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Memorandum

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subject: Legal Fees Incurred to Create an FDA-Approved ANDA

This memorandum responds to your request for assistance relative to issuing a Notice of Proposed Adjustments ("NOPA") regarding the capitalization of certain legal fees incurred in the process of obtaining Federal Food and Drug Administration approval of the Taxpayer's Abbreviated New Drug Application with a paragraph IV certification ("¶ IV certification"). This memorandum may not be used or cited as precedent.

LEGEND

G	=
B	=
Drug B	=
Specialty	=
Non-Specialty	=
ANDA One	=

ANDA Two =
NDA One =
U.S. Patent C =
C Patent =
U.S. Patent D =
D Patent =
U.S. Patent E =
E Patent =
Year One =
Year Two =
Year Three =
Year Four =
Year Five =
Year Six =
Year Seven =
Year Eight =
Year Nine =
Year Ten =
Year Eleven =
Year Twelve =

ISSUES

1. If a drug manufacturer files an Abbreviated New Drug Application ("ANDA") with a ¶ IV certification, are the legal fees the drug manufacturer incurs to defend against a 35 U.S.C. § 271(e)(2) patent infringement suit required to be capitalized under § 263(a) of the Internal Revenue Code and § 1.263(a)-4 of the Income Tax Regulations?

2. If a drug manufacturer files an ANDA with a ¶ IV certification, are the legal fees incurred for related filings and proceedings before the Food and Drug Administration ("FDA")
required to be capitalized under § 263(a) of the Internal Revenue Code and § 1.263(a)-4 of the Income Tax Regulations?

3. Whether the cost recovery of capitalized legal fees incurred in the process of creating an FDA-approved ANDA must be suspended until the FDA approves the ANDA, and then recovered pursuant to I.R.C. § 197 on a straight line basis over 15 years.

4. Whether, when annual cost recovery of the capitalized legal fees commences, the annual amount recovered must be capitalized pursuant I.R.C. § 263A.

5. Whether capitalizing the legal fees constitutes a change in method of accounting and, if so, whether there should be an I.R.C. § 481(a) adjustment and the measure of the adjustment.

CONCLUSIONS

1. Where a drug manufacturer files an ANDA with a ¶ 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.

2. The legal fees incurred for regulatory matters before the FDA in connection with obtaining an FDA-approved ANDA with a ¶ IV certification 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.

3. FDA-approved ANDAs are amortizable § 197 intangibles that are amortizable ratably over a 15-year period, beginning on the first day of the month that the FDA approval of the ANDA is acquired, provided that all applicable exclusionary periods have expired (*e.g.*, the effective date of the ANDA is not subject to a condition precedent, such as the expiration of the period of exclusivity barring the ANDA holder from immediately commencing marketing and selling of drugs the subject of the ANDA in the U.S.) and provided that the trade or business requirement is met.

4. The annual cost recovery of the legal fees that are capitalized must also be capitalized pursuant to § 263A.

5. The proposed capitalization is a change to the Taxpayer's method of accounting, with the first year at issue the year of change. A § 481(a) adjustment should be imposed measured by the aggregate amount of all legal fees expended to create the ANDA with a ¶ IV certification at issue that were deducted in prior years. The aggregate amount should be included in income in the year of change.

FACTS

1. **Taxpayer's Business**

G ("G" or "Taxpayer")[1] researches and develops generic drugs, with its business model to profit from selling the generic drugs that it develops.[2] Once it develops a generic drug, G seeks FDA approval to sell the drug in the United States. To obtain FDA approval, G submits Abbreviated New Drug Applications ("ANDAs") to the FDA.

From Year One to Year Nine, ANDAs that G submitted to the FDA had ¶ IV certifications requesting that the FDA approve G's generic drugs prior to the expiration of the patents covering the branded drugs that the generic drugs "mimic."[3] was an ANDA with a paragraph III certification ("¶ III certification), which requested FDA approval effective after the last patent protecting the branded drug expired.

ANDA certifications are explained in Facts, § 2.B., below.

During the years at issue, *i.e.*, Year Six and Year Seven, G incurred legal fees of $ and $, respectively, to obtain FDA approval to sell G's generic version of Specialty Drug B prior to the expiration of the patents covering Specialty Drug B. The ANDA, ANDA One, that G filed with the FDA for Specialty Drug B had a ¶ IV certification.[4] Specialty Drug B is a branded drug owned by B. B's branded drug is the subject of an FDA-approved New Drug Application ("NDA").

On its Year Six and Year Seven income tax returns, G deducted the legal fees incurred relative to its generic version of Drug B.

Whether the fees must be capitalized, rather than

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G stated that it licenses out the manufacturing and/or the distribution of some of its generic drugs that are the subject of the FDA-approved ANDAs; but, did not represent that it licenses out its ANDAs.

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[4] Only the fees relative to G's generic version(s) of Drug B are at issue.

deducted, is at issue. In applying tax law to the facts to resolve the issue, the laws that govern sales of new drugs in the United States must be considered.

2. Sales of New Drugs in the United States

No new drug can be legally sold in the United States without FDA approval. 21 U.S.C. § 355(a). The term "new drug" in § 355(a) includes generic drugs.[5] Thus, before G can sell its generic version of Drug B in the United States, G must have its generic version approved by the FDA.

