claims' grant of summary judgment de novo. *See Lua v. United States*, 843 F.3d 950, 954 (Fed. Cir. 2016). Interpretation of a statute or regulation is a question of law that we likewise review de novo. *See Butterbaugh v. Dep't of Justice*, 336 F.3d 1332, 1336 (Fed. Cir. 2003).

---

[4] In granting summary judgment to Actavis, the Court of Federal Claims ordered the government to refund Actavis the amount of taxes and interest it overpaid; the parties agreed to defer the question of the penalties the IRS imposed for failure to file. *See* J.A. 275 n.39 (citing ECF No. 30 at 1); J.A. 297 n.45. The propriety of the penalties is not before us.

III

The parties' principal disagreement is whether Actavis' Hatch-Waxman litigation expenses are deductible as ordinary business expenses or must, instead, be treated as capital expenditures not deductible in their entirety in the year they are incurred. They also dispute the method of analysis we should undertake to resolve the issue. Specifically, Actavis argues for us to apply the "origin of the claim" test set forth in *Woodward*, 397 U.S. at 572, and *United States v. Gilmore*, 372 U.S. 39 (1963). By contrast, the Commissioner insists that the appropriate standard is embodied in IRS regulations, specifically C.F.R. § 1.263(a)-4, which implements the "significant future benefit" methodology set out in *INDOPCO*, 503 U.S. at 79. We need not decide which test is applicable because, as we explain below, under either standard Actavis' Hatch-Waxman litigation expenses are deductible ordinary business expenses, not capital expenditures.[5]

A

Before we turn to application of the "origin of the claim" and "most significant benefit" tests, we note that the Court of Federal Claims applied yet another standard, one of its

---

[5] The government contends that *INDOPCO* overruled *Woodward/Gilmore*'s origin of the claim test and that C.F.R § 1.263(a)-4 clarifies *INDOPCO*'s application to intangible assets. *See* Open. Br. at 53-54. While we need not decide if the government is correct about the impact of *INDOPCO*, we are unaware of any court agreeing that the origin of the claim test has been overruled. Moreover, our court has applied this test several times since *INDOPCO*. *See, e.g.*, *Dana Corp. v. United States*, 174 F.3d 1344, 1350 (Fed. Cir. 1999); *Baylin v. United States*, 43 F.3d 1451, 1453-54 (Fed. Cir. 1995); *Stokely-Van Camp, Inc. v. United States*, 974 F.2d 1319, 1325 (Fed. Cir. 1992).

own creation. It adopted a two-step test, which it stated had been used previously by both the Commissioner and the Tax Court, and which it quoted the IRS as describing as follows:

> When legal fees are incurred in litigation, there is a two-step process for determining whether the fees must be capitalized. First, the origin of the claim doctrine must be applied to ascertain the character and nature of the expenditures. Second, the capitalization of intangibles regulations must be applied to determine, based on the ascertained character and nature, whether the expenditures are within any of the categories of expenditures that must be capitalized under the regulations.

J.A. 18-19 (emphasis omitted).

Our conclusion that the outcome is the same under both the "origin of the claim" and the "most significant benefit" tests, and our agreement with the trial court's conclusion that Actavis may deduct its Hatch-Waxman litigation expenses as ordinary and necessary business expenses, means we do not need to assess the correctness of the two-step approach of the IRS that was applied by the Court of Federal Claims.[6]

B

Under the "origin of the claim" test, the relevant inquiry is "whether the origin of the claim litigated is in the process of acquisition" of a capital asset. *Woodward*, 397 U.S. at 577; *see also Stokely-Van Camp, Inc. v. United States*, 974 F.2d 1319, 1324 (Fed. Cir. 1992) ("[I]f the origin

---

[6] Actavis endorses the Court of Federal Claims' hybrid approach, while insisting it prevails under any of the standards noted in this opinion. *See* Response Br. at 20, 28-36, 42-46, 55-56.

of an expenditure is capital in nature (such as the acquisition, enhancement, or disposition of a capital asset), the expenditure is not deductible as an ordinary business expense . . . ."). Here, the Commissioner insists the origin of the claim litigated in the Hatch-Waxman lawsuits against Actavis is Actavis' filing of ANDAs with Paragraph IV certifications. By contrast, Actavis contends that the origin of the claim giving rise to the expenses it seeks to deduct is the NDA holders' filings of complaints containing a Section 271(e) Claim. We agree with Actavis.

