156 T.C. No. 10

UNITED STATES TAX COURT

MYLAN, INC. & SUBSIDIARIES, Petitioner v.
COMMISSIONER OF INTERNAL REVENUE, Respondent

Docket Nos. 26976-16, 26977-16, 26978-16.

Filed April 27, 2021.

P, a U.S. corporation, is a manufacturer of brand name and generic pharmaceutical drugs. During 2012 to 2014 P incurred legal fees in connection with applications submitted to the Food & Drug Administration (FDA) for approval to market and sell generic versions of brand name drugs. As part of the application process P was required to provide a certification regarding the status of any patents that had been listed by the FDA as covering the respective brand name drug. On some applications P certified that listed patents covering the brand name drugs were invalid or would not be infringed by the manufacture of P's generic drugs. When it made such a certification, P was required to send notice letters to the brand name drug manufacturer and any patentees stating that P had made such a certification. Certification also constituted an act of patent infringement giving the brand name manufacturer and patentees the right to bring a patent infringement suit against P. At issue are the legal expenses incurred to prepare notice letters and legal expenses incurred in defending against these patent infringement suits.

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On its 2012, 2013, and 2014 returns, P deducted its legal expenses as ordinary and necessary business expenditures. Upon examination, R determined that these expenses were nondeductible capital expenditures required to be capitalized and subsequently disallowed P's claimed deductions for the expenses at issue. R thereafter issued a notice of deficiency for each of P's 2012, 2013, and 2014 taxable years determining deficiencies of $16,430,947, $12,618,695, and $20,988,657, respectively.

Held: The legal expenses P incurred to prepare notice letters are required to be capitalized because they were necessary to obtain FDA approval of P's generic drugs.

Held, further, the legal expenses P incurred to defend patent infringement suits are deductible as ordinary and necessary business expenses because the patent litigation was distinct from the FDA approval process.

William F. Nelson and James G. Steele III, for petitioner.

Emily J. Giometti, Lisa M. Rodriguez, Mary Helen Weber, Kathryn E. Kelly, and Nina P. Ching, for respondent.

URDA, Judge: Petitioner, Mylan, Inc. & Subsidiaries (Mylan), is a manufacturer of brand name and generic pharmaceutical drugs. From 2012 through 2014 it incurred significant legal expenses in preparing notice letters and defending patent infringement lawsuits related to its generic versions of certain brand name drugs. On its 2012 through 2014 Federal income tax returns, Mylan

claimed deductions for the legal fees as ordinary and necessary business expenses under section 162(a).[1] The Internal Revenue Service (IRS) subsequently disallowed these deductions, determining that the legal expenses were required to be capitalized pursuant to section 263(a). We conclude that the legal expenses Mylan incurred to prepare notice letters are required to be capitalized, while the litigation expenses Mylan incurred to defend patent infringement suits are deductible as ordinary and necessary business expenses.

Introduction

We begin by describing the highly reticulated statutory and regulatory scheme under which Mylan's legal expenses were incurred. Before a pharmaceutical company can market or sell a brand name or generic drug in the United States, it must first obtain approval from the Food & Drug Administration (FDA), the Federal agency responsible for, inter alia, the safety and efficacy of pharmaceuticals. See Federal Food, Drug, and Cosmetic Act, ch. 675, sec. 505, 52 Stat. at 1052 (1938) (codified as amended at 21 U.S.C. sec. 355 (2012)). Although the first step in requesting approval is the same for both brand name and generic

[1]Unless otherwise indicated, all section references are to the Internal Revenue Code (26 U.S.C.), as amended, in effect for the years at issue. Rule references are to the Tax Court Rules of Practice and Procedure. All amounts are rounded to the nearest dollar.

drugs, i.e., by submitting to the FDA a Form FDA 356h, Application To Market a New or Abbreviated New Drug or Biologic for Human Use, the roads diverge thereafter.

A. Brand Name Pharmaceuticals

1. New Drug Application

For brand name pharmaceuticals, a drug's manufacturer formally proposes that the FDA approve the new drug for sale and marketing in the United States through a new drug application (NDA). See, e.g., FTC v. Actavis, Inc., 570 U.S. 136, 142 (2013). The NDA must provide sufficient information for the FDA to review the drug's components, methods of manufacturing and testing, proposed uses and labeling, and results of clinical trials demonstrating that it is safe and effective. 21 U.S.C. sec. 355(b). The drug manufacturer then undergoes a "long, comprehensive, and costly testing process, after which, if successful, the manufacturer will receive marketing approval from the FDA." Actavis, 570 U.S. at 142; see also 21 U.S.C. sec. 355(d).

2. The Orange Book

NDA holders are required to submit patent information for patents that cover an FDA-approved brand name drug or an approved method of using that drug. See 21 U.S.C. sec. 355(b)(1), (c)(2); see also aaiPharma Inc. v. Thompson,

296 F.3d 227, 230 (4th Cir. 2002). Patents so disclosed are listed in a register maintained by the FDA, the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 405-406 (2012); aaiPharma, 296 F.3d at 231. The FDA does not confirm the accuracy of the information provided with the Patent & Trademark Office or the NDA applicant. See Am. Bioscience, Inc. v. Thompson, 269 F.3d 1077, 1080 (D.C. Cir. 2001); see also Caraco, 566 U.S. at 406-407; Apotex, Inc. v. Thompson, 347 F.3d 1335, 1349 (Fed. Cir. 2003).

B. Generic Pharmaceuticals

1. Hatch-Waxman Act

Until 1984, manufacturers of generic pharmaceuticals, like their brand name counterparts, were required to submit an NDA for FDA approval. See aaiPharma, 296 F.3d at 230-231. Congress altered course, however, in the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act or Act), Pub. L. No. 98-417, 98 Stat. 1585. In the Act Congress sought "to strike a balance between 'two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.'" aaiPharma, 296 F.3d at 230 (quoting

Abbott Labs. v. Young, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting on other grounds)); see also Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676 (1990); In re Lipitor Antitrust Litig., 868 F.3d 231, 240 (3d Cir. 2017).

2. Abbreviated NDA

a. FDA Submission

To implement the congressional purpose of bringing cheaper generic drugs to market, the Hatch-Waxman Act established a shortcut to FDA approval for manufacturers hoping to develop and market generic copies of brand name drugs previously approved by the FDA. See Actavis, 570 U.S. at 142; In re Lipitor, 868 F.3d at 240. Under this expedited approach, a generic drug manufacturer may submit an abbreviated new drug application (ANDA) that piggybacks on an approved brand name drug's NDA information by specifying that the generic has the "same active ingredients as, and is biologically equivalent to," the already-approved brand name drug. Caraco, 566 U.S. at 404-405 (citing 21 U.S.C. sec. 355(j)(2)(A)(ii), (iv)); see also Actavis, 570 U.S. at 142. Because the FDA would have previously determined the brand name drug to be safe and effective, the ANDA applicant can obtain approval while avoiding the "costly and time-consuming studies" needed to obtain approval for a brand name drug. See Eli Lilly, 496 U.S. at 676.

b. Approval

The "FDA will approve an * * * [ANDA] and send the applicant an approval letter if none of the reasons in § 314.127 for refusing to approve the * * * [ANDA] applies." 21 C.F.R. sec. 314.105(d) (2014); see also 21 U.S.C. sec. 355(j)(4). Title 21 C.F.R. sec. 314.127 (2014), in turn, enumerates a number of technical reasons for the rejection of an ANDA including failure to show that the generic has the same active ingredients as the brand name drug, failure to show bioequivalence between the drugs, failure to establish that the production methods would preserve the generic's identity, strength, quality, and purity, and failure to show proper labeling. See also 21 U.S.C. sec. 355(j)(4). None of the listed grounds relates to patent issues. See id.; 21 C.F.R. sec. 314.127.