The FDA approval process for generic drugs builds off the FDA approval process for innovator drugs (*i.e.,* new non-generic drugs that were never before approved by the FDA for sale in the United States).[6] In order to obtain FDA approval to market and sell innovator drugs, significant safety and efficacy studies must be completed and approved by the FDA.[7] The approval process for generic drugs is abbreviated compared to the innovator drug approval process; however, obtaining FDA approval of a generic drug application with a ¶ IV certification (**the type of application submitted by G herein**) is significantly different from obtaining FDA approval of a generic drug application with any other type of certification. ANDA certifications are explained in Facts, § 2.B., below.

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[5] "A generic drug is identical -- or bioequivalent -- to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use." U.S. Food and Drug Administration, *Generic Drugs: Questions and Answers*, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm (last visited July 23, 2015).

[6] Innovator drugs are sometimes referred to as pioneer drugs. See U.S. Food and Drug Administration Center for Drug Evaluation and Research Approved Drug Products with Therapeutic Equivalence Evaluations, *Orange Book Preface*, *Statistical Criteria for Bioequivalence,* http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm (last visited July 23, 2014) (34th ed.) ("Under the Drug Price Competition and Patent Term Restoration Act of 1984, manufacturers seeking approval to market a generic drug product must submit data demonstrating that the drug product is bioequivalent to the **pioneer (innovator)** drug product." (emphasis added)).

[7] See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(a) (2012). Unlike generic drugs, which generally can be developed and approved in a few years, the drug development and approval process for an innovator drug takes approximately 10 to 12 years to complete and is composed of four stages: preclinical or discovery research, clinical development, regulatory approval, and postmarketing requirements. See also IRS Coordinated Issue Paper LMSB-04-1007-073, *Non-Refundable Upfront Fees, Technology, Access Fees, Milestone Payments, Royalties and Deferred Income Under a Collaboration Agreement*, Section title "Pharmaceutical/Biotechnology Drug Development Process," reprinted in Tax Notes Today, 2007 TNT 204-17 (October 22, 2007)(describing process to obtain FDA approval of new non-generic drug). The status of this Coordinated Issue Paper has been "moved from an active to monitoring status. . ." 2010 TNT 237-27 (December 10, 2010).

A. Innovator Drugs

The vehicle for obtaining FDA approval of a new innovator drug is a New Drug Application ("NDA").[8] The NDA must disclose all patents that cover the innovator drug. 21 C.F.R. § 314.53 (2011). If the FDA approves a NDA, the drug covered by the NDA and the patent information provided to the FDA are included in the FDA's publication "Approved Drug Products with Therapeutic Equivalence and Evaluations," referred to as the "Orange Book."

Due to the time and resources involved in performing the clinical studies and fulfilling the other requirements that must be met to obtain FDA approval of a NDA, most drugs that are the subject of a NDA are patented. A United States patent generally grants the patent holder the right to exclude others from the unauthorized using, making or selling of any drug within the scope of the patents covering the innovator drug in the United States until the patents expire.[9] Having the right to exclude enables recovery of the costs incurred to create the branded drug, to conduct the clinical trials, and to obtain FDA approval. Patent exclusivity is critical to generating profits from selling the drug.

An exception to the general rule relative to the right to exclude unauthorized use of inventions covered by patents was enacted in 1984 as part of the regime for the abbreviated approval of generic drugs, and provides that no infringement occurs when a patented drug is used, even without authority from the patent holder, if used to develop a generic drug in preparation for obtaining FDA approval. 35 U.S.C. § 271(e)(1). See § 2.B., below, Generic Drugs (discussion of 1984-enacted regime).

Even if all patents covering an FDA-approved NDA are held to be invalid, or are expired, that does not affect the status of the NDA.[10] However, separate from, or in addition to, patent exclusivity, there can be regulatory exclusivity for an innovator drug, *e.g.*, three-year exclusivity for new uses of a FDA-approved drug based on additional clinical studies. 21 U.S.C. § 355(c)(3)(E)(iii)-(iv).

Most FDA-approved innovator drugs are registered or trademarked, in addition to being patented. These drugs are generally referred to as branded drugs regardless of the status of the patents.

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[8] U.S. Food and Drug Administration, *New Drug Application (NDA)*, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm (last visited July 15, 2015).

[9] 35 U.S.C. § 154(a)(1).

[10] The status of the NDA can be impacted by failure to comply with on-going FDA requirements or adverse reactions to the drug. See 2013 NSAR 1001F, 2013 WL 1280198, Addendum A § 3, Post Approval Maintenance of NDAs and ANDAs.

B. Generic Drugs

Initially, generic drugs were approved under the same process used to obtain approval of branded drugs, and mere use of a patented drug to develop a new drug for FDA approval constituted infringement.[11] In 1984 Congress passed legislation designed to encourage the development and selling of generic versions of FDA-approved innovator drugs in the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act), Pub. L. No. 98–417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (2010) and 35 U.S.C. § 271(e) (2010)). The Hatch-Waxman Act is a single interdependent regulatory regime[12] that balances the benefits and burdens of increased public access to lower cost generic drugs[13] among patent holders, innovator drug developers and generic drug developers. One of the specifically stated purposes of the Hatch-Waxman Act was to expedite the availability of less costly generic drugs. IRS AM 2014-006, 2014 WL 4495163 (September 12, 2014, p. 2). In addition to expediting review of the safety and bioequivalence of generic drug products prior to approval for marketing, the ANDA process was also designed to accelerate the resolution of any patent infringement issues that may arise from the manufacture, use, or sale of a generic equivalent of an innovator drug. Id.