In analyzing the origin of a claim, the taxpayer's motivation for making the expenditure in question is irrelevant. *See Woodward*, 397 U.S. at 578. Thus, for example, we do "not even consider the taxpayer's motives or purposes in undertaking defense of the litigation" in which the expenses are incurred. *Id.*; *see also Ark. Best Corp. v. Comm'r*, 485 U.S. 212, 223 (1988) (holding that taxpayer's motivation in purchasing asset is irrelevant to determination of whether the asset is a capital asset). Also irrelevant are the consequences of the litigation for the taxpayer. *See Woodward*, 397 U.S. at 578 ("The Court rejected a test that looked to the consequences of the litigation."); *see also Gilmore,* 372 U.S at 49 ("[T]he 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 was 'business' or 'personal' and hence whether it is deductible or not under [Section 161].") (emphasis added). However, we also must be careful not to allow our inquiry to become so formalistic that it ignores how the litigation fits into a larger transaction. *See Woodward*, 397 U.S. at 577; *Gilmore*, 372 U.S. at 47-49.

With these considerations in mind, we conclude, as did the Court of Federal Claims, that the claim being litigated in a Hatch-Waxman lawsuit originates in patent infringement. The origin of the claim is *not* the acquisition of FDA approval of an ANDA.

While the ANDA filer is, of course, pursuing the capital asset of an FDA approved ANDA, which gives the ANDA filer the right to sell its generic drug product, Hatch-Waxman litigation does not determine whether the ANDA is, or is not, approved. Only the FDA has the power to approve an ANDA and authorize the applicant to market and sell the approved drug product in the United States. Hatch-Waxman litigation typically proceeds in parallel with the FDA's regulatory review, but the two lanes are distinct. The district court is entrusted with resolving patent infringement and invalidity, but it has no role in assessing whether the proposed generic drug is safe, effective, and bioequivalent to the reference branded drug. Likewise, the FDA "lacks both expertise and authority to review patent claims." *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 406-07 (2012) (internal quotation marks omitted). As the Court of Federal Claims put it, the "generic drug company is not obligated to demonstrate patent invalidity or noninfringement to the FDA to obtain ANDA approval, nor is it obligated to show the technical acceptability of its ANDA application to the court during Hatch-Waxman litigation." J.A. 33. The Hatch-Waxman and FDA processes are fundamentally separate.

That the origin of the claim in Hatch-Waxman litigation is a patent claim brought by the NDA holder, and *not* the pursuit of effective FDA approval of an ANDA sought by the ANDA filer, is further supported by the fact that any combination of outcomes is possible. That is, a party could win or lose in the litigation and that same party could succeed or fail in the FDA review – without either being influenced by the other. Specifically, even if the patentee prevails on its Section 271(e) Claim, proving that its patent is infringed and defeating any invalidity challenge, the FDA may or may not approve the ANDA. Alternatively, if the patentee fails to prove infringement of its patent or fails to defeat an invalidity challenge, the FDA still may or

may not approve the ANDA. There is no impact on the outcome of one process from the outcome of the other process.