FDA approval of an ANDA, however, does not necessarily mean that a generic drug may be sold and marketed. A generic drug, rather, "may be introduced * * * into interstate commerce when approval of the * * * [ANDA] for the drug product becomes effective." 21 C.F.R. sec. 314.107(a) (2014); see also 21 U.S.C. sec. 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug."). As a general matter, the "approval shall be made effective immediately".

21 U.S.C. sec. 355(j)(5)(B)(iii). In certain instances approval comes with a delayed effective date. Such an approval is tentative and does not become final until the effective date, id. cl. (iv)(II)(dd)(BB), which means that a new drug product may not be introduced or delivered for introduction into interstate commerce until approval of the ANDA is effective, id. subsec. (a).

3. Patent Protections

In addition to endorsing a more simplified process for bringing generics to market, the Hatch-Waxman Act "contains a complex set of provisions designed to protect the intellectual property rights of * * * [brand name] drug companies and others holding patents on brand name drugs." aaiPharma, 296 F.3d at 231.

a. Patent Litigation

The Hatch-Waxman Act created "special procedures" for identifying and resolving patent disputes. See Actavis, 570 U.S. at 143; In re Lipitor, 868 F.3d at 240; see also Apotex, 347 F.3d at 1338 ("The Act also sought to facilitate the resolution of patent-related disputes over pharmaceutical drugs by creating a streamlined mechanism for identifying and resolving patent issues related to the proposed generic products."). When filing an ANDA, a generic drug manufacturer must make one of four "certifications" with respect to each drug for which there is a patent listed in the Orange Book. 21 U.S.C. sec. 355(j)(2)(A)(vii).

Most relevant to these cases, a generic drug manufacturer may certify that any patent "is invalid or will not be infringed by the manufacture, use, or sale" of the generic version (paragraph IV certification). Id. subcl. (IV); see also Actavis, 570 U.S. at 143.

A paragraph IV certification "automatically counts as patent infringement, see 35 U.S.C. § 271(e)(2)(A) (2006 ed., Supp. V), and often 'means provoking litigation'". Actavis, 570 U.S. at 143 (quoting Caraco, 566 U.S. at 407); see also Purepac Pharm. Co. v. Thompson, 354 F.3d 877, 879 (D.C. Cir. 2004) ("In essence, applicants use paragraph IV certifications to challenge the validity of brand-name manufacturers' patents."); Apotex, 347 F.3d at 1339. An ANDA applicant making a paragraph IV certification is required to notify the patentees and holder of the approved NDA implicated by its certification that it has made such certification within 20 days of the ANDA's filing. See 21 U.S.C. sec. 355(j)(2)(B)(ii) and (iii). This notification letter, inter alia, must include a detailed statement laying out the factual and legal bases for the applicant's conclusion that the patent is invalid or not infringed. See id. cl. (iv).

The patentees and the NDA holder are entitled to bring suit in Federal District Court, with remedies including a court order that "the effective date of any approval of the drug * * * is not earlier than the date of the expiration of the patent

which has been infringed" and injunctive relief precluding the ANDA applicant from commercial manufacture. 35 U.S.C. sec. 271(e)(2)(A), (4)(A) (2012); see also 28 U.S.C. sec. 1338(a) (2012) (providing that the Federal District Courts have original jurisdiction over "any civil action arising under any Act of Congress relating to patents"). "Notwithstanding th[e] defined act of infringement, a district court's inquiry in a suit brought under [35 U.S.C.] § 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.'" Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997) (quoting 21 U.S.C. sec. 355(j)(2)(A)(vii)(IV)). "The only difference in actions brought under [35 U.S.C.] § 271(e)(2) is that the allegedly infringing drug has not yet been marketed and therefore the question of infringement must focus on what the ANDA applicant will likely market if its application is approved, an act that has not yet occurred." Id.

b. Effective FDA Approval

The date on which a 35 U.S.C. sec. 271(e)(2) (Section 271(e)(2)) suit is initiated has consequences for the approval of the generic drug becoming effective. If a suit is brought within 45 days of notice of an ANDA with a paragraph IV certification, it triggers a 30-month stay during which the FDA is

prohibited from granting "effective" approval to the ANDA while the parties litigate patent validity or infringement. See 21 U.S.C. sec. 355(j)(5)(B)(iii); Actavis, 570 U.S. at 143.[2]

If the FDA approves the ANDA during the 30-month stay period, it will issue a "tentative approval letter". 21 C.F.R. sec. 314.107(b)(3)(v). "In order for an approval to be made effective * * *, the applicant must receive an approval letter from the agency indicating that the application has received final approval." Id. "Tentative approval of an application does not constitute 'approval' of an application and cannot, absent a final approval letter from the agency, result in an effective approval under paragraph (b)(3) of this section." Id.

"If the courts decide the matter * * * [during the 30-month stay] period, the FDA follows that determination; if they do not, the FDA may go forward and give [effective] approval to market the generic product." Actavis, 570 U.S. at 143; see also 21 U.S.C. sec. 355(j)(5)(B)(iii) (explaining that approval "shall be made effective upon the expiration of the thirty-month period" absent court action).[3]

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[2]Although a patent suit may be brought outside the 45-day window, the filing of such a suit does not prohibit the FDA from making its approval effective.

[3]Thus, if the court concludes that the patent was invalid or not infringed, FDA approval becomes effective on the same date as entry of the judgment. See 21 U.S.C. sec. 355(j)(5)(B)(iii)(I) (2012); see also 21 C.F.R. sec. 314.107(b)(3)(ii)

(continued...)

"The generic manufacturer then has the option to launch 'at risk,' meaning that, if the ongoing court proceeding ultimately determines that the patent was valid and infringed, the generic manufacturer will be liable for the brand-name manufacturer's lost profits despite the FDA's approval." In re Lipitor, 868 F.3d at 241.

c. 180-Day Exclusivity Period

Once approval of an ANDA becomes effective, the generic drug manufacturer may begin commercially marketing the drug. See 21 U.S.C. sec. 355(a); see also Eli Lilly, 496 U.S. at 677. "In order to encourage paragraph IV challenges, thereby increasing the availability of low-cost generic drugs, * * * [21 U.S.C. sec. 355(j)(5)(B)(iv)] provides that the first company to win FDA approval of an ANDA containing a paragraph IV certification has the right to sell its drug without competition for 180 days." Purepac, 354 F.3d at 879; see also Teva Pharms., USA, Inc. v. Leavitt, 548 F.3d 103, 104-105 (D.C. Cir. 2008). "Marketing exclusivity is valuable, designed to compensate manufacturers for research and development costs as well as the risk of litigation from patent

[3](...continued)
(2014). If the court concludes that there has been infringement, effective FDA approval waits for patent expiration. See 21 U.S.C. sec. 355(j)(5)(B)(iii)(II); see also 21 C.F.R. sec. 314.107(b)(3)(iii).

holders." Teva Pharms., USA, Inc., 548 F.3d at 104; see also Actavis, 570 U.S. at 144 ("Indeed, the Generic Pharmaceutical Association said * * * that the 'vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period.'"); In re Lipitor, 868 F.3d at 241.