The Hatch-Waxman Act provides that a generic drug approval application can "piggyback" on the safety and efficacy studies conducted for the FDA-approved innovator drug that the generic drug "mimics" if the generic drug is bioequivalent,[14] which enables generic drug development to be less costly. To enable this "piggyback" process, the exception to infringement in 35 U.S.C. § 271(e)(1) was enacted by the Hatch-Waxman Act to speed up the commencement of generic drug development. Prior to 1984, generic drug developers could not develop a generic version until all patents expired since mere use, without more, generally constituted infringement. Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858 (Fed.Cir.), cert. denied, 469 U.S. 856 (1984). Thus, prior to the enacted Hatch-Waxman Act exception to infringement, even after the patent expired, effectively, the innovator drug holder had continued exclusivity during the time it took for the generic drug to be developed and to be approved by the FDA. The creation of this exception to infringement to expedite generic

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[11] Id.

[12] "It seems probable that Congress – for the reasons we discuss in text – would have regarded § 201 [patent law changes] and § 202 [FDCA law changes] as related parts of a single legislative package, as we do." Eli Lilly v. Medtronic, 496 U.S. 661, 670 n. 3.

[13] U.S. Food and Drug Administration, *Generic drugs: questions and answers*, http://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm, (last visited July 7, 2015). Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discount from the branded price.

[14] See footnote 5, above (explanation of bioequivalent).

drug development is one of the critical interdependent parts of the Hatch-Waxman Act regime.

To end the exception to infringement in 35 U.S.C. § 271(e)(1) and to expedite the vetting of the validity and enforceability of patents that the NDA holder asserted provided exclusivity, the Hatch-Waxman Act made the filing of an ANDA an act of infringement, but with limited remedies as stated in 35 U.S.C. §271(e)(2). Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 669-676 (1990). Other than filing a claim for an award of fees and costs pursuant to 35 U.S.C. § 285 for an exceptional case (*e.g.*, frivolous ¶ IV certification or trial misconduct),[15] the potential remedies available under 35 U.S.C. § 271(e)(2) are those set forth in 35 U.S.C. § 271(e)(4), paraphrased as follows:

(A) An order that the effective date of the FDA approval of the ANDA be no earlier than expiration of the patent (*i.e.*, delaying the marketing and selling of the ANDA products);

(B) An injunction to prevent commercialization of the ANDA products until the patents expire;

(C) Only if the ANDA products were commercialized, damages or other monetary relief; and

(D) For infringement by a biological product, a permanent injunction in certain circumstances.

The flush language of 35 U.S.C. § 271(e)(4) provides (emphasis added):

> The remedies prescribed by subparagraphs (A), (B), (C), and (D) are the **only remedies** which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

Establishing bioequivalence, while necessary, is not all that is required for a generic drug owner to obtain FDA approval. As part of the interdependent regime enacted by the Hatch-Waxman Act, each step required by the Hatch-Waxman Act must be followed. One step requires that the generic drug owner submit an ANDA to the FDA. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j) (2012).

As a **condition precedent** to the FDA accepting a submitted ANDA for filing, the ANDA applicant must certify that its generic drug will not infringe on the patents disclosed by the NDA holder.[16] There are four types of possible certifications:

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[15] 35 U.S.C. § 285 provides that "The court in exceptional cases may award reasonable attorney fees to the prevailing party."

[16] 21 U.S.C. § 355(j)(2)(A)(vii)(I) through (IV).

Paragraph I: Patent information on the drug has not been filed with the FDA.

Paragraph II: The original patent has expired.

Paragraph III: The date on the patent will expire. (The FDA will not finally approve until the patent expires).

Paragraph IV: The patent is invalid or will not be infringed. This fourth certification is known as a ¶ IV certification.

For applications with a ¶ IV certification, where FDA approval to market and sell the new generic drug is requested to be effective prior to the expiration of the branded drug's patents, the generic drug maker incurs expenses not only for development of the drug, as with other types of ANDAs, but also legal fees for evaluation of the patents relative to their validity and the scope of the claims in the patents (since the ¶ IV certification must be in good faith).[17] The filer of an ANDA with a ¶ IV certification also assumes the risk of expensive and lengthy 35 U.S.C. § 271(e)(2) litigation, discussed below.

The FDA's evaluation of a new generic drug for approval "considers whether the proposed drug would infringe a patent" listed for the referenced branded drug because, even if the generic drug is bioequivalent to the branded drug so the generic drug can piggyback off the studies conducted by the branded drug owner, "the FDA cannot authorize a generic drug that would infringe a patent . . . ." Caraco Pharmaceutical Labs v. Novo Nordisk, 132 S. Ct. 1670, 1675-76 (2012). The certifications that must be included in an ANDA are "significant, in that [the type of certification] determines the date on which approval of an ANDA . . . can be made effective, and hence the date on which commercial marketing may commence." Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 677 (1990); 35 U.S.C. § 355(j)(5)(B); Mylan Laboratories, Inc. v. Thompson, 332 F. Supp.2d 106, 110 (D.D.C.), aff'd 389 F.3d 1272 (D.C. Cir. 2004) ("The approval of an ANDA depends, in part, upon the applicant submitting 'a certification . . . with respect to each patent . . . ."), citing 21 U.S.C. §§ 355(j)(2)(A)(vii); 355(j)(7).

Once the FDA is satisfied that a generic drug the subject of an ANDA is bioequivalent to the referenced branded drug, if the ANDA has a certification under paragraph I or II, the FDA may approve the ANDA effective immediately. If the ANDA has a certification under paragraph III, the FDA may grant approval effective on the patent expiration date. When the FDA can grant final approval of an ANDA with a ¶ IV certification is not as straight-forward as it is for ANDAs with paragraph I – III certifications.

