PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

_____

Nos. 22-1193, 21-1194 and 22-1195

_____

MYLAN INC & SUBSIDIARIES

v.

COMMISSIONER OF INTERNAL REVENUE,
Appellant

_____

On Appeal from the United States Tax Court
(IRS-1: 16-26976, 16-26977 and 16-26978)
Tax Court Judge: Honorable Patrick J. Urda

_____

Argued
January 12, 2023

Before: JORDAN, PHIPPS and ROTH, *Circuit Judges*

(Filed July 27, 2023)

_____

Clint Carpenter [ARGUED]
Arthur T. Catterall
United States Department of Justice
Tax Division
950 Pennsylvania Avenue, NW
P.O. Box 502
Washington, DC 20044

Emily J. Giometti
550 Main Street
Suite 9-351
Cincinnati, OH 45202

Lisa M. Rodriguez
Office of District Council
Internal Revenue Service
One Newark Center – Ste. 1500
Newark, NJ 07102

Mary H. Weber
Internal Revenue Service
Office of Chief Counsel
312 Elm Street – Ste. 2350
Cincinnati, OH 45202
Counsel for Appellant

Gregory G. Garre [ARGUED]
Eric Konopka
Latham & Watkins
555 11th Street, NW – Ste. 1000
Washington, DC 20004

Bryan M. Killian
William F. Nelson
James G. Steele, III
Morgan Lewis & Bockius
1111 Pennsylvania Avenue, NW – Ste. 800 North
Washington, DC 20004
Counsel for Appellee

Matthew Hellman
Adam G. Unikowsky
Jenner & Block
1099 New York Avenue, NW – Ste. 900
Washington, DC 20001
Counsel for Amicus Appellee

OPINION OF THE COURT

JORDAN, *Circuit Judge*.

I. OVERVIEW

The Commissioner of Internal Revenue[1] appeals a ruling of the United States Tax Court allowing Mylan, Inc., a manufacturer of generic drugs, to deduct as ordinary and necessary business expenses the legal fees it incurred in defending itself against patent infringement lawsuits brought under the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585. According to the Commissioner, such fees ought to be

[1] The Commissioner now in office is Daniel I. Werfel.

understood as a cost of acquiring approval from the U.S. Food and Drug Administration ("FDA") to market Mylan's generic drugs and should therefore be treated as capital expenditures. The Tax Court, in a thorough and well-reasoned opinion, explained why the Commissioner is wrong. Based on our own precedent and the sound reasons given by the Tax Court, we will affirm.

II. BACKGROUND

A. Regulatory Overview

To understand the outlines of this dispute, it will first be helpful to have in mind the FDA approval process for generic drugs, as well as the rules of taxation distinguishing between deductions and capitalization.

1. The Hatch-Waxman Act

Drug manufacturers must obtain FDA approval to market any new pharmaceutical in the United States. *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(a) (2022) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed ... is effective with respect to such drug."). Typically, a manufacturer submits a New Drug Application ("NDA") to the agency, and so begins "a long, comprehensive, and costly testing process, after which, if successful, the manufacturer will receive marketing approval from the FDA." *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 142 (2013) (citing 21 U.S.C. § 355(b)(1)). That process is formidable, and, until 1984, generic drug manufacturers needed to comply with it fully, even though they were marketing essentially identical

versions of preexisting, FDA-approved drugs. *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 230-31 (4th Cir. 2002). If the business risks and costs involved in the regulatory process were not already a high enough barrier to the creation of generic drugs, legal liability loomed as well, since the development and testing of a proposed generic drug was deemed to be an act of patent infringement, as stated in *Roche Products, Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 861 (Fed. Cir. 1984).

In an effort to change the risk-reward ratio and entice the development and marketing of generic drugs, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, codified at portions of Title 35 and Title 21 of the U.S. Code. The Hatch-Waxman Act established an expedited process for obtaining FDA approval to sell generic drugs. Rather than filing an NDA, generic manufacturers could now file an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. § 355(j). 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." *Actavis*, 570 U.S. at 142 (internal quotation marks omitted). The Hatch-Waxman Act also effectively overturned the ruling in *Roche Products* by providing a legal safe harbor for the development of generic drugs prior to the expiration of a branded drug manufacturer's patents.[2] *See* 35 U.S.C. § 271(e)(1) ("It shall

[2] Patent owners ordinarily enjoy the right to exclude others from making, using, or selling a patented invention for "20 years from the date on which the application for the patent

not be an act of infringement to make, use, offer to sell, or sell within the United States … a patented invention … solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs[.]"); *see also Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1349, 1357-58 (Fed. Cir. 2003) (recognizing that the passage of the Hatch-Waxman Act, in relevant part, 35 U.S.C. § 271(e)(1), effectively overruled its prior holding in *Roche Products* by "enabl[ing] generic manufacturers to test and seek approval to market during the patent term"). Finally, the Act grants certain successful ANDA filers a 180-day period of exclusivity to market the first approved generic version of a brand-name drug. 21 U.S.C. § 355(j)(5)(B)(iv).