FINDINGS OF FACT

Mylan is a group of affiliated corporations that join in the filing of consolidated Federal income tax returns. Mylan, Inc., a Pennsylvania corporation and the common parent of that group, maintained its principal place of business in Canonsburg, Pennsylvania, when it timely filed the petitions in these consolidated cases.

I. Mylan's Legal Expenses

Mylan manufactures both brand name and generic pharmaceuticals. During the years relevant to these cases, Mylan regularly submitted ANDAs to obtain FDA approval for generic versions of brand name drugs, including Celebrex, Lunesta, and Nexium. As necessary to win FDA approval, Mylan set forth detailed information to establish that the generic drug was bioequivalent to the brand name drug, that the generic drug shared the same active components, and that the manufacturing process would preserve the generic drug's identity, strength, and purity.

Each ANDA also included a certification as to any patent listed in the Orange Book as covering the brand name drug. During the years relevant to these cases, Mylan regularly included paragraph IV certifications, asserting that one or more patents covering the respective brand name drug were invalid or would not be infringed by Mylan's generic version. Although Mylan understood that paragraph IV certifications often resulted in litigation, it further recognized that such certifications offered both the earliest opportunity to bring its generic versions to market and the possibility (in some cases) of first-to-file exclusivity.

After filing ANDAs with paragraph IV certifications, Mylan prepared and sent formal notice letters to the brand name drug manufacturers and patentees implicated by the certifications. The letters set forth in detail Mylan's explanations as to the invalidity of the patents at issue or the reasons that the manufacture, use, or sale of its generic version did not infringe such patents. Mylan also informed the FDA when it sent these notice letters.

During 2012 through 2014, Mylan regularly defended itself against Section 271(e)(2) suits brought in response to ANDAs with paragraph IV certifications. The FDA was not a party to these suits. Mylan did notify the FDA if a lawsuit was brought within 45 days of the issuance of the notice letter, in

consideration of the automatic 30-month stay mandated by 21 U.S.C. sec. 355(j)(5)(B)(iii).

The FDA's scientific and regulatory review of Mylan's ANDAs with paragraph IV certifications proceeded without regard to any Section 271(e)(2) litigation. In some instances during the years at issue the 30-month stay expired during the pendency of the litigation, and Mylan obtained FDA approval for the generic drug at issue before the suit's conclusion. When that occurred, Mylan would continue defending the Section 271(e)(2) suit. On two occasions during the relevant years, Mylan elected to launch an approved generic drug "at risk", i.e., after the expiration of the 30-month stay but before the resolution of the litigation.

When Mylan won or lost a Section 271(e)(2) suit during the years at issue, it notified the FDA and provided a copy of the final judgment or mandate. If Mylan won, it was entitled to launch the generic drug at issue immediately upon approval by the FDA without waiting for the expiration of the patents covering the brand name drug. If Mylan lost, the FDA would deem Mylan to have converted its paragraph IV certification (that the patents listed in the Orange Book were invalid or were not infringed) into a paragraph III certification (that approval was sought for a period beginning after the expiration of such patents). If Mylan lost the suit

after the ANDA had been approved, the FDA would convert the approval to a tentative approval effective after the expiration of the relevant patents.

Mylan also informed the FDA of other court action during the years at issue. Mylan apprised the FDA when it entered into settlements to resolve Section 271(e)(2) suits, communicating the terms of the settlement agreement including any license permitting Mylan to begin selling its generic drug before the expiration of the patents covering the brand name drug. And Mylan informed the FDA when the court issued or vacated preliminary injunctions prohibiting the marketing or sale of its generic drugs before patent expiration.

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 Section 271(e)(2) suits. During the years at issue Mylan reported legal expenses with respect to approximately 120 suits involving ANDAs with paragraph IV certifications and 15 additional ANDAs with paragraph IV certifications for which suits had not yet been filed.

II. IRS Examination and Tax Court Proceedings

Mylan timely filed a consolidated Form 1120, U.S. Corporation Income Tax Return, for each of its 2012, 2013, and 2014 taxable years. On those returns Mylan deducted $46,991,172, $39,684,483, and $44,060,180, respectively, for

legal fees and expenses it broadly attributed to the litigation of Section 271(e)(2) suits during those years.

Mylan's deductions for the years at issue broke down into the following expense categories: (1) the legal fees described above that Mylan incurred to prepare paragraph IV notice letters and defend Section 271(e)(2) suits during 2012 through 2014; (2) legal fees of $832,769, $1,472,572, and $3,669,397, respectively, which Mylan incurred with respect to generic drugs (a) for which no Section 271(e)(2) suit was ever brought, (b) for which Section 271(e)(2) suits were brought but disposed of before the respective year for which the fees were claimed, and (c) for which Section 271(e)(2) suits were brought (or joined by Mylan) following the respective year for which the fees were claimed; and (3) legal fees of $1,771,790 which Mylan incurred in 2014 with respect to drugs that had already been approved by the FDA and commercially launched.

The IRS examined Mylan's 2012 through 2014 returns and determined that, with the exception of the third category of expense (i.e., the amounts incurred for previously approved and launched copies), all of the foregoing legal expenses were nondeductible capital expenditures required to be capitalized under

section 263(a) and subject to amortization under section 197. It consequently disallowed Mylan's claimed deductions, save for the $1,771,790 claimed for 2014.

The IRS thereafter issued notices of deficiency for each of Mylan's 2012, 2013, and 2014 taxable years determining deficiencies of $16,430,947, $12,618,695, and $20,988,657, respectively. Mylan filed timely petitions with this Court for redetermination of the IRS' determinations for its 2012 through 2014 taxable years. We consolidated the cases, and a trial was held in Washington, D.C. At trial Mylan put on fact witnesses, and both parties presented expert testimony regarding internal FDA processes writ large and, more specifically, the typical course of dealing between an ANDA applicant and the FDA during the submission process for an ANDA with a paragraph IV certification.[4]

OPINION

The Commissioner's determinations in a notice of deficiency are presumed correct, and the taxpayer bears the burden of proving them erroneous. Rule 142(a); Welch v. Helvering, 290 U.S. 111, 115 (1933). "In exploring the relationship between deductions and capital expenditures," we are mindful of the

[4]A total of six expert witnesses testified at trial, with each party offering three experts. The Court admitted all the expert witness reports offered, including the rebuttal reports. Although the expert witnesses testified extensively at trial, their testimony is not necessary for the purposes of deciding these cases.

"familiar rule * * * that the burden of clearly showing the right to the claimed deduction is on the taxpayer." INDOPCO, Inc. v. Commissioner, 503 U.S. 79, 84 (1992) (quoting Interstate Transit Lines v. Commissioner, 319 U.S. 590, 593 (1943)).

I. Deductibility Versus Capitalization

A. General Principles

Section 162(a) allows a deduction for "all the ordinary and necessary expenses paid or incurred during the taxable year in carrying on any trade or business".[5] By contrast, section 263(a) provides that "[n]o deduction shall be allowed" for a capital expenditure. Deductions are exceptions to the "norm" of capitalization. See INDOPCO, Inc. v. Commissioner, 503 U.S. at 84. Where section 162 and section 263 each apply to a given expenditure, the capitalization requirement controls and functions to bar the deduction. See sec. 161; see also Commissioner v. Idaho Power Co., 418 U.S. 1, 17-18 (1974).