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[17] 21 U.S.C. § 355(j)(2)(A)(vii). Certification does not connote that the generic drug maker bears the ultimate burden of persuasion if sued. Cf. Medtronic v. Mirowski Family Ventures, LLC, 134 S. Ct. 843, 850 (2014) (holding that a patentee retains the burden of persuasion in a declaratory judgment action brought by another, stating *inter alia:* "A complex patent can contain many pages of claims and limitations. A patent holder is in a better position than an alleged infringer to know, and to be able to point out, just where, how, and why a product (or process) infringes a claim of that patent.").

For applications with an ANDA ¶ IV certification, there are additional requirements and variables which determine when FDA approval may be effective, including:

- An applicant filing an ANDA with a ¶ IV certification must provide notice to the NDA holder and all patent holders of the patents listed in the Orange Book for the FDA-approved NDA, *i.e.*, the referenced or listed branded drugs, that an ANDA has been filed to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent and that the applicant has certified that the patents are either invalid or not infringed ("¶ IV Notice"). A detailed statement of the factual and legal basis of the applicant's opinion that the patents are invalid or will not be infringed also must be included in the ¶ IV Notice. 21 U.S.C. § 355(j)(2)(B)(iii), (iv).

- The ¶ IV Notice must be sent within 20 days of the postmark date of the notification from the FDA that the ANDA with a ¶ IV certification has been accepted for filing. 21 U.S.C. § 355(j)(2)(B)(ii).

- If neither the patent holders nor the NDA holder brings an infringement suit within 45 days from the date on which the ¶ IV Notice was received, FDA approval of the ANDA with a ¶ IV certification shall be made effective immediately if otherwise approvable, *e.g.*, bioequivalent. 21 U.S.C. § 355(j)(5)(B)(iii).

- However, if a patent holder or NDA holder files a patent infringement lawsuit pursuant to 35 U.S.C. § 271(e)(2) within 45 days of the ¶ IV Notice, FDA approval shall be made effective upon the expiration of a thirty-month period beginning on the date of the receipt of the ¶ IV Notice ("30-month stay"). 21 U.S.C. §355(j)(5)(B)(iii).[18]

    - If prior to expiration of the 30-month stay, the court finally rules that the patent is not valid or is not infringed, FDA approval shall be made effective on the date that the court enters judgment that the patent that is the subject of the certification is invalid or not infringed. 21 U.S.C. §355(j)(5)(B)(iii)(I).

    - If prior to expiration of the 30-month stay, the court determines that the patent has been infringed, then FDA approval shall be made effective on the infringed patent expiration date as determined by the court. 21 U.S.C. §355(j)(5)(B)(iii)(II); 35 U.S.C. §271(e)(4)(A).[19]

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[18] The 30-month stay could be shorter or longer, as the court may order in the event either party to the action failed to reasonably cooperate in expediting the action. 21 U.S.C. §355(j)(5)(B)(iii).

[19] The statute provides further rules as to the date the FDA approval may be effective if there is an appeal of the district court decision. 35 U.S.C. 355(j)(5)(B)(iii)(II).

While the FDA is not a party to the litigation, once the court rules on the validity of the patent and, if ruled valid, whether it has been infringed, the ANDA applicant is required to submit a copy of the entry of the order of judgment to the FDA. 21 C.F.R. § 314.107(e).

- Unless the court issues a preliminary injunction prior to the expiration of the 30-month stay, FDA approval of the ANDA with a ¶ IV certification shall be made effective upon expiration of the 30-month stay. 21 U.S.C. §355(j)(5)(B)(iii)(III) and (IV). If the FDA-approved ANDA with a ¶ IV certification becomes effective while the litigation is still pending,

    - The holder (owner) of the ANDA with a ¶ IV certification may decide to wait for a final ruling from the court before commercializing the approved drug, or

    - The holder of an ANDA with a ¶ IV certification may decide to commercialize the drug, even though exposed to the risk of being sued for lost profits if the patent is found to be valid and infringed.

To provide an incentive to file ANDAs with ¶ IV certifications to challenge potentially invalid patents, and to encourage generic drug makers to undertake the potentially substantial litigation costs associated with such challenges, the Hatch-Waxman Act includes a 180-day exclusivity period (beginning from the first commercial offering of its drug) for first applicants filing an ANDA with a ¶ IV certification. 21 U.S.C. §355(j)(5)(B)(iv). See FTC v. Actavis, Inc., 133 S. Ct. 2223, 2228-29 (2013), *rev'g and remanding sub nom.* FTC v. Watson Pharms., Inc., 677 F.3d 1298 (11th Cir. 2012) (Act provides a special incentive to first applicant to file with a ¶ IV certification by providing a 180-day exclusivity period during which no other generic drug can compete with the brand name drug); Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc., 527 F.3d 1278, 1283 (Fed. Cir. 2008) (point of 180-day period is "to incentivize ANDA filers to challenge the validity of listed patents or design around those patents as early as possible . . . ."); Sandoz, Inc. v. FDA, 439 F. Supp. 2d 26, 29, 33-34 (D.D.C. 2006), aff'd, 2006 U.S. App. LEXIS 22343 (D.C. Cir. 2006) ("Congress ... provid[ed] first-filers with a 180-day exclusivity period in order to reward their risk-taking and encourage further patent challenges in the future."); Mylan Laboratories, Inc. v. Leavitt, 484 F. Supp. 2d 109, 116 (D.D.C. 2007) (importance of the 180-day exclusivity period evident by fact that "Mylan is doing whatever it can, and construing the law in all ways possible, to remain for as long as possible the exclusive marketer of a generic version of amlodipine besylate."); S. Rep. No. 107-167, 2002 WL 1350511, at 4 (2002) (the 180-day period encourages generic drug makers "to challenge weak or invalid patents ... so consumers can enjoy lower drug prices.").