In passing the Hatch-Waxman Act, Congress "attempted to balance the goal of making available more low cost generic drugs with the value of patent monopolies in incentivizing beneficial pharmaceutical advancement." *In re Lipitor Antitrust Litig.*, 855 F.3d 126, 134 (3d Cir. 2017) (cleaned up). "The Act seeks to accomplish this purpose, in part, by encouraging manufacturers of generic drugs ... to challenge weak or invalid patents on brand name drugs so consumers can enjoy lower drug prices." *Id*. at 134-35 (cleaned up). To that end, the Act requires the FDA to decide on an expedited basis whether to approve an ANDA. 21 U.S.C. § 355(j)(5)(A) (imposing a 180-day deadline on the agency to approve or disapprove the application, absent mutual agreement with the applicant). And, in tandem with that

---

was filed[.]" 35 U.S.C. § 154(a)(2); *Minerva Surgical, Inc. v. Hologic, Inc.*, 141 S. Ct. 2298, 2303 (2021).

approval process, the Act seeks "to facilitate the resolution of patent-related disputes over pharmaceutical drugs" through a "streamlined mechanism for identifying and resolving patent issues related to the proposed generic products." *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1338 (Fed. Cir. 2003).

That "streamlined mechanism" involves brand-name manufacturers listing the patents that cover their drugs in an FDA publication known as the Orange Book,[3] and generic drug

[3] The publication is formally titled "Approved Drug Products With Therapeutic Equivalence Evaluations," but is commonly called the Orange Book, "after the color of its cover." *Ethypharm S.A. Fr. v. Abbott Lab'ys*, 707 F.3d 223, 227 (3d Cir. 2013). That volume is available online at http://www.fda.gov/cder/ob/ (last visited May 30, 2023). *See generally, e.g.*, 21 U.S.C. § 355(j)(7)(A)(i) ("the Secretary shall publish and make available to the public … a list … of the official and proprietary name of each drug which has been approved for safety and effectiveness[.]"); *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 404-06 (2012). *See also* 21 C.F.R. § 314.53(c)(2)(ii)(P)(3), (c)(3) (2023) (brand-name manufacturers must provide the FDA with descriptions of any "method-of-use" patents it holds in order to "assist … ANDA applicants" in the ANDA application process). The FDA does not evaluate the substance or validity of patents published in the Orange Book. *See Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1080 (D.C. Cir. 2001) ("The FDA, pursuant to longstanding practice and its own regulations, and based on its acknowledged lack of expertise and resources … accept[s] at face value the accuracy of [brand-name patent] holders' … declarations" in the Orange Book).

manufacturers in turn certifying in their ANDA filings that they "will not infringe" any relevant patents, or that the patents are invalid. *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S et al.*, 566 U.S. 399, 406 (2012); 21 U.S.C. § 355(b). The generic drug manufacturer can provide that assurance in one of four ways: by certifying (1) that no patent information on the branded drug has been submitted to the FDA (a Paragraph I certification); (2) that any relevant patents have expired (a Paragraph II certification); (3) that any relevant patents will expire on a stated date, implying that they will have expired by the time the generic drug goes to market with FDA approval (a Paragraph III certification); or (4) that any relevant patents are "invalid or will not be infringed by the manufacture, use, or sale of the new [generic] drug for which the [ANDA] is submitted" (a Paragraph IV certification). 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).[4] That last type of certification, under Paragraph IV, is the most frequent and the kind that is germane here.

A Paragraph IV certification is, by virtue of the Hatch-Waxman Act, a technical act of patent infringement, so it "often means provoking litigation." *Actavis*, 570 U.S. at 143 (internal quotation marks omitted). Indeed, it is designed to give patentholders a chance to start the dispute-resolution process without waiting for the creation of a case or controversy by an ordinary act of infringement, such as the

[4] While not relevant here, generic drug manufacturers can also make a so-called "section viii statement," which asserts that the generic manufacturer will market the drug for a method of use not covered by the branded drug maker's patents. 21 U.S.C. § 355(j)(2)(A)(viii).

manufacture, use, or sale of a copy-cat drug. *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 144 n.6 (3d Cir. 2017). When making a Paragraph IV certification to the FDA, the generic drug manufacturer is obligated to send notice of the certification to the brand-name manufacturer, explaining in detail the factual and legal bases for the claim that the patent is invalid or will not be infringed. 21 U.S.C. § 355(j)(2)(B). At that point, the branded drug maker can choose to respond to the technical act of infringement by filing suit, by negotiating,[5] or by walking away from the fight. Assuming it chooses to file suit, the brand-name manufacturer will invoke 35 U.S.C. § 271(e)(2), which provides:

> 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.

35 U.S.C. § 271(e)(2).

Patent infringement suits launched under § 271(e)(2) as a result of a Paragraph IV certification are often called ANDA suits and are functionally the same as other patent infringement suits, *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569

[5] Any negotiation would have to comport with federal antitrust law. *F.T.C. v. Actavis, Inc.*, 570 U.S. 136 (2013).

(Fed. Cir. 1997), though their timing is different.[6] ANDA suits are preemptive, occurring before the release of a potentially