To be sure, the litigation may well affect the *timing* of when FDA final approval becomes *effective*, permitting sale of the generic drug product, but it does not affect *whether* the FDA grants such approval. As long as the NDA holder files a Section 271(e) Claim within 45 days of receiving the Paragraph IV Notice, the automatic 30-month stay prohibits the FDA from providing final, effective approval of an ANDA. The FDA is free to conduct and complete its technical review of the ANDA and give it tentative approval, *see, e.g.*, *Centene Corp. v. Merck & Co.*, 2024 WL 5244598, at *5 (D.N.J. Dec. 30, 2024) (discussing tentative FDA approval of ANDA during 30-month stay), but until the expiration of the 30-month period, that approval may not be made effective, which the ANDA filer needs before it can sell its generic drug product. In this way (among others), Hatch-Waxman litigation may delay effective approval and market entry. Similarly, at the conclusion of the litigation, if the patentee has prevailed on its Section 271(e) Claim, the FDA must refrain from converting any tentative approval to effective, final approval until after expiration of the patents covering the reference branded drug. *See* 21 U.S.C. § 355(j)(5)(B)(iii); *Mylan*, 76 F.4th at 243 ("[E]ven if the generic manufacturer loses the patent suit after receiving effective approval, the FDA does not revoke or suspend approval, but merely converts the approval to a tentative approval effective after the expiration of the relevant patents."); *see also* 21 C.F.R. § 314.107(g). But none of this injects the district court in the FDA approval process; it merely means that the litigation has consequences for when the result of that approval process becomes effective. Such *consequences*, however, do not transform the *origin* of the claim being litigated. *See Woodward*, 397 U.S. at 578.

In short, the issues in the litigation and the issues in the regulatory approval process are different, and they are resolved by different decision-makers. Because the

litigation expenses incurred by the ANDA filer are incurred in defending against the Section 271(e) Claim – that is, while proceeding in the Hatch-Waxman lawsuit "lane" – and *not* in seeking to obtain FDA approval, it is proper to deem the origin of the claim giving rise to the expenses in question as being the patent claim.

Further confirmation that the origin of the claim rests in the patentholder's decision to sue, and not in the ANDA filer's decision to seek drug approval from the FDA, is the fact that infringement litigation cannot provide the ANDA filer what it wants – only the FDA can. As the Third Circuit aptly put it: "When generic manufacturers like Mylan defend themselves in patent infringement suits resulting from a Paragraph IV certification, they obtain no rights from a successful outcome. They acquire neither the intangible asset of a patent nor an FDA approval." *Mylan*, 76 F.4th at 246 n.24. From the ANDA filer's perspective, Hatch-Waxman litigation often results only in delaying effective FDA approval of the ANDA; it cannot result in effective FDA approval occurring sooner than it would have if the lawsuit had never been brought.

We recognize that the Supreme Court has observed that filing an ANDA with a Paragraph IV certification "often means provoking litigation." *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 143 (2013) (internal quotation marks omitted). And it is undeniable that the Hatch-Waxman Act's creation of the Section 271(e) Claim establishes a relationship between the patent litigation and the FDA regulatory review process. But it does not follow that the lawsuit is actually *part of* the FDA process. Hence, here, the "origin of the claim litigated," i.e., the Section 271(e) Claim, is *not* "in the process of acquisition itself" of the asset Actavis aims to acquire, which is effective FDA approval. *See Woodward*, 397 U.S. at 577 (explaining that test is whether "origin of the claim litigated is in the process of acquisition itself"). The actual claim being litigated, and therefore generating the

expenses Actavis wishes to deduct, is a patent infringement claim.

A contrary conclusion would lead to an incongruous outcome. It appears to be undisputed that, as the Third Circuit noted in *Mylan*, 76 F.4th at 241, "brand-name drug companies can . . . deduct the litigation expenses they incur in" Hatch-Waxman lawsuits, through which they are asserting their patent rights and defending their market exclusivity. "[I]mposing very different tax treatment on the warring sides in an ANDA dispute, as the Commissioner advocates, is at odds with the careful statutory balance [embodied in the Hatch-Waxman Act] of improving access to lower-cost generic drugs while respecting intellectual property rights." *Id.* at 245 n.23. This differential tax treatment would result in an artificial distinction between the parties to the same Hatch-Waxman lawsuit. *See Gilmore*, 372 U.S. at 48 (warning that courts "should be slow to attribute to Congress a purpose producing such unequal treatment among taxpayers, resting on no rational foundation").