The "primary effect" of a payment's classification as a deductible business expense or nondeductible capital expenditure is seen in the timing of the

[5]An expense is "ordinary" if it is customary or usual within a particular trade, business, or industry or relates to a common or frequent transaction in the type of business involved. See Deputy v. du Pont, 308 U.S. 488, 495 (1940). An expense is "necessary" if it is appropriate and helpful to the operation of the taxpayer's business. See Commissioner v. Tellier, 383 U.S. 687, 689 (1966).

taxpayer's cost recovery. INDOPCO, Inc. v. Commissioner, 503 U.S. at 83. Whereas a deduction for an ordinary and necessary business expenditure may be taken in the current year and yields an immediate corresponding reduction in taxable income, a capital expenditure typically results in recovery of a taxpayer's expenditure over a longer period through amortization and depreciation deductions. See Ill. Tool Works, Inc. v. Commissioner, 355 F.3d 997, 1000 (7th Cir. 2004), aff'g 117 T.C. 39 (2001); PNC Bancorp, Inc. v. Commissioner, 212 F.3d 822, 827 (3d Cir. 2000) (citing INDOPCO, Inc. v. Commissioner, 503 U.S. at 83-84), rev'g 110 T.C. 349 (1998). Section 263(a) thus "prevent[s] a taxpayer from utilizing currently a deduction properly attributable, through amortization, to later tax years when the capital asset becomes income producing." Commissioner v. Idaho Power Co., 418 U.S. at 16.

Whether a given expenditure is deductible under section 162 or must instead be capitalized under section 263(a) turns on the particular facts of each case. See INDOPCO, Inc. v. Commissioner, 503 U.S. at 86; see also Santa Fe Pac. Gold Co. & Subs. v. Commissioner, 132 T.C. 240, 262 (2009); FMR Corp. & Subs. v. Commissioner, 110 T.C. 402, 415 (1998); Norwest Corp. & Subs. v. Commissioner, 108 T.C. 265, 280 (1997). An expenditure, no matter its type, may be deductible in one setting but nevertheless required to be capitalized in another.

See Lychuk v. Commissioner, 116 T.C. 374, 388 (2001); see also Am. Stores Co. & Subs. v. Commissioner, 114 T.C. 458, 469 (2000) ("Simply because other cases have allowed a current deduction for similar expenses in different contexts does not require the same result * * * [in another case].").

B. Capitalization of Intangibles

An expenditure generally must be capitalized where it is determined that the expenditure either: (1) creates or enhances a separate and distinct asset, or (2) otherwise generates significant benefits for the taxpayer extending beyond the current taxable year. Santa Fe Pac. Gold Co. v. Commissioner, 132 T.C. at 262; see also INDOPCO, Inc. v. Commissioner, 503 U.S. at 87; Lincoln Sav. & Loan Ass'n v. Commissioner, 403 U.S. 345, 354 (1971). In response to difficulties in administering the significant future benefits standard in the context of intangible assets, the IRS and the Department of the Treasury proposed regulations that "defined the exclusive scope of the significant future benefit test through the specific categories of intangible assets for which capitalization is required". 67 Fed. Reg. 77702 (Dec. 19, 2002). As adopted, section 1.263(a)-4(b)(1), Income Tax Regs., requires the capitalization of amounts paid, inter alia: (1) to acquire an existing intangible; (2) to create certain types of intangibles identified in section 1.263(a)-4(d), Income Tax Regs.; (3) to create or enhance various "separate and

distinct" intangibles; and (4) to create or enhance a "future benefit" identified in subsequent guidance published by the IRS.

1. Relevant Intangibles

For its part, section 1.263(a)-4(d)(5), (7), and (9), Income Tax Regs., enumerates certain "created intangibles", including "rights obtained from a governmental agency", contract termination fees, and amounts paid to another to defend or perfect title to intangible property.[6] With respect to rights obtained from a governmental agency, section 1.263(a)-4(d)(5)(I), Income Tax Regs., specifies: "A taxpayer must capitalize amounts paid to a governmental agency to obtain, renew, renegotiate, or upgrade its rights under a trademark, trade name, copyright, license, permit, franchise, or other similar right granted by that governmental agency." Whether an amount is paid to create an intangible under paragraph (d) is determined on the basis of "all of the facts and circumstances, disregarding

[6]A special 12-month rule applies to the created intangibles identified in sec. 1.263(a)-4(d), Income Tax Regs. Pursuant to that rule, "a taxpayer is not required to capitalize under this section amounts paid to create (or to facilitate the creation of) any right or benefit for the taxpayer that does not extend beyond the earlier of--(I) 12 months after the first date on which the taxpayer realizes the right or benefit; or (ii) The end of the taxable year following the taxable year in which the payment is made." Id. para. (f)(1). The rule is subject to various exceptions, including for "amounts paid to create (or facilitate the creation of) an intangible that constitutes an amortizable section 197 intangible within the meaning of section 197(c)." Id. subpara. (3).

distinctions between the labels used in this paragraph (d) to describe the intangible and the labels used by the taxpayer and other parties to the transaction." Id. subpara. (1).

As also germane to these cases, section 1.263(a)-4(d)(9)(I), Income Tax Regs., provides that a "taxpayer must capitalize amounts paid to another party to defend or perfect title to intangible property if that other party challenges the taxpayer's title to the intangible property." As described in the preamble to the proposed regulations, "[t]his is consistent with existing regulations" and "is not intended to require capitalization of amounts paid to protect the property against infringement and to recover profits and damages as a result of infringement." 67 Fed. Reg. 77705 (Dec. 19, 2002). "As under current law, these costs are generally deductible." Id. (citing Urquhart v. Commissioner, 215 F.2d 17 (3d Cir. 1954), rev'g 20 T.C. 944 (1953)); see also T.D. 9107, 2004-1 C.B. 447, 450 ("The final regulations retain the rule contained in the proposed regulations.").

2. Facilitative Costs

The direct costs of creating intangibles are not the only costs that must be capitalized under section 1.263(a)-4, Income Tax Regs. Taxpayers are further required to capitalize any amounts "paid to facilitate * * * an acquisition or creation" of, among other things, an intangible described in paragraph (d). Id.

para. (b)(1)(v). This provision "recognizes that capitalization is required not only for the cost of an asset itself, but for the ancillary expenditures incurred in acquiring, creating, or enhancing the intangible asset." 67 Fed. Reg. 77705 (citing Woodward v. Commissioner, 397 U.S. 572 (1970)).

"[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." Sec. 1.263(a)-4(e)(1)(I), Income Tax Regs. Whether an amount is "paid in the process of investigating or otherwise pursuing" a given transaction "is determined * * * [on the basis of] all of the facts and circumstances." Id. "[T]he fact that the amount would (or would not) have been paid but for the transaction is relevant, but is not determinative." Id. For purposes of this inquiry, "the term transaction means 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. subpara. (3).

C. Litigation Expenses

The deductibility of a legal expense generally depends upon the origin and character of the claim with respect to which the expense was incurred. See United States v. Hilton Hotels Corp., 397 U.S. 580, 583 (1970); Woodward v. Commissioner, 397 U.S. at 577-578; United States v. Gilmore, 372 U.S. 39, 48-49

(1963); see also Wellpoint, Inc. v. Commissioner, 599 F.3d 641, 647 (7th Cir. 2010), aff'g T.C. Memo. 2008-236; Newark Morning Ledger Co. v. United States, 539 F.2d 929, 935 (3d Cir. 1976). Under this "origin of the claim" test, "the substance of the underlying claim or transaction out of which the expenditure in controversy arose governs whether the item is a deductible expense or a capital expenditure, regardless of the motives of the payor or the consequences that may result from the failure to defeat the claim." Santa Fe Pac. Gold Co. v. Commissioner, 132 T.C. at 264-265; see also Woodward v. Commissioner, 397 U.S. at 578. "Thus, legal expenses directly connected with (or pertaining to) the taxpayer's trade or business are deductible under Section 162 as ordinary and necessary business expenses", while "expenses arising out of the acquisition, improvement or ownership of property are capital expenditures under Section 263(a) and are not currently deductible." Meade Emory et al., "Legal Expenses of Patent Defense Held Deductible", 70 J. Tax'n 180 (1989); see also Am. Stores Co. v. Commissioner, 114 T.C. at 468 (citing Commissioner v. Heininger, 320 U.S. 467 (1943), Commissioner v. Tellier, 383 U.S. 687, 689-690 (1966), and INDOPCO, Inc., v. Commissioner, 503 U.S. at 83).