[6] The Commissioner argues that ANDA suits differ from ordinary patent litigation in two ways. First, he asserts that ordinary patent litigation concerns disputes about pre-existing intangible assets while an ANDA suit occurs "in the process of pursuing the acquisition of an intangible." (Reply Br. at 16.) But that argument assumes what the Commissioner must prove – that ANDA litigation expenses are part of the process of obtaining FDA approval of a drug, and, as we hold today, they are not. Second, he argues that ANDA litigation is different in kind from ordinary patent litigation because it involves a "*deemed* infringer as a matter of law[,]" "not an *alleged* infringer[.]" (Reply Br. at 15.) But that distinction is a red herring. It is true that the statute declares a Paragraph IV certification to be an act of infringement, *see* 35 U.S.C. § 271(e)(2), but, as we have stated before, such "infringement" "is a legal construct that permits a patent holder to initiate suit without having to wait for the generic manufacturer to actually make, use, or sell a generic version of the patented drug." *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 144 n.6 (3d Cir. 2017); *accord Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990) (stating that the function of § 271(e)(2) is to define a "somewhat artificial" act of infringement); and *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed Cir. 2003) (stating that § 271(e)(2) "created an artificial act of infringement"). That technical act of infringement "does not speak to whether the disclosed generic drug does, in fact, infringe the cited patent." *Wellbutrin*, 868 F.3d at 144 n.6*; accord Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1325 (Fed. Cir. 2012) ("Section 271(e)(2)(A) defines the filing of an ANDA as

infringing product into the market. *Id.* The Hatch-Waxman Act encourages brand-name manufacturers to file an infringement complaint within 45 days of receiving notice of a Paragraph IV certification, because doing so triggers a 30-month stay of FDA approval of the generic. 21 U.S.C. § 355(j)(5)(B)(iii) and 35 U.S.C. § 271(e)(2)(A). The stay serves, in effect, as an automatic injunction. The FDA review process continues during the stay, but the generic manufacturer cannot bring its drug to market while the litigation is ongoing, even if the FDA completes its review favorably. *See Actavis*,

---

an act of infringement, but it does not alter the underlying patent infringement analysis[.]"); and *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed Cir. 1997) ("[Section] 271(e)(2) provide[s] patentees with a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity.").

Furthermore, a court can rule that an ANDA applicant did not infringe a patent, even after an "infringement" action under § 271(e)(2) is filed. *See, e.g., Genentech, Inc. v. Sandoz Inc.*, 55 F.4th 1368, 1381 (Fed. Cir. 2022) (affirming a district court's holding of non-infringement in an ANDA suit filed under § 271(e)(2)); *Pernix Ireland Pain DAC v. Alvogen Malta Operations Ltd.*, 323 F. Supp. 3d 566, 630 (D. Del. 2018) (holding that defendant's generic pain medication did not infringe plaintiff's brand-name drug in an ANDA suit under § 271(e)(2) because plaintiff's alleged patents were invalid); *Reckitt Benckiser LLC v. Amneal Pharm. LLC*, 276 F. Supp. 3d 261, 263, 287, 292 (D.N.J. 2017) (holding that defendant's ANDA for a generic version of Mucinex did not "literally" infringe plaintiff's patents in a suit filed under § 271(e)(2)).

570 U.S. at 143 ("If the brand-name patentee brings an infringement suit within 45 days, the FDA then must withhold approving the generic … while the parties litigate patent validity (or infringement) in court."). The brand-name manufacturer thus has the possibility of preventing effective FDA approval of the generic drug until the original patent expires, if litigation is filed within 30 months of expiration.

Once a generic manufacturer has obtained FDA approval for its ANDA, it must wait for the approval to become effective, which occurs either upon resolution of the litigation in its favor within the 30-month period, 21 U.S.C. § 355(j)(5)(B)(iii)(I), or, if litigation is still pending, upon the expiration of the 30-month stay, *id.* § 355(j)(5)(B)(iii); *see also Actavis*, 570 U.S. at 143 (explaining that if a § 271(e)(2) suit is not resolved within the 30-month period, "the FDA may go forward and give approval to market the generic product").[7] Again, and of especial importance here, brand-name manufacturers do not always file a lawsuit in response to a Paragraph IV certification.[8] Therefore, an ANDA

[7] ANDA approval could also be effective almost immediately, if the patentee fails to file suit within 45 days. 21 U.S.C. § 355(j)(5)(B)(iii).

[8] Mylan's general counsel testified during the Tax Court proceedings that patentholders sue "maybe 75 percent of the time" in response to those certifications. (Supp. App. at 70:1-6.) The same testimony gave examples of Mylan ANDA filings, such as that for the cancer drug imatinib sold under the brand name Gleevec, where Mylan filed a Paragraph IV certification and "didn't get sued." (Supp. App. at 82:1-5.) Mylan not only issues but also receives notices of Paragraph

accompanied by a Paragraph IV certification could receive effective approval and go to market without any attendant patent litigation.

While giving branded drug manufacturers the opportunity to vindicate their patent rights, the Hatch-Waxman Act simultaneously motivates generic manufacturers to file Paragraph IV certifications. Most notably, the Act grants a valuable 180-day period of exclusivity to the first applicant of a generic version of a brand-name drug approved after its maker has submitted a Paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)(iv). "During that period … no other generic can compete with the brand-name drug," a right of exclusivity that is "possibly worth several hundred million dollars." *Actavis*, 570 U.S. at 143-44 (internal quotation marks omitted).

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. *See, e.g.*, 21 C.F.R. § 314.127 (2023) (listing reasons the FDA will refuse approval of an ANDA, none of which concern patent litigation under § 271(e)(2)). Whether the application is approved or rejected turns on scientific and technical issues, 21 U.S.C. § 355(j)(4) (listing grounds for disapproval, none of which concern patents), as the FDA "does not independently assess [a] patent's scope" and "lacks 'both [the] expertise and [the]

IV certifications, *see* Supp. App. at 69:16-25, and its general counsel testified that there are "tactical and business and legal strategic considerations on the brand company side about whether suing … is worth the time and effort and expense[.]" (Supp. App. at 81:14-24.)

authority' to review patent claims[.]" *Caraco*, 566 U.S. at 406-07 (second and third alterations in original).[9] And, while an ANDA suit may affect the timing of the FDA's effective approval of a generic drug application, litigation does not control the timing of the FDA's review. 21 U.S.C. § 355(j)(5)(A).