Additionally, it is well-settled that once a Section 271(e) Claim is filed, it is litigated in essentially the same manner as an ordinary Section 271(a) patent infringement claim. *See Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997) ("[A] district court's inquiry in a suit brought under § 271(e)(2) is the same as it is in any other infringement suit, *viz.*, whether the patent in question is invalid or will not be infringed by the manufacture, use, or sale of the drug for which the [ANDA] is submitted.") (internal quotation marks and emphasis omitted). It is undisputed that in ordinary Section 271(a) patent litigation, both the patentee and the accused infringer are permitted to treat their legal expenses as deductible business expenses. J.A. 1213 ("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."). Logically, then, because the

substance of the litigation is the same for a Section 271(a) Claim, the expenses incurred in litigating a Section 271(e) Claim should be deductible as well.

In urging us to conclude that Actavis' litigation expenses cannot be deducted, the government argues that it is the Paragraph IV certification that triggers the Hatch-Waxman lawsuit. We disagree. While the ANDA filing with a Paragraph IV certification is an "artificial act of infringement" under the Hatch-Waxman Act, and its filing is a necessary predicate to a Section 271(e) Claim, neither the ANDA itself nor the Paragraph IV certification (or the Paragraph IV Notice to the NDA holder) are sufficient to manifest the ensuing litigation, as the NDA holder must make an affirmative decision to bring a suit. While Actavis undoubtedly anticipates Hatch-Waxman litigation as a near-certain consequence of the large majority of its ANDA filings that contain Paragraph IV certifications, such suits are not automatic, and whether they occur is beyond the control of Actavis.[7]

The government also relies heavily on *Woodward*, 397 U.S. at 597, in which the Supreme Court concluded that the origin of the claim standard required capitalization of expenses incurred by the taxpayer in the course of litigation to determine the price at which the taxpayer would acquire an asset: the minority shares in a company in which the taxpayer was the controlling shareholder. The sale process, which was necessary for acquisition of the asset, could not have been completed without a price being set, and due to a failure of negotiation, the price could not

---

[7] The record in *Mylan* included testimony of Mylan's general counsel that patentees who receive Paragraph IV Notices sue ANDA filers approximately 75% of the time. *See* 76 F.4th at 238 n.8; *see also* J.A. 328 (Actavis expert testifying that NDA holders elect not to file Section 271(e) Claims in "nearly half of all" cases).

be set without the litigation. Therefore, as the Supreme Court found, the taxpayer's litigation expenses were incurred in the process of acquisition of the asset itself. In our situation, by contrast, resolution of the patent litigation is not a prerequisite to FDA approval (or even to effective FDA approval) of the ANDA. Filers, like Actavis, of an ANDA with a Paragraph IV certification can obtain effective FDA approval even without a district court decision (i) if no patent litigation is ever filed against them; (ii) if a Section 271(e) Claim is filed more than 45 days after the NDA holder receives the Paragraph IV Notice, which results in no 30-month stay of FDA approval; or (iii) after expiration of the 30-month stay if the Section 271(e) Claim is still being litigated.

Finally, the government observes that "[a]cquiring . . . pre-expiration approval is the only potential benefit of making a paragraph IV certification – which infringes the patents and invites litigation – instead of a non-infringing paragraph III certification." Gov. Open. Br. at 50. Relatedly, the government acknowledges that ANDA filers would prefer not to get sued, but adds that when they are sued the only reason they defend themselves against a Section 271(e) Claim is because they want ANDA approval that is effective before the expiration of the applicable patents and that defaulting on a Section 271(e) claim does not risk subjecting a defendant to damages liability. *See* Oral Arg. at 00:54-2:24.[8] These points are true, but they are not decisive in (or even strongly relevant to) the inquiry into the *origin of the claim* that generated Actavis' expenditures. We are required to focus on the nature of the proceeding itself, not on the taxpayer's motivation for being

---

[8] *Available at* https://oralarguments.cafc.uscourts.gov/default.aspx?fl=23-1320_06072024.mp3.

engaged in the litigation nor the impact the litigation may have on the taxpayer's assets. *See Gilmore*, 372 U.S. at 48.

For all of these reasons, we conclude that the origin of the claim giving rise to the litigation expenses incurred by Actavis in the various Hatch-Waxman lawsuits in which it defended itself in 2008 and 2009 is the NDA holders' assertions of their patent rights. It is not the ANDA filer's pursuit of FDA approval to sell its proposed generic drug product. Thus, application of the origin of the claim test demonstrates that Actavis' Hatch-Waxman litigation expenses are deductible as ordinary and necessary business expenses.