Patent law has long distinguished suits for the defense of title to intellectual property from patent infringement litigation.[7] The former involves the disposition or acquisition of a capital asset, and expenses in litigating such a suit have been treated as capital--even before the Supreme Court embraced the origin of the claim test. See, e.g., Estate of Baier v. Commissioner, 533 F.2d 117, 120 (3d Cir. 1976) (holding that litigation expenses incurred incident to a dispute over the terms of a disposition are capital), aff'g 63 T.C. 513 (1975); Urquhart v. Commissioner, 215 F.2d at 19-20; Safety Tube Corp. v. Commissioner, 168 F.2d 787 (6th Cir. 1948) (requiring legal fees to be capitalized where controversy involved title and ownership of a patent), aff'g 8 T.C. 757 (1947).

Patent infringement litigation is a different creature altogether, sounding in tort. See Schillinger v. United States, 155 U.S. 163, 169 (1894); Giesecke+Devrient GmbH v. United States, 150 Fed. Cl. 330, 344 (2020). Such "litigation is a far cry from removing a cloud of title, or defending ownership of property." Urquhart v. Commissioner, 215 F.2d at 20. Usually "what a patent

[7]While recognizing the nonprecedential nature of most forms of IRS administrative guidance, see sec. 6110(k)(3), we note that the IRS has recognized this distinction as well, see, e.g., 67 Fed. Reg. 77705 (Dec. 19, 2002) (citing Urquhart v. Commissioner, 215 F.2d 17 (3d Cir. 1954), rev'g 20 T.C. 944 (1953)); Priv. Ltr. Rul. 201536006 (Sept. 4, 2015); Field Serv. Advisory 199925012 (June 25, 1999) ("[A]n acceptance by the Service of Urquhart has developed."); Tech. Adv. Mem. 8831001 (Apr. 8, 1988).

owner loses from infringement is the acquisition of 'a just and deserved gain' from the exploitation of the invention embodied in his patent." Mathey v. Commissioner, 177 F.2d 259, 263 (1st Cir. 1949) (quoting 3 Walker on Patents (Deller's Ed.) § 281), aff'g 10 T.C. 1099 (1948). Therefore, "an award of damages in patent [infringement] litigation is ordinarily an award of compensation for gains or profits lost by the patent owner and hence is taxable to him as income in the year received." Id.

As the U.S. Court of Appeals for the Third Circuit, to which an appeal in these cases would lie absent a stipulation to the contrary, see sec. 7482(b)(1)(B), has observed, litigation expenses for taxpayers "engaged in the business of exploiting and licensing patents * * * are peculiarly normal" to their business, Urquhart v. Commissioner, 215 F.2d at 19. "[F]or taxpayers engaged in the trade or business of creating and licensing intangible assets, the costs incurred in prosecuting an action for * * * infringement will most likely be deductible as a business expense." Phillip F. Postlewaite et al., Federal Income Taxation of Intellectual Properties & Intangible Assets, para. 1.03 (2021), 1998 WL 1038665.

Moreover, costs incurred by a business to defend against tort claims generally have been held deductible for the current taxable year. See, e.g., Kornhauser v. United States, 276 U.S. 145, 153 (1928). Both we and our

predecessor have permitted the deduction of costs incurred in defending patent infringement suits. See F. Meyer & Bro. Co. v. Commissioner, 4 B.T.A. 481, 482 (1926) (holding that amount paid by defendant in patent infringement suit for an accounting was an ordinary and necessary expense); Addressograph-Multigraph Corp. v. Commissioner, a Memorandum Opinion of this Court dated Feb. 5, 1945, 4 T.C.M. (CCH) 147, 166 (1945) (upholding treatment of amounts incurred in defending patent infringement suits as ordinary and necessary business expenses). The deductibility of these expenses is consistent with the treatment of damages paid in the wake of such litigation. Schnadig Corp. v. Gaines Mfg. Co., 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.").

II. Analysis

In these cases, the parties dispute whether the legal fees at issue were incurred to facilitate the acquisition of a right obtained from a Government agency. We will begin by identifying the underlying transaction, i.e., the acquisition of the right, before determining whether the respective fees were paid in the process of investigating or otherwise pursuing that transaction.

A. The Transaction

The parties before us both describe the relevant transaction as the acquisition of an FDA-approved ANDA with a paragraph IV certification. However, the parties ascribe very different meanings to this general formulation. Mylan asserts that the acquisition of an FDA-approved ANDA with a paragraph IV certification occurs when the FDA completes its scientific and technical review and issues either a tentative or final approval letter. The Commissioner asserts that the acquisition of an FDA-approved ANDA with a paragraph IV certification refers to obtaining effective approval of an ANDA with a paragraph IV certification.

The Commissioner's interpretation is the more persuasive. Section 1.263(a)-4(b)(i)(v), Income Tax Regs., requires capitalization of amounts paid to facilitate the acquisition or creation of an intangible. As relevant here, created intangibles include "certain rights obtained from a governmental agency", such as "rights under a trademark, trade name, copyright, license, permit, franchise, or other similar right granted by that governmental agency." Id. para. (d)(5)(i).[8]

[8]Neither party contends that FDA-approved ANDAs are subject to the 12-month rule of sec. 1.263(a)-4(f), Income Tax Regs. We therefore do not

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Although the "FDA will approve an * * * [ANDA] and send the applicant an approval letter" as long as it satisfies the scientific and technical requirements set forth in 21 C.F.R. sec. 314.127, see 21 C.F.R. sec. 314.105(d); see also 21 U.S.C. sec. 355(j)(4), this approval does not confer any rights on an applicant until it becomes "effective", see 21 U.S.C. sec. 355(j)(5)(B); 21 C.F.R. sec. 314.107(a). Only at that point does the right attach, which then allows for a generic drug to be "introduced or delivered for introduction into interstate commerce". 21 C.F.R. sec. 314.107(a); see also 21 U.S.C. sec. 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.").

Mylan has not shown, and we have not found, any authority demonstrating that approval before it becomes effective confers rights equivalent to "rights under a trademark, trade name, copyright, license, permit, franchise, or other similar right granted by that governmental agency." Sec. 1.263(a)-4(d)(5)(i), Income Tax Regs. We accordingly adopt the Commissioner's interpretation of the transaction.

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[8](...continued)
address the application vel non of that rule to these cases.

B. Relevant Legal Fees

1. Paragraph IV Notice Letters

We next consider the proper characterization of the legal fees Mylan incurred during 2012 through 2014 to prepare notice letters relating to its filing of ANDAs with paragraph IV certifications. An applicant for an ANDA with a paragraph IV certification "shall give notice" to "each owner of the patent that is the subject of the certification" and the holder of the NDA with respect to the brand name drug covered by such patents. 21 U.S.C. sec. 355(j)(2)(B)(iii). The notice is required to inform the recipients of the ANDA submission and to explain in detail "the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Id. cl. (iv). After providing that notice, the applicant is required to submit an amendment to its ANDA reflecting that the notice had been given. See 21 C.F.R. sec. 314.95(b).