2. Tax Deductions and Capitalizations

Turning now to the pertinent tax law, § 162(a) of the Internal Revenue Code ("Code") allows a taxpayer to deduct "all the ordinary and necessary expenses paid or incurred

[9] Further, if a brand-name manufacturer objects to the FDA's decision about an ANDA, its remedy lies in an action under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 702-706, not under patent law. *See, e.g.*, *Minn. Mining and Mfg. Co. v. Barr Lab'ys, Inc.*, 289 F.3d 775, 777 (Fed. Cir. 2002) (holding that a claim about Paragraph IV certification notice compliance under the Hatch-Waxman Act "cannot be enforced by a private party in a patent infringement action, but must be enforced, if at all, only in the context of an action under the Administrative Procedure Act"); *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1378-80 (Fed. Cir. 2002) (indicating that, because an action asserting a claim against the FDA under the Hatch-Waxman Act is "not tied to any recognized patent infringement" action, the claim "might properly be brought under the APA"); *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1077 (D.C. Cir. 1998) (affirming a successful challenge to the FDA's interpretation of the Hatch-Waxman Act's ANDA requirements, with no mention of patent law).

during the taxable year in carrying on any trade or business[.]" 26 U.S.C. § 162(a). In contrast, § 263 of the Code "allows no deduction for a capital expenditure[.]" *INDOPCO, Inc. v. Comm'r*, 503 U.S. 79, 83 (1992) (citing 26 U.S.C. § 263(a)(1)). For nearly a century, courts have examined and explained the distinctions between deductions and capital expenditures. *INDOPCO*, 503 U.S. at 85 n.5 (collecting cases). In addition, and especially important here, certain Treasury Regulations lay out the rules for applying § 263 to intangible assets, as more fully described herein. They require capitalization for "an amount paid to facilitate … an acquisition or creation of [certain types of] intangible[s.]" 26 C.F.R. § 1.263(a)-4(b)(1)(v) (2023).[10]

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 – for example, expenditures made to acquire the intangible asset of FDA approval to market a drug are amortized over 15 years.[11] 26 U.S.C. §§ 167(a) (depreciation)

[10] The regulations incorporate multiple references to various types of intangibles, the costs for which should be capitalized. A representative sample includes an ownership interest in a corporation, a futures contract, a lease, computer software, or certain rights obtained from a governmental agency, like a trademark, patent, copyright, or an FDA approval. 26 C.F.R. § 1.263(a)-4(c), (d).

[11] A "license, permit, or other right granted by a governmental unit or an agency or instrumentality thereof,"

and 197(a) (amortization). The idea is to match expenses with the relevant revenues during the taxable period, resulting in a more accurate income tax calculation. *See Comm'r v. Idaho Power Co.*, 418 U.S. 1, 16 (1974) ("[Section 263 of the Code] serves to prevent a taxpayer from utilizing currently a deduction properly attributable, through amortization, to later tax years when the capital asset becomes income producing."). The Supreme Court explained in *INDOPCO, Inc. v. Commissioner*, 503 U.S. 79 (1992), that "deductions are exceptions to the norm of capitalization," and that the rules governing them should be "strictly construed[,] and [deductions] allowed only as there is a clear provision therefor" in the Internal Revenue Code. *Id.* at 84 (internal quotation marks omitted). "[T]he burden of clearly showing the right to the claimed deduction is on the taxpayer." *Id.* "Although the mere presence of an incidental future benefit – '*some* future aspect' – may not warrant capitalization, a taxpayer's realization of benefits beyond the year in which the expenditure is incurred is undeniably important in determining whether the appropriate tax treatment is immediate deduction or capitalization." *Id.* at 87.

It has long been the rule that taxpayers may deduct the costs of defending one's business against a tort because mounting such a defense is an ordinary business response. *See Comm'r v. Heininger*, 320 U.S. 467, 471-72 (1943) (holding that legal expenses incurred in defending a business from "threatened destruction" by an adverse postal designation were deductible as ordinary and necessary business expenses). That

---

such as an FDA approval to market a drug, is amortized "over [a] 15-year period." 26 U.S.C. § 197(a), (d)(1)(D).

principle has been captured by current IRS regulations. *See* 26 C.F.R. § 1.263(a)-5(*l*) (Example 18) (stating that "amounts paid by [a taxpayer] to its outside counsel … to resolve … tort liability … are not required to be capitalized").

It has likewise long been the rule that patent infringement claims "sound[] in tort." *Schillinger v. United States*, 155 U.S. 163, 169 (1894). Consistent with that longstanding principle, both the U.S. Court of Appeals for the Sixth Circuit and the Tax Court have held that litigation costs incurred by defendants in patent infringement suits are indeed deductible. *See Schnadig Corp. v. Gaines Mfg. Co., Inc.*, 620 F.2d 1166, 1169 (6th Cir. 1980) ("When an infringer is required to pay damages to a design patentee, the amount so paid is deductible from his income tax."); *Meyer & Bro. Co. v. Comm'r*, 4 B.T.A. 481, 482 (1926) (holding that a defendant's payment to a court-appointed accountant to determine patent infringement damages was deductible as an ordinary and necessary business expense).[12] This is a natural corollary to our own precedent, *Urquhart v. Commissioner*, stating that litigation expenses a patentee incurs in enforcing its patents are ordinary and necessary business expenses because they are "peculiarly normal to the business in which … [patentee] taxpayers [a]re engaged." 215 F.2d 17, 19 (3d Cir. 1954); *cf. Mathey v. Comm'r*, 177 F.2d 259, 263 (1st Cir. 1949) ("[W]hat a patent owner loses from infringement is the acquisition of a just and deserved gain from the exploitation of the invention embodied in his patent[,]" so "an award of damages ... is ordinarily an award of compensation for gains or profits lost