An applicant that files a substantially complete ANDA with a ¶ IV certification on the first day that a substantially complete application with a ¶ IV certification is filed, and lawfully

maintains that certification, is considered a "first applicant."[20] Any ANDA with a ¶ IV certification filed subsequent to that first day "shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant." 21 U.S.C. §355(j)(5)(B)(iv)(I)(emphasis added). Accordingly, since the applications filed after the "first applicant" filing cannot be effective until the expiration of the "first applicant's" 180-day period, the FDA **cannot** approve any ANDA with a ¶ IV certification for the same referenced branded drug that will compete with the generic drug owned by the "first applicant" during the exclusivity period.

An applicant for an ANDA with a ¶ IV certification who obtains 180-day exclusivity is able to gain dramatic financial benefits and market share because its generic version of the patented drug is the only generic drug on the market competing with the higher-priced innovator drug.[21] See FTC v. Actavis, 133 S. Ct. 2223, 2229 (2013) ("this 180-day period of exclusivity can prove valuable, possibly 'worth several hundred million dollars'" (quoting) Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U.L. Rev. 1553, 1579 (2006)). Indeed, the Generic Pharmaceutical Association said in 2006 that the 'vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period.'")(citing to Petitioner's Brief).[22]

The 180-day exclusivity period can be forfeited. 21 U.S.C. §355(j)(5)(D). An ANDA with a ¶ IV certification can be **separately transferred** by the applicant for value and the **exclusivity period can be waived in favor of another** generic manufacture, sometimes for great value. 21 C.F.R. § 314.72 (change in ownership of application). See Mylan Pharms., Inc. v. Shalala, 81 F. Supp. 2d 30, 42 (D.C.C. 2000) (citing Granutec, Inc. v. Shalala, 46 U.S.P.Q.2d (BNA) 1398, 1405(4th Cir.1998) (per curiam, unpublished disposition)). However, with or without 180 days of exclusivity, an ANDA ¶ IV is valuable. ANDAs with ¶ IV certifications are still submitted to the FDA for approval after it is known that the 180-day exclusivity will probably not be awarded, *e.g.*, the FDA website may already list other ANDA ¶ IVs filed for the same referenced FDA-approved branded drug.

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[20] Since the "first applicant" is defined as anyone who submits a substantially complete ANDA with a ¶ IV certification on that "first day", there may be more than one "first applicant" that qualifies. 21 U.S.C. §355(j)(5)(B)(iv)(II)(bb).

[21] Again, there may be more than one "first applicant," but there would still be some advantage to at least limiting the competition to those that were able to file a substantially complete application on that same first day.

[22] For analysis of the value of the 180-day exclusivity period, the impact that the exclusivity period has on the bottom line of the generic drug makers, and the unintended consequences of the 180-day exclusivity period to the stated goal of the Hatch-Waxman regime to speed generic drugs to market, see C. Scott Hemphill and Mark A. Lemley, Earning Exclusivity: Generic Drug Incentives And The Hatch-Waxman Act, 77 Antitrust L.J. 947 (2011)(in particular, notes 25-29 contain useful illustrations of the value of the exclusivity period).

FDA approval of an ANDA with a ¶ IV certification may be withdrawn or altered if a patent infringement suit is filed after the 45-day period and a court determines that the patent has been infringed. See Mylan Labs. v. Thompson, 389 F.3d 1272 (D.C. Cir. 2004). If FDA approval of the ANDA becomes effective while the patent infringement suit is still pending, the ANDA applicant may choose to wait for a final ruling from the court before commercializing the approved drug, or may decide to commercialize the drug "at risk" of being sued for lost profits if the patent is later found to be valid and infringed.

3. Steps Taken by G to Create an FDA-Approved ANDA with a Paragraph IV Certification for Drug B

On , Year Two, B's NDA One for Specialty Drug B was approved by the FDA.[23] Thereafter, G developed a generic version of Drug B. G decided to file an ANDA with a paragraph IV certification so G could obtain FDA approval to sell its generic version of Drug B prior to the expiration of the Drug B patents listed in the Orange Book, hopefully with a 180-day exclusivity period.

G commenced the actions required by law to obtain an FDA-approved ANDA with a ¶ IV certification. One of the steps required obtaining legal advice to support G's good faith certification as to the status of the patents listed in the Orange Book as protecting Drug B.

In Year Four, G submitted to the FDA a ANDA,[24] ANDA One, with a ¶ IV certification for G's generic version of Drug B. On , Year Five the FDA accepted G's ANDA with a ¶ IV certification for filing,[25] and G timely notified B[26] of the filing, informing B that G had certified to the FDA that the following Orange Book-listed patents were invalid or not infringed by G's generic version of Drug B.

(1) U.S. Patent C ("C Patent"), expires no earlier than , Year Eleven;[27]
(2) U.S. Patent D ("D Patent"), expires no earlier than , Year Ten;[28] and

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G was a first filer for Drug B.[29]

4. Litigation, and Filings

The common underlying theme of the disputes was that G sought expedited FDA approval to commercialize its generic version of Drug B, while B sought to delay FDA approval, to defend its patents from G's attacks on their validity, and to protect B's market share relative to Drug B.