C

We reach the same conclusion under the Commissioner's preferred analytical approach, which is to apply C.F.R. § 1.263, the IRS regulation which implements the "significant future benefit" standard and was adopted in response to *INDOPCO*.[9] As relevant here, C.F.R. § 1.263 requires capitalization of "[a]n amount paid to create an intangible" and of "[a]n amount paid to *facilitate* . . . creation of [such] an intangible." 26 C.F.R. § 1.263(a)-4(b)(ii), (v) (emphasis added). The provision further provides that "an amount is paid to facilitate the acquisition or creation of an intangible (the transaction) if the amount is paid in the process of investigating or otherwise pursuing the transaction." *Id.* § 1.263(a)-4(e)(1)(i). It then defines "transaction" as "all of the factual elements comprising an acquisition or creation of an intangible and includes a

---

[9] On appeal, the government has abandoned its previous contention that *INDOPCO*'s "significant future benefits" test applies independently of the IRS regulation and argues, instead, that we should apply the regulation.

series of steps carried out as part of a single plan." *Id.* § 1.263(a)-4(e)(3).

Applying C.F.R. § 1.263, the question of whether Actavis' Hatch-Waxman litigation expenses may be deducted or must instead be treated as capital expenditures turns on whether the litigation *facilitates* the "transaction" of Actavis' acquisition of the intangible asset of effective FDA approval of its ANDA. The government emphasizes the breadth of the regulation, focusing on its definition of "facilitate," which includes "the process of investigating or otherwise pursuing the transaction." Gov't Open. Br. at 31-32; *see also* 26 C.F.R. § 1.263(a)-4(e)(1)(i). However, for the reasons we have already explained, and reiterate below, Hatch-Waxman litigation is not part of the "process of . . . pursuing" approval of an ANDA.

As we have noted, the FDA regulatory approval process and Hatch-Waxman litigation may proceed in parallel. But neither "facilitates" the other. Obtaining regulatory approval from the FDA requires the ANDA filer to show that its proposed generic drug product is safe, effective, and bioequivalent to the reference drug of the NDA holder. Prevailing in Hatch-Waxman litigation requires the ANDA filer to defeat the NDA holder's patent infringement claim or prove the patent claims are invalid. There is no necessary link between these two showings: whether the NDA holder succeeds or fails before the FDA, it may also succeed or fail in the district court.

The intangible asset sought by the ANDA filer is final, effective approval of the ANDA itself – and acquisition of that asset is not facilitated by Hatch-Waxman litigation. As we explained in connection with the origin of the claim standard, and as is equally true even if C.F.R. § 1.263 governs, that intangible asset is pursued through, and can be granted only by, the FDA. The district court presiding over the related Hatch-Waxman lawsuit has no power to grant approval of an ANDA; its only ability to impact FDA

approval is to delay its effectiveness, first through the automatic 30-month stay and, after entering a final judgment in favor of the patentee, until expiration of the last of the pertinent patents. Thus, the Hatch-Waxman litigation does *not* facilitate the acquisition of the FDA-approved ANDA, and hence it does not facilitate acquisition of an asset providing a significant future benefit.

C.F.R § 1.263 describes exemplary applications of the regulation, and the Commissioner contends that our case is analogous to Example 10 of C.F.R. § 1.263(a)-5(l). Example 10 describes *American Stores Co. v. Commissioner*, 114 T.C. 458 (2000), which involved litigation initiated by competition regulators who were attempting to prevent a proposed corporate acquisition. In Example 10, the expenses incurred by the proposed acquirer in litigating against regulators are said to "facilitate the acquisition of" an asset – the corporation being acquired – and are, therefore, capital expenditures. 26 C.F.R. § 1.263(a)-5(l). Our situation is distinguishable. While the competition regulators against whom the taxpayer was litigating in Example 10 would have stopped the acquisition and deprived the taxpayer of the asset it was pursuing had they prevailed in the lawsuit, in a Hatch-Waxman lawsuit the litigation has no impact on whether the asset (ANDA approval) is obtained, although its effectiveness may be delayed. Therefore, even assuming the antitrust litigation expenses in Example 10 facilitated the acquisition transaction involved there, it does not follow that the Hatch-Waxman litigation expenses incurred by Actavis "facilitated" effective FDA-approval of its ANDAs in a similar manner.[10]