[12] The opinion in *Meyer & Bro.* was issued by an earlier version of the Tax Court known as the Board of Tax Appeals.

by the patent owner and hence is taxable to him as income in the year received.") (internal quotation marks omitted). For reasons we are about to explain, we hold today that it makes no difference in deciding the question of deductibility whether the patent litigation expenses are incurred by the patentee or the alleged infringer. Nor does it matter that the deductibility question arises in the context of an ANDA suit.

a) Tax Determinations for Intangibles

In *INDOPCO*, the Supreme Court addressed how to determine tax liabilities relating to the acquisition of intangible assets. It specifically held that "investment banking, legal, and other costs" incurred during a friendly acquisition in which a company was transformed from a publicly held entity to a wholly owned subsidiary were not deductible because they "b[ore] the indicia of capital expenditures[,]" and that was because "the [acquisition] produced significant benefits ... that extended beyond the tax year in question[.]" *INDOPCO*, 503 U.S. at 88, 90. After the *INDOPCO* decision, the IRS issued regulations addressing capitalization of expenses to acquire, create, or enhance intangible assets. 26 C.F.R. § 1.263(a)-4; *id.* § 1.263(a)-5 (2023). Those regulations govern how and when to capitalize expenditures incurred to create or acquire intangible assets, like a government "license" in the form of FDA approval to market a drug. *Id.* § 1.263(a)-4(d)(1), (d)(5)(i). The regulation relevant here mandates capitalization of amounts paid to "facilitate" the acquisition or creation of intangibles. *Id.* § 1.263(a)-4(b)(1)(v). "Facilitation" is described as follows:

> [A]n 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. Whether an amount is paid in the process of investigating or otherwise pursuing the transaction is determined based on all of 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.

Id. § 1.263(a)-4(e)(1)(i).

In promulgating the capitalization regulations and providing examples,[13] the IRS emphasized that, consistent with

[13] Several examples follow in the regulation that illustrate the scope and limits of "facilitation," and, during oral argument, counsel for the Commissioner said that Example 10 from 26 C.F.R. § 1.263(a)-5(*l*) (2023) is the most analogous to the present case. Example 10 describes an attempted corporate acquisition in which competition regulators file suit to prevent the acquisition. The costs incurred to defend against such antitrust litigation must be capitalized, says the Commissioner, because the "amounts incurred … facilitate [the] acquisition." (Opening Br. at 46) (citing 26 C.F.R. § 1.263(a)-5(l)). The Commissioner believes that since antitrust litigation and ANDA litigation are both elective, once litigation is triggered, all costs associated with resolving the litigation must be capitalized. But a merger threatened by antitrust litigation cannot occur without resolution of the litigation, whereas the

"current law" and specifically in light of our decision in *Urquhart*, 215 F.2d 17, the rules are "not intended to require capitalization of amounts paid to protect ... property against infringement." Guidance Regarding Deduction and Capitalization of Expenditures, 67 Fed. Reg. at 77705 (Dec. 19, 2002). The IRS then provided an example reflecting the rule applied in *Urquhart*. 26 C.F.R. § 1.263(a)-4(e)(5) (Example 6).[14] Relying on that interpretative guidance, generic drug manufacturers had, for many years, commonly deducted ANDA litigation expenses, without objection from the IRS.

Beginning in 2011, however, the IRS issued several non-binding memoranda asserting that generic drug companies should capitalize and amortize the costs of defending patent infringement suits filed in response to Paragraph IV certifications.[15] The reasoning of the memoranda seems to be,

---

same is not true for FDA approval of an ANDA. As explained further herein, an ANDA suit – even when triggered – is not a precondition to receiving an FDA approval of the ANDA. Thus, the example is not analogous and does not foreclose Mylan's argument for the deductibility of its litigation expenses.

[14] The Commissioner agrees that "Example 6 illustrates the rule applied in *Urquhart*[.]" (*See* Reply Br. at 15 n.4.)

[15] *See* IRS Office of Chief Counsel, Memo. No. 20114901F, Attorney Fees Incurred to Defend Against Patent Infringement Claims and to Investigate Patents, 2 (Sept. 14, 2011), https://www.irs.gov/pub/irs-lafa/114901f.pdf; IRS Office of Chief Counsel ("The attorney fees incurred to defend actions for patent infringement pursuant to 35 U.S.C.

in essence, that the expenses should be viewed as payments toward the acquisition of FDA approval of ANDAs. That is certainly the position the Commissioner is taking here.[16] And yet, the Commissioner also says that brand-name drug

---

§ 271(e)(2) for submitting ANDAs to market and sell generic drugs before the expirations of the listed patents must be capitalized."); IRS Office of Chief Counsel, Memo. No. 20114703F, Cost Recovery of Capitalized Attorney Fees Incurred to Defend Against Patent Infringement Claims and to Investigate Patents, 2 (Sept. 27, 2011), https://www.irs.gov/pub/irs-lafa/114703f.pdf ("As franchises, FDA-approved ANDAs are amortizable I.R.C. § 197 intangibles …."); IRS Office of Chief Counsel, Memo. No. AM2014-006, Legal Fees Incurred by Drug Manufacturers Under the Hatch-Waxman Act, 1-2 (Aug. 11, 2014), https://www.irs.gov/pub/irs-utl/AM2014-006.pdf ("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.").