For the years at issue, Year Six and Year Seven, legal fees were incurred by G relative to (A) a Year Five lawsuit that continued during Year Six and Year Seven; (B) additional FDA filings and proceedings that resulted in Year Six and Year Seven fees; (C) a Year Six proceeding; and (D) a Year Seven lawsuit. These proceedings are addressed in subsections 4. A. through 4. D., below. A third lawsuit was filed in Year Nine that is briefly addressed in subsection 4. E., evidencing G was still pursing FDA approval of its ANDA after the years at issue.

A. Year Five Lawsuit

i. Complaint

Within 45 days of G's ¶ IV notification, on [31], Year Five,[30] a lawsuit titled [32], [33] was initiated.[34] [35] Pursuant to

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[29] Id.

[30]

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21 U.S.C. §355(c)(3)(C), by filing within the 45-day period, B obtained an automatic stay that barred the FDA from approving G's ANDA for thirty months.

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Both pleadings relied solely on 35 U.S.C. § 271(e)(2) for the allegations of infringement. Both pleadings alleged the 'D and 'C Patents were valid. Neither alleged that G had commercialized its generic version of Drug B.

The prayer for relief requested that:

- The court declare that by filing the ANDA G had infringed the 'D and 'C Patents;[40]
- The court declare that the FDA cannot approve G's ANDA as effective prior to the date both patents are expired;[41]

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38 Id.

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- The court issue an injunction barring commercialization of G's generic drug prior to expiration of the patents and prior to the expiration of any other exclusivity for Drug B, but, did not allege any specific regulatory exclusivity as applying;[42]
- [43]
- [44]

[45]

, Year Five, G filed its Answer,

- [46]
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[47]

- Denied that the plaintiffs were entitled to the relief they sought under 35 U.S.C. § 271(e)(4).[48]

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- The 'C Patent would not be infringed by commercialization of G's generic version of Drug B.[49]
- The 'D Patent would not be infringed by commercialization of G's generic version of Drug B [50]
- The 'D and 'C Patents are invalid .[51]
- [52]
- [53] :
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For the 'D Patent, G relied solely on invalidity; but, for the 'C Patent, G relied on invalidity and non-infringement.

G's prayer for relief requested that:

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- The court declare the 'D and 'C Patents are invalid and not infringed;
- The court order that the FDA can approve the ANDA immediately once it is otherwise ready for approval; and

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B did not add any new claims or causes of actions in its response to the above-described pleading.

The litigation that followed resulted in over filings between , Year Five and , Year Nine.

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59 Id.

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[61] Id.

[62] Id.

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ii. Amended Complaint[65]

The amended complaint mirrored the complaint,

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G's prayer for relief requested that[71]:

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- [78]

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iii. Year Five Lawsuit's Year Seven Trial and Results

There was a trial in Year Seven,[80] [81]

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,[86] ,[87] [88]

On , Year Nine, a settlement conference was held between G and B.[89]

[90] :

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3. .[91]

.[92] It is not known what, if any, rights and benefits G obtained in the settlement.

B. **Filings Giving Rise to Year Six Fees**

In Year Five, B submitted an amendment to NDA One that was at issue in the Year Five Lawsuit.

U.S. Patent E ("E Patent"),[93] which expires on , Year Twelve.[94]

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[86]

[87]

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[92] Id.

[93]

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then submitted a new ANDA relative to Drug B, ANDA Two.

,[96] seeking approval of the FDA to sell G's generic version of Drug B prior to the expiration of the listed patents.[97]

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C. Year Six and Year Seven Proceedings

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, Year Seven, B filed amendments

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D. **Year Seven Lawsuit**

On , Year Seven, B filed another lawsuit against G,[104] with the Year Seven lawsuit also with respect to ANDA One,[105]

All infringement claims in the Year Seven-initiated lawsuit were based solely on 35 U.S.C. § 271(e)(2).[106] B only requested relief available under 35 U.S.C. § 271 (e)(4),[107]

[108]

[109]

The added E Patent was issued on , Year Three,[110] and does not expire until , Year Twelve[111] – after the 'D Patent expires. B's claims with respect to the E Patent were the same , *i.e.*, B only alleged infringement from the filing of ANDA One with a ¶ IV certification under 35 U.S.C. § 271(e)(2). The only relief B requested was that allowed by 35 U.S.C. § 271(e)(4),

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At no time in the Year Seven-initiated lawsuit did B allege G had commercialized its generic version of Drug B

B's prayer for relief requested

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G's answer was similar to its answer to the Year Five-initiated lawsuit .

For the 'D Patent, [112], asserted G did not infringe the D Patent because one could not infringe an invalid patent,[113] admitted certifying that, in G's opinion, the 'D Patent is invalid [114] and denying B was entitled to the relief requested with respect to the 'D Patent.[115] Thus, if the 'D Patent is ruled valid, there is no allegation of non-infringement based on G's generic drug being outside the scope of the 'D Patent.

G's response to the Complaint was more detailed with respect to the E Patent, for example:

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, requested the Court:[120]

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G's prayer for relief requested the court:[127]

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B did not raise any new claims.

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. G alleged that it is prejudiced by B's actions in filing suit on the E Patent.