This notice requirement is also a part of the ANDA itself. Under 21 U.S.C. sec. 355(j)(2)(B)(i), the applicant that makes a paragraph IV certification "shall include" in its ANDA a statement that the applicant "will give notice" as outlined in 21 U.S.C. sec. 355(j)(2)(B). And failure to provide such notice has tangible consequences as "certifications become effective only upon notification." Purepac, 354 F.3d at 890.

The notice described above thus is a required step in securing an FDA-approved ANDA for those applicants that make a paragraph IV certification. Sec. 1.263(a)-4(e)(3), Income Tax Regs. Although Mylan argues that the notice serves to facilitate patent litigation, Congress has made the notice a prerequisite for ANDA approval. Consequently, the legal expenses Mylan incurred to prepare, assemble, and transmit such notice letters constitute amounts incurred "investigating or otherwise pursuing" the transaction of creating FDA-approved ANDAs, id. subpara. (1)(i), and must be capitalized, see also id. para. (l), Example (1) (concluding that payments to outside counsel to prepare license application facilitated the creation of an intangible).

2. Section 271(e)(2) Litigation Expenses

We reach a different conclusion with respect to Mylan's Section 271(e)(2) litigation expenses incurred during the years at issue. In the Hatch-Waxman Act, Congress sought to encourage the entry of low-cost generic drugs into the marketplace while softening the risk to cost-intensive innovation by giving brand name drug manufacturers the opportunity to avail themselves of patent law protections before sustaining damages. Among other changes made to accomplish these objectives, the Hatch-Waxman Act moved up the timeline of patent litigation with respect to generic copies of brand name drugs subject to a patent listed in the

Orange Book. Although the filing of an ANDA with a paragraph IV certification triggers the opportunity for patent litigation as well as the FDA review process, this statutory design does not transform patent litigation into a step in the ANDA approval process. The patent litigation expenses at issue accordingly are not subject to capitalization.

a. Hatch-Waxman Regime

We start by considering the ANDA approval process. The FDA reviews an ANDA to ensure that certain safety standards are met and that the generic copy has the same active ingredients as, and is "bioequivalent" to, the approved brand name drug. See 21 U.S.C. sec. 355(j)(2)(A), (4); see also Actavis, 570 U.S. at 142; Caraco, 566 U.S. at 404-405. According to 21 U.S.C. sec. 355(j)(4), the FDA "shall approve" an ANDA unless it fails to satisfy certain technical requirements enumerated in the statute and accompanying regulations, including failure to show that the generic has the same active ingredients as the brand name drug, failure to show bioequivalence between the drugs, failure to establish that the production methods would preserve the generic's identity, strength, quality, and purity, and failure to show proper labeling. See also 21 C.F.R. secs. 314.105(d), 314.127.

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. 21 U.S.C. sec. 355(j)(4)(F).

A review of the patent litigation framework implemented by the Hatch-Waxman Act likewise fails to suggest that such litigation is an element of the approval process for ANDAs with paragraph IV certifications. "[T]o guard against infringement of patents relating to * * * [brand name] drugs", Eli Lilly, 496 U.S. at 676-677, Congress devised a system where a certification that a patent covering the brand name drug is invalid or not infringed "automatically counts as patent infringement", Actavis, 570 U.S. at 143. The new cause of action embodied in Section 271(e)(2) was a direct response to Congress' decision to end the prohibition on use of brand name pharmaceuticals for research and development before the expiration of patents covering such pharmaceuticals. See

35 U.S.C. sec. 271(e)(1).[9] The technical act of infringement provided an earlier trigger for a patent suit "so that courts could promptly resolve infringement and validity disputes before the ANDA applicant had engaged in the traditional statutorily defined acts of infringement." AstraZeneca Pharms. LP v. Apotex Corp., 669 F.3d 1370, 1377 (Fed. Cir. 2012); see also Bristol-Myers Squibb Co. v. Royce Labs., Inc., 69 F.3d 1130, 1135 (Fed. Cir. 1995) (holding that a Section 271(e)(2) suit makes "it possible for a patent owner to have the court determine whether, if a particular drug were put on the market, it would infringe the relevant patent").

Although the Hatch-Waxman Act moved up the timing of patent litigation, its character remained unchanged. "Notwithstanding th[e] defined act of infringement, 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.'" Glaxo, 110 F.3d at 1569 (quoting 21

[9]"For those who consider legislative history relevant," Warger v. Shauers, 574 U.S. 40, 48 (2014), in its report on the bill proposing what became the Hatch-Waxman Act, the House Energy & Commerce Committee stated that "[t]he purpose of sections 271(e)(1) and (2) is to establish that experimentation with a patented drug product, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement", H.R. Rept. No. 98-857 (Part 1), at 45 (1984), 1984 U.S.C.C.A.N. 2647, 2678.

U.S.C. sec. 355(j)(2)(A)(vii)(IV)); see also Alcon Research Ltd. v. Barr Labs., Inc., 745 F.3d 1180, 1186 (Fed. Cir. 2014); Abbott Labs. v. TorPharm, Inc., 300 F.3d 1367, 1373 (Fed. Cir. 2002).[10] "The only difference in actions brought under § 271(e)(2) is that the allegedly infringing drug has not yet been marketed and therefore the question of infringement must focus on what the ANDA applicant will likely market if its application is approved, an act that has not yet occurred." Glaxo, 110 F.3d at 1569.

The Commissioner counters that a Section 271(e)(2) suit is a step in obtaining effective approval of an ANDA with a paragraph IV certification. He asserts that the Hatch-Waxman regime incentivized the filing of ANDAs with paragraph IV certifications by the prospect of market entry before patent expiration and lucrative first-to-file exclusivity and that Section 271(e)(2) suits ineluctably followed. We are not persuaded. Although Congress erected a framework that promotes the prompt resolution of patent issues, aaiPharma, 296 F.3d at 232, the Commissioner fails to demonstrate how encouraging early and

[10]Again, for those who wish to consider legislative history, the House Energy & Commerce Committee noted in its report that "[t]he provisions of this bill relating to the litigation of disputes involving patent validity and infringement are not intended to modify existing patent law with respect to the burden of proof and the nature of the proof to be considered by the courts in determining whether a patent is valid or infringed." H.R. Rept. No. 98-857 (Part 1), supra at 28, 1984 U.S.C.C.A.N. at 2661.

expeditious patent litigation shows that such litigation is an element of acquiring effective FDA approval of an ANDA with a paragraph IV certification.

The Commissioner also points to statutory provisions linking the effective date of approval to the outcome of Section 271(e)(2) suits as supporting his view. As an initial matter, we note that a Section 271(e)(2) suit is not required to obtain effective approval of an ANDA with a paragraph IV certification, see 21 U.S.C. sec. 355(j)(5)(B)(iii), and that a brand name drug manufacturer is under no obligation to initiate such a suit in response to an ANDA with a paragraph IV certification. Both of these points belie the idea that a Section 271(e)(2) suit is a step in obtaining an effective FDA approval.