[16] The Commissioner contended before the Tax Court that Mylan's defense of ANDA suits "occurred as a step in the process of seeking FDA-approved ANDAs." (Supp. App.135.) The Commissioner continues to argue on appeal that "Mylan's legal fees were incurred to facilitate the creation of intangible assets (*i.e.*, the FDA approvals) and were therefore capital expenditures, which must be capitalized and deducted ratably over a multi-year (in this case, 15-year) amortization period." (Opening Br. at 4.)

companies can continue to deduct the litigation expenses they incur in the same lawsuits.

3. Mylan's Claimed Deductions

From 2012 to 2014, Mylan regularly submitted ANDAs to the FDA, often including Paragraph IV certifications stating that the particular proposed generic drug at issue would not infringe valid patents. In consequence of those Paragraph IV certifications, Mylan had to defend itself in about 120 patent infringement suits brought under § 271(e)(2), and, in the process, has incurred tens of millions of dollars in legal fees. Mylan incurred additional but much lower legal fees in preparing the notice letters associated with the Paragraph IV certifications. In total, "Mylan incurred legal fees of $46,158,403, $38,211,911, and $38,618,993 during 2012, 2013, and 2014, respectively, to prepare notice letters and to litigate the [ANDA] suits." (App. at 16.) Mylan deducted those amounts in the years incurred.

The IRS responded that Mylan could not deduct the nearly $130 million of legal expenses incurred from 2012 to 2014, and, hence, that its additional tax liability was about $50 million across that period. The result was the issuance of notices of deficiency for each of the three tax years, and Mylan petitioning the Tax Court for redetermination.

B. Procedural History

The Tax Court consolidated all three cases and held a trial, which consisted largely of "expert testimony regarding internal FDA processes … [and] the typical course of dealing between an ANDA applicant and the FDA during the

submission process for an ANDA with a paragraph IV certification." (App. at 18.) After the trial, the Tax Court issued an opinion holding that the "legal expenses [Mylan] incurred to prepare notice letters [we]re required to be capitalized because they were necessary to obtain FDA approval of [its] generic drugs[,]" but – and this is the heart of the dispute – the Court also held that "the legal expenses [Mylan] incurred to defend patent infringement suits [we]re deductible as ordinary and necessary business expenses because the patent litigation was distinct from the FDA approval process." (App. at 2.)

The Tax Court identified the underlying taxable "transaction" as effective FDA approval of an ANDA with a Paragraph IV certification, and the parties do not take issue with that. (App. at 29-30.) The parties have also accepted the Tax Court's determination that the costs of preparing notice letters must be capitalized as a necessary element of acquiring such approval.[17] The issue that is left is whether Mylan's tens of millions of dollars in litigation costs to defend against patent infringement suits are ordinary and necessary business expenses, and so deductible, or were incurred to facilitate the acquisition of ANDA approvals, and so should have been capitalized.

[17] The tax deficiency thus due from Mylan was in aggregate $1,960,993. The parties do not contest that part of the Tax Court's judgment.

III. DISCUSSION[18]

This appeal comes down to what the word "facilitate" means. IRS regulations require capitalization of amounts paid to "facilitate" the acquisition or creation of intangible assets. 26 C.F.R. § 1.263(a)-4(b)(1)(v), (d)(1), (d)(5)(i). The regulations say that an expense "facilitate[s] 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) (2023). A "transaction" is then defined as "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." *Id*. § 1.263(a)-4(e)(3). Again, "[i]n 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." *Id*. § 1.263(a)-4(e)(1)(i).

Mylan argues that ANDA litigation costs do not facilitate the acquisition of FDA approval since approval can be granted regardless of the resolution of the litigation. The Commissioner responds that if a generic drug company chooses to make a Paragraph IV certification – thereby seeking

[18] The Tax Court had jurisdiction over Mylan's petitions for redetermination under 26 U.S.C. §§ 6213(a), 6214, and 7442. We have jurisdiction under 26 U.S.C. § 7482(a)(1). We review the Tax Court's legal conclusions, including its interpretation of the Internal Revenue Code and associated regulations, de novo, and its factual findings for clear error. *DeNaples v. Comm'r*, 674 F.3d 172, 176 (3d Cir. 2012); *Conn. Gen. Life Ins. Co. v. Comm'r*, 177 F.3d 136, 143 (3d Cir. 1999).

to benefit from the 180-day exclusivity period for first-to-market generics – then it triggers the requisite step of resolving any litigation from a Paragraph IV certification. The Commissioner contends, in other words, that litigation is a choice and is a "part of the statutory process for pursuing effective approval of [an] ANDA." (Opening Br. at 31.)