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."[139] that "the majority of the profits are earned during the 180-day exclusivity ."[140] the remaining profits are earned during the second 6-months ."[141]

G , pointing out it spent over in discovery

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B acknowledged that it had applied for a second 30-month stay based on the Year Seven-initiated lawsuit which could stay launch for almost three years from initiating the Year Seven litigation regardless of the outcome of the Year Five-initiated litigation.[147]

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144 Id.

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[160]

.[161] It is not known what, if any, benefits or rights G obtained as a result of the settlement. It is not known whether G was reimbursed for any of the Year Six and Year Seven fees at issue.

E. Year Nine Lawsuit

While the Year Five and Year Seven-initiated lawsuits were still proceeding (addressed above),

[162]

[163]

[164]

[166] G submitted a new ANDA to the FDA , ANDA Two, which piggybacks on G's ANDA One.

On , Year Nine, B filed a third suit against G.[167] The Year Nine-initiated lawsuit is with respect to

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[160]

[161]

[162]

[163]

[164]

[165]

[166] Id.

[167]

.[168]

.[169] In its Answer, G asserts, its generic version of Drug B has been reformulated so as not to be within scope of the .[170]

TAXPAYER'S POSITION

G asserts that the legal fees at issue are currently deductible under § 162, arguing that the fees arose during G's ordinary course of business, primarily relying upon Urquhart v. Commissioner, 215 F.2d 17 (3d Cir. 1954). G also argues that the litigation legal fees at issue arose from its ¶ IV certification, not its ANDA filing. According to G, litigation fees related to its ¶ IV certification are ordinary and necessary pursuant to Urquhart.

G argues that the Service's reliance upon the origin of claim doctrine to support the capitalization of patent infringement litigation legal fees is an attempt to usurp existing case law, § 263(a) and the Treasury Regulations thereunder.[171] G also argues that the Service elevates form over substance in derogation of United States v. Hilton Hotels Corp., 397 U.S. 580 (1970), which stated "'we cannot see why the order in which those operations occurred . . . should make any difference . . . .'"[172] G further argues that the Service's integration of G's ANDA filing with the B-initiated litigation is a "type of event comingling" that "Treasury went out of its way to try to prevent" by stating in the preamble to the capitalization of intangibles regulation that capitalization will not be proposed solely on the grounds of a future benefit unless the IRS publishes guidance requiring capitalizing of the expenditure.[173] G also cites to Rev. Rul. 78-389, 1978-2 C.B. 125.

With respect to the application of the capitalization of intangible regulations, G agrees that an ANDA is within the definition of a franchise and that amounts paid to the FDA for filing its ANDA must be capitalized under Treas. Reg. § 1.263(a)-4(d)(5)(i).[174] G also

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170 Id.

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agrees that the legal fees at issue "must be analyzed under the facilitative transaction provisions of regulation § 1.263(a)-4(e)."[175] However, G argues that, under its analysis, the legal fees at issue cannot be facilitative.

In its analysis, G asserts that the plain language definition of facilitate is "to make easier".[176] G then argues the fees at issue cannot be facilitative given the litigation delayed the ANDA approval, which does not make obtaining the ANDA easier, and that the Service's position does not adequately take this delay into consideration. G cites to Reg. § 1.263(a)-4(e)(5) Example 6 as additional support, arguing legal fees incurred relative to infringement suits cannot facilitate the creation of an intangible.
G also asserts that the capitalization of the legal fees is not required because it does not have title to any of the patents at issue in the litigation.

G maintains the Hatch-Waxman Act "does not link the ANDA approval process to the patent litigation, rather the Act allows the two activities to proceed independently without unduly influencing one another."[177] G asserts the Service "attempts to turn an infringement event created under Hatch-Waxman into a de facto facilitative relationship."[178]

COMMISSIONER'S POSITION

None of the fees at issue for Year Six and Year Seven can be deducted. Rather, all fees must be capitalized as stated in the Generic Legal Advice issued by the Office of Chief Counsel, IRS AM 2014-006, 2014 WL 4495163 (Aug. 11, 2014) and the below Law and Analysis.

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LAW AND ANALYSIS

In general, costs to defend against a claim of patent infringement are deductible on the theory that a taxpayer is protecting or maintaining its income-generating business. However, the law has long recognized that otherwise deductible costs, when incurred in a capital transaction, must be capitalized. Commissioner v. Idaho Power Co., 418 U.S. I (1974).

I.R.C. § 263(a) generally prohibits deductions for capital expenditures, with deductions the exception to the norm of capitalization. The norm of capitalization was explained in Indopco v. Commissioner, 503 U.S. 79 (1992), as follows:

> In exploring the relationship between deductions and capital expenditures, this Court has noted the "familiar rule" that "an income tax deduction is a matter of legislative grace and that the burden of clearly showing the right to the claimed deduction is on the taxpayer." **The notion that deductions are exceptions to the norm of capitalization finds support in various aspects of the Code**. Deductions are specifically enumerated and thus are subject to disallowance in favor of capitalization. See §§ 161 and 261. Nondeductible capital expenditures, by contrast, are not exhaustively enumerated in the Code; rather than providing a "complete list of nondeductible expenditures," § 263 serves as a general means of distinguishing capital expenditures from current expenses.