Title 21 sec. 355(j)(5)(B)(iii), on which the Commissioner relies, does not suggest a different result. Where "the courts decide the matter within * * * [the 30-month stay] period, the FDA follows that determination; if they do not, the FDA may go forward and give approval to market the generic product." Actavis, 570 U.S. at 143. Title 21 sec. 355(j)(5)(B)(iii) thus ties the effective date to the outcome of a Section 271(e)(2) suit.

Congress' decision to coordinate effective FDA approval with the outcome of a Section 271(e)(2) suit does not convert such litigation into a link in the ANDA approval chain. To the contrary, a Section 271(e)(2) suit serves the same

function as a normal patent infringement suit under 35 U.S.C. sec. 271(a), namely, allowing patent holders the opportunity to vindicate their intellectual property rights. Moreover, the primary relief available in a Section 271(e)(2) suit, i.e., prohibiting introduction of the infringing product into the market until expiration of the applicable patent, is the same relief available in a normal patent infringement suit (through an injunction), only tailored for the unique context where the infringing product has not yet been introduced into the market. See 35 U.S.C. sec. 271(e)(4)(A).[11] The statutory coordination between the outcome of Section 271(e)(2) litigation and FDA effective approval ensures that the FDA does not run afoul of a District Court's resolution of the intellectual property rights of the parties when deciding whether to grant approval. See Caraco, 566 U.S. at 405 ("[T]he FDA cannot authorize a generic drug that would infringe a patent[.]").

Section 271(e)(2) litigation is a vehicle built for the patent holder. It is the patent holder that has the choice to bring litigation within 45 days of notice, with the consequences described in 21 U.S.C. sec. 355(j)(5)(B)(iii). The legal expenses

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[11]We note that this point was made by Representative Henry Waxman before the enactment of the Hatch-Waxman Act, for those who find such statements worth considering. See 130 Cong. Rec. 24427 (1984) (statement of Rep. Henry Waxman). Mr. Waxman observed that, under then-current patent law, "if someone markets a competitive product, * * * [brand name drug manufactures] can go to court and sue for an injunction, or they can sue for treble damages for infringement of that patent." Id.

incurred in defending such suits relate to determining the patent holders' intellectual property rights with respect to brand name drugs. Absent the filing of such a suit by a patent holder, the generic drug manufacturer is under no obligation to demonstrate that a patent is invalid or not infringed to obtain FDA approval. In other words, a patent on a brand name drug presents no impediment to FDA approval of a generic version unless the patent holder decides to take advantage of the mechanism Congress provided for an early adjudication of the patent holder's rights.[12] We cannot conclude that such litigation--controlled by and primarily benefiting patent holders--is a step in the FDA approval process for the generic drug.

As a final matter, section 1.263(a)-4(e)(1)(i), Income Tax Regs., identifies "the fact that the amount would (or would not) have been paid but for the

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[12]Our view on this point is consistent with that expressed by Representative Waxman, again for those who consider such statements. In responding to an objection to the 30-month stay, Mr. Waxman noted that "[t]he facts of life are that a generic drug manufacturer will await, as a practical matter, until the decision of a court on a patent challenge before that manufacturer markets a generic drug." 130 Cong. Rec. 24427. He continued that "[t]he 30-month period is one that gave further assurance to the brand-name drug manufacturer that the generic drug manufacturer would not put his competitor on th[e] market until that court decision came through." Id. Mr. Waxman did not suggest either that the patent litigation is connected with obtaining FDA approval, or that the 30-month stay was more than reassurance to brand name drug manufacturers in the patent context.

transaction" as a relevant, although not dispositive, factor in evaluating whether an expense facilitates a transaction. On a surface level, this factor appears to weigh in favor of the Commissioner's position: absent the transaction to obtain FDA approval, the generic drug manufacturer would not make a paragraph IV certification, the patent holder would not initiate a Section 271(e)(2) suit, and the generic drug manufacturer would not incur litigation expenses defending that suit. Nonetheless "a district court's inquiry in a suit brought under § 271(e)(2) is the same as is in any other infringement suit". Glaxo, 110 F.3d at 1569. Even absent the transaction, the patent holder would doubtless seek to defend its intellectual property against a potential infringer, and the generic manufacturer would incur the same litigation costs in defending such suit. We are not persuaded that the litigation expenses would not have been incurred but for the transaction.[13]

In summary, the Hatch-Waxman Act made coordinated changes to several areas of law, including the FDA approval process and patent law, to serve its goals of encouraging the entry of low-cost generic drugs into the marketplace while affording patent protections to brand name drug manufacturers. See, e.g., In re

[13]Again, for those who wish to consider Mr. Waxman's views on this point, he noted that under then-current patent law, "if someone markets a competitive product, * * * [brand name drug manufacturers] can go to court and sue for an injunction, or they can sue for treble damages for infringement of that patent." 130 Cong. Rec. 24427.

Lipitor, 868 F.3d at 240; Am. Bioscience, 269 F.3d at 1079. Despite the coordination devised by Congress, Section 271(e)(2) litigation is not a step in obtaining effective FDA approval of an ANDA with a paragraph IV certification. Accordingly, expenses Mylan incurred in defending Section 271(e)(2) suits were not "paid to facilitate" the transaction and are not required to be capitalized.

b. Origin of the Claim

The origin of the claim test likewise indicates that Section 271(e)(2) litigation expenses should be treated as deductible ordinary and necessary business expenses. Under this test, we inquire "whether the origin of the claim litigated is in the process of acquisition", enhancement, or other disposition of a capital asset. Woodward v. Commissioner, 397 U.S. at 577; see also Santa Fe Pac. Gold Co. v. Commissioner, 132 T.C. at 264-265.

The legal expenses at issue arose out of actions initiated by patent holders to protect their intellectual property from infringement and exploitation. See, e.g., Glaxo, 110 F.3d at 1569 ("[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.'" (quoting 21 U.S.C. sec. 355(j)(2)(A)(vii)(IV))). Patent infringement suits are creatures of tort,

Schillinger, 155 U.S. at 169; Giesecke+Devrient GmbH, 150 Fed. Cl. at 344, with an aim of preventing and recovering damages to the patent holder's business of exploiting its patent, see Urquhart v. Commissioner, 215 F.2d at 20.

The U.S. Court of Appeals for the Third Circuit has previously explained the proper treatment of expenses incurred in litigating an infringement suit. See id. at 18-19. In that case the taxpayers attempted to deduct various legal expenses associated with patent infringement litigation, and the IRS disallowed the deductions on the ground that they were capital expenditures for the protection or perfection of property rights. Id. We sustained the IRS' determination. Urquhart v. Commissioner, 20 T.C. 944. The Third Circuit disagreed, pointing out that patent infringement "litigation is a far cry from removing a cloud of title, or defending ownership of property." Urquhart v. Commissioner, 215 F.2d at 20. It reasoned that the litigation instead "arose out of and related directly to the exploitation of the invention embodied in the patent" and thus held that the litigation expenses were incurred not to defend or protect title but rather, "to prevent (and recover) damage to their business, that is, to protect, conserve and maintain their business profits." Id.[14] The Department of the Treasury explicitly

[14]Although Urquhart preceded Woodward v. Commissioner, 397 U.S. 572 (1970), by nearly 20 years, we note that the Third Circuit's analysis of the

(continued...)

endorsed the Third Circuit's holding in Urquhart in the preamble to its proposed regulations on the capitalization of intangible assets. See 67 Fed. Reg. 77705 (noting that the proposed regulation was consistent with "existing regulations" and "current law" and "is not intended to require capitalization of amounts paid to protect the property against infringement").