The Third Circuit in *Mylan* distinguished Example 10 just as we have done, explaining: "a merger threatened by

---

[10] The Commissioner also cites C.F.R § 1.263(a)-4(e)(5) Example 4, which is based on *Woodward*'s "origin of the claim" test, which we analyzed above.

antitrust litigation cannot occur without resolution of the litigation, whereas the same is not true for FDA approval of an ANDA. . . . [A]n ANDA suit, . . . is not a precondition to receiving an FDA approval of the ANDA." 76 F.4th at 240 n.13. And in *Mylan*, both the Third Circuit and the Tax Court expressly applied C.F.R § 1.263(a)-4. *Id.* at 242. They both accepted the Commissioner's premise that the "transaction" being evaluated was "effective FDA approval of an ANDA with a Paragraph IV certification." *Id.* The Third Circuit explained in detail why Hatch-Waxman litigation does *not* facilitate that transaction within the meaning of the regulation. *See id.* at 244 ("Patent litigation, if it occurs at all after a Paragraph IV certification, does not facilitate acquisition of an FDA-approved ANDA because the two processes are distinct and ultimately separate. If anything, an ANDA suit makes acquisition of FDA approval more difficult because it slows it down.").

While the Hatch-Waxman lawsuit and the FDA regulatory review process "can and do co-exist," they "do not depend on each other." *Id.* at 245. Therefore, "Paragraph IV certifications do not transform ordinary patent infringement litigation into a facilitating step for generic drug approval." *Id.* "'Congress' decision to coordinate effective FDA approval with the outcome of a Section 271(e)(2) suit' through the 30-month stay mechanism, 21 U.S.C. § 355(j)(5)(B)(iii), 'does not convert such litigation into a link in the ANDA approval chain,'" and does not, thus, "facilitate" the ANDA filer's pursuit of the intangible asset of effective FDA approval. *Id.* at 245-46 (quoting *Mylan*, 156 T.C. at 159). We agree with the Third Circuit on each of these points.

In arguing that *Mylan* is wrongly decided, the government mostly repeats contentions we have already rejected in connection with applying the origin of the claim standard. Most particularly, the government writes, "[t]he *only* reason a paragraph IV applicant defends against a Hatch-Waxman suit is to obtain FDA approval that is effective

prior to the patent-expiration date." ECF No. 32 at 1 (response of United States to notice of supplemental authority). But just because this is the ANDA filer's motivation, and the impact of the litigation might be to end delay of effective FDA approval, it does not follow that the expenses incurred by the generic filer in the Hatch-Waxman suit "facilitate" that approval. The ANDA filer would prefer *not* to be sued and then to obtain final FDA approval that becomes effective upon the FDA's completion of its regulatory review, without a 30-month stay and risk of losing the litigation and needing to wait until the expiration of all pertinent patents. Hence, the reality that an ANDA filer making a Paragraph IV certification has the option, upon being named a defendant in an NDA holder's Section 271(e) Claim, of converting to a Paragraph III certification and choosing not to defend the lawsuit, does not render the lawsuit – which cannot result in the district court granting effective FDA approval – a *facilitating* step in the FDA regulatory approval process.

We conclude, therefore, that under C.F.R § 1.263, Actavis' Hatch-Waxman litigation expenses do not "facilitate" Actavis' pursuit of the intangible asset of effective FDA approval of its ANDA. Therefore, these expenditures are not capital expenditures but are, instead, ordinary and necessary business expenses that may be deducted in the year in which they are incurred.

IV

We have considered the government's remaining arguments but find them unpersuasive. Because the costs incurred in defending Hatch-Waxman litigation are deductible as business expenses, whether considered under the "origin of the claim" standard or C.F.R. § 1.263, we affirm the Court of Federal Claims' grant of summary judgment for Actavis and against the government.

AFFIRMED