There are several flaws in the Commissioner's reasoning, at least one of which is exposed by the plausible scenario of a generic manufacturer receiving FDA-approval of an ANDA even when the manufacturer loses the patent case it is called on to defend. For example, if the litigation is still going on after the 30-month stay expires and if the generic has met all the FDA requirements for an ANDA, nothing prevents the FDA from issuing effective approval.[19] 21 U.S.C. § 355(j)(5)(B)(iii) (stating that Paragraph IV "approval shall be made effective upon the expiration of the thirty-month period"); *Actavis*, 570 U.S. at 143 (noting that if ANDA litigation is unresolved by the end of the 30-month period, then

[19] By contrast, Paragraph IV notice letters – which the Tax Court correctly held must be capitalized – are a precondition for FDA approval of a generic to go to market before the expiration of the brand-name patent. There is no conceivable scenario in which an applicant could receive an FDA-approved ANDA by Paragraph IV certification without having to first issue a notice letter to the brand-name patentholder. *See* 21 U.S.C. § 355(j)(2)(B)(iii) (stating that an applicant "shall give notice" to "each owner of the patent that is the subject of the certification" and to "the holder of the approved" NDA of the brand-name drug "that is claimed by the patent or a use of which is claimed by the patent").

"the FDA may go forward and give approval to market the generic product"). And even 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. Mylan also presented testimony at the Tax Court that FDA approval sometimes occurs after the resolution of patent litigation. For instance, Mylan prevailed in an infringement action in 2012, which was affirmed in 2013, but the FDA did not approve Mylan's generic drug until 2015.

Nothing prevents a generic manufacturer from commercially marketing its approved drug under the cloud of patent litigation, as long as it has an effective FDA-approved ANDA. That is known as launching "at risk" because, while going to market under such conditions is lawful, generic manufacturers subject themselves to potential infringement damages if the patentholder ultimately prevails in an ANDA suit. *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 241 (3d Cir. 2017). Mylan twice took generic drugs to market under those circumstances. Win or lose, the outcome of patent litigation is irrelevant to the FDA's review; the generic is considered either safe and effective, or not. 21 U.S.C. § 355(j). And all of this assumes that the patent owner chooses to file suit in the first place, which, according to evidence before the Tax Court, does not happen in a substantial percentage of instances where a Paragraph IV certification is made.

The Commissioner does not, and cannot, dispute any of that.[20] Instead, the Commissioner focuses on the statute's

[20] The Commissioner concedes that, under the Act, ANDA "approval will become effective before the [brand-

restrictions of FDA approval during the 30-month stay and argues that the linkage of patent litigation to the Hatch-Waxman Act creates an inseparable, interdependent process. But the examples just given refute that notion. While it is true that, for up to 30 months, the Hatch-Waxman Act delays the effective approval of an ANDA during follow-on litigation, that interplay between regulatory approval and litigation is unrelated to the FDA's final safety and effectiveness review. The FDA can approve an ANDA for an infringing generic and deny an ANDA for a non-infringing generic.

Put differently, ultimate FDA approval is never decided by the outcome of patent litigation under § 271(e)(2), even if it is delayed by such litigation. That the Hatch-Waxman Act affects when suit can be brought is noteworthy but certainly not determinative.[21] In short, as well summarized by the Tax Court:

---

name] patent expires … upon the expiration of the 30-month period, if the [§ 271(e)(2)] litigation is still pending at that time[.]" (Opening Br. at 12.)

[21] It is true, as the Commissioner argues, that the expenses incurred in defending against these ANDA suits "would not be incurred but for" the filing of an ANDA with a Paragraph IV certification. (Opening Br. at 34.) But that does not mean that those costs should be interpreted as having been paid to facilitate the transaction in question. But-for causation and facilitation are not synonymous, as the regulations themselves make abundantly clear. *See* 26 C.F.R. § 1.263(a)-4(e)(1)(i) ("In determining whether an amount is paid to facilitate a transaction, the fact that the amount would (or

> The outcome of a Section 271(e)(2) suit has no bearing on the FDA's safety and bioequivalence review. The FDA continues its review process during the pendency of the patent infringement suit and may issue a tentative or final approval before the suit is resolved. The FDA does not analyze patent issues as part of its review, and neither the statute nor regulations suggest that patent issues might block approval of an ANDA. And winning a patent litigation suit does not ensure that the generic drug manufacturer will receive approval, as the FDA can disapprove an ANDA for not meeting safety and bioequivalence standards.

(App. at 33-34.)

Despite all that, the Commissioner says that "facilitate" should be interpreted broadly to include any litigation costs associated with an ANDA.[22] He claims that the plain

---

would not) have been paid but for the transaction is relevant, but is not determinative.").

[22] The Commissioner does not argue that any deference is owed to his interpretation, and none is. The Commissioner's interpretation was not issued in a rulemaking or agency adjudication and does not enjoy *Chevron* deference. *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984); *see also United States v. Mead Corp.*, 533 U.S. 218, 221, 226-27 (2001) (agency implementation of a statutory provision enjoys *Chevron* deference only when it is clear from Congress that such a ruling carries the "force of law"). And

dictionary meaning of "facilitate" supports that reading, because the patent litigation helps bring about FDA approval, making the acquisition easier and less difficult. (Reply Br. at 22 (citing *Facilitate*, *Merriam-Webster's Collegiate Dictionary* 447 (11th ed. 2003) ("defining 'facilitate' as 'to make easier: help bring about [growth]'")). He stresses that, under the Hatch-Waxman Act, generic manufacturers like Mylan could certify in several ways that they will not infringe Orange-Book-listed patents – ways that do not provoke litigation as Paragraph IV certifications often do. The argument goes that, if generic manufacturers elect to file a Paragraph IV certification to benefit from exclusive marketing opportunities, they "invit[e]" litigation that then becomes a "precondition to obtaining the special benefit that proceeding under [P]aragraph IV affords." (Opening Br. at 39.) But, as we have just explained, that is simply not so. Patent litigation, if it occurs at all after a Paragraph IV certification, does not facilitate the 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. As the Court of Federal Claims said in a recent decision analyzing substantially the same issue we now confront, "Hatch-Waxman litigation can only *delay*, never accelerate, final ANDA approval[.]"