The litigation expenses at issue here likewise arose out of patent infringement claims. See Santa Fe Pac. Gold Co. v. Commissioner, 132 T.C. at 264-265 ("[T]he substance of the underlying claim or transaction out of which the expenditure in controversy arose governs whether the item is a deductible expense or a capital expenditure[.]" (Emphasis added.)). Under the reasoning of Urquhart, the litigation expenses of the patent holders that initiated infringement suits against Mylan seem clearly deductible.

We see no reason that Mylan should face different treatment. Expenses incurred in defending patent infringement claims have been found deductible in the past. See F. Meyer & Bro. Co. v. Commissioner, 4 B.T.A. at 482; Addressograph-Multigraph Corp. v. Commissioner, 4 T.C.M. (CCH) at 166. Although Section 271(e)(2) litigation usually occurs before marketing and sale of

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[14](...continued)
litigation expenses perceptively anticipated the origin of the claim test that the Supreme Court adopted.

the generic drug, the purpose of the suit remains to protect future business profits.[15] Cf. Urquhart, 215 F.2d at 20; Mathey v. Commissioner, 177 F.2d at 263. We conclude that the litigation expenses that Mylan incurred in defending Section 271(e)(2) suits arose out of the ordinary and necessary activities of its generic drug business and accordingly are deductible. See Am. Stores Co. v. Commissioner, 114 T.C. at 468.

In short, the Commissioner fails to convince us that the substance of the underlying claim arises out of the acquisition, ownership, or improvement of property as might support the capitalization of Mylan's Section 271(e)(2) litigation expenses. Indeed, we struggle to see the nature of the property right that the Commissioner has in mind. Although a generic drug manufacturer must assert in an ANDA with a paragraph IV certification that listed patents covering the brand name drug are invalid or not infringed by the generic version, the manufacturer is not required to undertake affirmative litigation to establish that point as a condition of entering its generic on the market. It thus does not appear

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[15]Where a generic drug has been launched "at risk," i.e., after the conclusion of the 30-month stay but before the resolution of the litigation, the plaintiff in the Section 271(e)(2) suit may seek damages as in a normal infringement suit. See 35 U.S.C. sec. 271(e)(4)(C). As explained, such infringement damages have been treated as deductible business expenses of the infringing party. See Schnadig Corp. v. Gaines Mfg. Co., 620 F.2d 1166, 1169 (6th Cir. 1980).

that Section 271(e)(2) litigation relates to the acquisition or enhancement of any right of a generic drug manufacturer, such that the expenses incurred in that litigation must be capitalized. This litigation instead gives the brand name drug manufacturer a chance to protect its intellectual property. In this circumstance, the origin of the claim test suggests that Mylan's litigation expenses are deductible.

c. Regulatory Examples

Certain examples set forth in sections 1.263(a)-4(e) and 1.263(a)-5(l), Income Tax Regs., illustrating the scope of the term "facilitate" in section 1.263(a)-4(e)(1)(i), Income Tax Regs., offer further support for our conclusion. As an initial matter, the parties spar over whether we should consider the regulations set forth in section 1.263(a)-5(l), Income Tax Regs., which address the treatment of "[a]mounts paid or incurred to facilitate an acquisition of a trade or business, a change in the capital structure of a business entity, and certain other transactions", given that the issue before us relates to section 1.263(a)-4(e), Income Tax Regs., which bears on "[a]mounts paid to create or acquire intangibles" as applies to our cases. Both provisions include a nearly identical description of the term "facilitate", and we will consider the regulatory examples to the extent they illuminate the common term.

We believe that the most apposite example is section 1.263(a)-5(l), Example (18)(i), Income Tax Regs. This example discusses the treatment of legal fees paid in connection with bankruptcy proceedings implicating tort liability of the taxpayer. It provides:

> X corporation is the defendant in numerous lawsuits alleging tort liability based on X's role in manufacturing certain defective products. X files a petition for reorganization under Chapter 11 of the Bankruptcy Code in an effort to manage all of the lawsuits in a single proceeding. X pays its outside counsel to prepare the petition and plan of reorganization, to analyze adequate protection under the plan, to attend hearings before the Bankruptcy Court concerning the plan, and to defend against motions by creditors and tort claimants to strike the taxpayer's plan. [Id.]

The example concludes, in relevant part, that the legal expenses paid by X "to prepare, analyze or obtain approval of the portion of X's plan of reorganization that resolves X's tort liability do not facilitate the reorganization and are not required to be capitalized, provided that such amounts would have been treated as ordinary and necessary business expenses under section 162 had the bankruptcy proceeding not been instituted." Id. Example (18)(ii). We see a strong parallel here, where patent litigation is connected with but distinct from the broader project of obtaining effective FDA approval of ANDAs with paragraph IV certifications. The conclusion reached by the example, i.e., that the separate litigation expenses should not be capitalized, thus attaches here.

The Commissioner argues that section 1.263(a)-4(e)(5), Example (4), Income Tax Regs., provides the more apt comparison. In that example U owns a majority of the shares in T while M is a minority shareholder. See id. U and M disagree over a perpetual extension of T's charter, which, under State law, requires U to buy out M. See id. A dispute over the proper value of M's stock spawns litigation and $25,000 in litigation expenses. See id. The example concludes that the litigation expenses facilitate the acquisition of stock by helping to establish the purchase price and thus must be capitalized. See id.

Despite the complicated backdrop, the principle illustrated by this example is straightforward: litigation expenses incurred to establish a necessary element of the transaction (i.e., the purchase price) facilitate it and are subject to capitalization. We believe the instant case is not comparable. The patent litigation expenses were not incurred in connection with a necessary element of obtaining effective FDA approval but to resolve the question of patent rights. As such, the example finds no purchase here.

C. Conclusion

We hold that the disputed legal expenses that Mylan incurred during the years at issue to prepare paragraph IV notice letters must be capitalized pursuant to section 263(a), whereas expenses incurred to litigate Section 271(e)(2) suits are

currently deductible pursuant to section 162(a). The IRS' determinations as set forth in the notices of deficiency are accordingly sustained for amounts incurred to prepare paragraph IV notice letters.

III. Amortization of Mylan's Legal Expenses

Lastly we turn briefly to the amortization (that is, the incremental recovery) of Mylan's expenses for the years at issue. Though Mylan has raised various concerns regarding the equitable and policy implications of requiring generic drug manufacturers to recover their legal expenses over a 15-year term, we understand Mylan's arguments to be geared toward advocating its general position that its expenses are not capital expenditures.

When the IRS determined to disallow Mylan's deductions, part of its determination reflected that Mylan's expenses were subject to amortization over a 15-year period pursuant to section 197. See sec. 197(a). In general, where section 197 applies, no other method of depreciation or amortization is permitted. Id. subsec. (b).

Mylan does not contest in its posttrial briefing the substance of the IRS' determination that, assuming Mylan's expenses were capital, section 197 provides the method for amortization of those expenses. Mylan is therefore deemed to have conceded the section 197 amortization issue. See Mendes v. Commissioner, 121

T.C. 308, 312-313 (2003); Leahy v. Commissioner, 87 T.C. 56, 73-74 (1986); see also Ohde v. Commissioner, T.C. Memo. 2017-137, at *2 n.2. We accordingly sustain the IRS' determination that Mylan's expenses fall within the bounds of section 197.

IV. Conclusion

In sum Mylan is liable for tax deficiencies as to amounts incurred to prepare paragraph IV notice letters for its 2012, 2013, and 2014 taxable years.

To reflect the foregoing,

Decisions will be entered under Rule 155.