---

there is nothing relevant but ambiguous in the pertinent regulations to trigger deference to the agency's interpretation of its own rules under *Auer v. Robbins*, 519 U.S. 452 (1997). *See Kisor v. Wilkie*, 588 U.S.___, 139 S. Ct. 2400, 2415 (2019) ("[A] court should not afford *Auer* deference [to an agency's interpretation of its own regulations] unless the regulation is genuinely ambiguous.").

Actavis Labs., FL, Inc. v. United States, 161 Fed. Cl. 334, 370 (2022).

Such reasoning, the Commissioner insists, "focuses on the wrong 'process.'" (Reply Br. at 19.) Even though he has argued primarily that an ANDA suit is a necessary step or element in acquiring an FDA-approved ANDA, the Commissioner's fallback position is it does not follow "that the regulation requires capitalization *only* of costs associated with a 'required' step or element of the acquisition." (Reply Br. at 20.) Instead, he contends that "*any* amount paid in the 'process of [investigating or otherwise] pursuing' the acquisition must be capitalized[.]" (Reply Br. at 20, 19 (citing 26 C.F.R. § 1.263(a)-4(e)(1)(i)).) Since § 271(e)(2) litigation costs are made in pursuit of an ANDA, he says, they therefore fit that category. But that argument assumes the conclusion that ANDA litigation expenses are in pursuit of – or "facilitate" the acquisition of – an FDA-approved ANDA, which, as we have explained, they do not; the processes can and do co-exist but do not depend on each other in the way the Commissioner contends, even though both are part of the Hatch-Waxman regime.

All in all, Paragraph IV certifications do not transform ordinary patent infringement litigation into a facilitating step for generic drug approval. Instead, suits filed in response to a Paragraph IV certification are functionally like any other patent infringement suit, although they operate under a different set of time constraints than do other suits. *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 [patent] infringement suit[.]"). The different timing reflects the careful balancing of

competing interests achieved by the Hatch-Waxman Act. In exchange for expedited generic drug approval, Congress provided an option for patentholders to file a preemptive suit before sustaining damages caused by potentially infringing generics. That mere shift in timing does not justify disparate tax treatment of litigation expenses for generic manufacturers defending against alleged patent infringement. If it did, the very purpose of the Hatch-Waxman Act – to encourage generic drug development – would be impeded by forcing substantial additional costs onto generic manufacturers. [23]

The Tax Court therefore correctly determined that litigation in response to a Paragraph IV certification is distinct from the FDA's scientific review process and not actually facilitative of generic drug approval. We agree with its holding that "Congress' decision to coordinate effective FDA approval with the outcome of a Section 271(e)(2) suit" through the 30-

[23] Amicus Accessible Medicines argues that "[p]arity in the tax treatment of generic and branded drug manufacturers' litigation expenses is essential to generic manufacturers' ability to provide lower-cost generic medicines[,]" (Amicus Br. at 2), and holding otherwise would "jeopardize … patient[] … access to lower-cost generic drugs, in direct contravention of Hatch-Waxman's purposes." (Amicus Br. at 4.) We are inclined to agree but recognize that policy issues implicated by the word "parity" may go beyond what we are required to address here. It is enough to say today that imposing very different tax treatment on the warring sides in an ANDA dispute, as the Commissioner advocates, is at odds with the careful statutory balance of improving access to lower-cost generic drugs while respecting intellectual property rights.

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."[24] (App. at 37.)

[24] The Commissioner also asserts that the "origin of the claim" and "future benefits" tests from the Supreme Court support his position, but for largely the same reasons explained in this opinion, those additional arguments fail. The "origin of the claim" test involves the "simple[] inquiry whether the origin of the claim litigated is in the process of acquisition itself." *Woodward v. Comm'r*, 397 U.S. 572, 577 (1970). If so, the litigation costs incurred must be capitalized. *Id*. at 577-78. Additionally, in *INDOPCO, Inc. v. Comm'r*, 503 U.S. 79 (1992), the Court established the rule that costs associated with the creation or acquisition of a distinct and separate intangible asset that "produce[s] significant benefits … that extend[] beyond the tax year in question" should be capitalized. *Id.* at 88, 90. The Commissioner argues that those tests support his position because the substance of the underlying claim in ANDA litigation arises out of the acquisition of effective FDA approval and such FDA approval bestows on generic drug manufacturers an asset that produces valuable future benefits. Once peeled back, the Commissioner's arguments rely on the same faulty premise we have already rejected – that the litigation costs facilitate the acquisition of an effective FDA approval.

Critically, 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. Furthermore, it is unclear why the Commissioner's "future benefits" logic would not also extend to ordinary patent infringement litigation costs. When

IV. CONCLUSION

For the foregoing reasons, we will affirm the decision of the Tax Court.

businesses succeed in defending themselves against ordinary patent infringement suits, they "may obtain several years' worth of revenue that would have been unavailable if the patent had stood in the way." (Amicus Br. at 6.) So, by the Commissioner's reasoning, ordinary patent infringement litigation as well as § 271(e)(2) litigation appear to fit the same rationale for tax capitalization, a result not even the Commissioner tries to justify.