503 U.S. at 84 (citations omitted) (emphasis added).

I. CAPITALIZATION OF LEGAL FEES

When legal fees are incurred in litigation, there is a two-step process for determining whether the fees must be capitalized.[179] First, the origin of the claim doctrine must be

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[179] A two-step process to determine whether expenditures are capitalized or deducted when the expenditures arise from litigation is standard. See Chrysler Corporation v. Commissioner, 436 F.3d 644, 660 (6th Cir. 2006)(affirming a Tax Court opinion requiring capitalization of a 1985 payment to redeem stock and quoting Keller Street Dev. Co. v. Comm'r, 688 F.2d 675, 678 (9th Cir. 1982) as follows:

> Characterization of a transaction for taxation is a two step process. The initial step is to discover the origin of the claim from which the tax dispute arose. This attribution determination is critical to proper tax characterization because of the inherently factual nature of taxation. Once a transaction is placed in its proper context, the nature of that transaction becomes discernible and its tax character may be identified. Thus, the second step, the actual tax characterization, is dependent upon the proper resolution of the preliminary attribution question.

applied to ascertain the character and nature of the expenditures. Second, the capitalization of intangibles regulations must be applied to determine, based on the ascertained character and nature, whether the expenditures are within any of the categories of expenditures that must be capitalized under the regulations.

A. **Origin of the Claim**

Pursuant to United States v. Gilmore, 372 U.S. 39, 49 (1963) "[t]he origin and character of the claim with respect to which an expense was incurred, rather than its potential consequences upon the fortunes of the taxpayer, is the controlling basic test of whether the expense . . . is deductible or not. . .." In Gilmore, the origin of the claim test was applied to distinguish non-deductible personal expenditures from deductible business expenditures.

In Woodward v. Commissioner, 397 U.S. 572 (1970), the Supreme Court explained, in the context of distinguishing a deductible business expenditure from a capitalizable business expenditure, that:

> [A] standard based on the origin of the claim litigated comports with this Court's recent ruling on the characterization of litigation expenses for tax purposes in United States v. Gilmore, 372 U.S. 39 (1963). This court there held that the expense of defending a divorce suit was a nondeductible personal expense, even though the outcome of the divorce case would affect the taxpayer's property holdings, and might affect his business reputation. The Court **rejected a test that looked to the consequences of the litigation, and did not even consider the taxpayer's motives or purposes** in undertaking defense of the litigation, but rather examined the origin and character of the claim against the taxpayer, and found that the claim arose out of the personal relationship of marriage.

397 U.S. at 578 (1970) (emphasis added).

The total rejection of the primary purpose test and any test that considers the consequences of the litigation has been the law ever since the above-cited Supreme Court cases. See, *e.g.,* Anchor Coupling v. United States, 427 F.2d 429, 434 (7th Cir. 1970)(rejected primary purpose test in favor of the origin of the claim test for settlements); Brown v. United States, 526 F.2d 135, 139 (6th Cir. 1975)("the test of deductibility relates to origin rather than purpose"); American Stores v. Commissioner, 114 T.C. 458, 470 (2000) (reiterates that the primary purpose test has been rejected, and states the "nature of the transaction out of which the expenditure in controversy arose governs ... regardless of the motives. . . ."). See also Commissioner v. Lincoln

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The Keller Street Dev. Co. court had further explained, after the Chrysler Corp.-quoted passage, that "[a]ttribution through the 'origin of the claim' test was first explained by the Supreme Court in United States v. Gilmore, 372 U.S. 39 . . . (1963) . . . ." 688 F.2d at 678.

Savings & Loan Ass'n, 403 U.S. 345, 354 (1971)("It is not enough, in order that an expenditure qualify as an income tax deduction, . . . that it serves to fortify . . . purpose and operation."); Rev. Rul. 78-389, 1978-2 C.B. 125("[T]he courts have looked to the origin and character of the litigation . . . .).

In general, the above cases establish that, in applying the origin of the claim test, the primary purpose and the consequences are not relevant. The origin of the claim test is an objective inquiry to determine the origin and character of the claim, taking into account all of the facts and circumstances; it is not a test dependent on the formal titles to pleadings or subjective motives.

In Cavanaugh v. Commissioner, T.C. Memo 2012-324, 2012 Tax Ct. Memo LEXIS 325, the Tax Court clarified its position on the origin of a claim doctrine relative to a frequently cited Tax Court case, stating:

> We've often cited Boagni [v. Commissioner, 59 T.C. 708 (1973)], but some courts have urged caution in reading too much into the [oft] quoted passage's mention of the litigation's *objectives* and the deductions' *purposes* . . . [as] impermissibly close to the focus on "consequences" that Gilmore forbade and the primary-purpose test that Gilmore and Woodward rejected. We won't read our precedent to put us in conflict with the Supreme Court: ... "[A]lthough we are instructed by Boagni v. Commissioner *** to consider all facts and circumstances, we are bound by the rule established by United States v. Gilmore *** to look at the origin of the underlying claim, and not the consequences."
>
> [H]owever we paraphrase the test, Gilmore limits what facts we can consider. We won't, therefore, look at the harm that [the suit] might have caused . . . or its other possible consequences.

2012 Tax Ct. Memo LEXIS 325, at *13-*14 (citations omitted, except for Supreme Court cases).

Further, as stated in Lychuk v. Commissioner, 116 T.C. 374, 393-416 (2001),[180] expenditures are not *ipso facto* deductible because they are routine recurring expenses of a business. Lychuk applied Lincoln Savings & Loan Ass'n, Indopco, Gilmore, Woodward and Helvering v. Winmill, 305 U.S. 79 (1938), and found "payments made with a sufficiently direct connection to the acquisition, creation, or enhancement of a capital asset must be capitalized even when those payments are made in the course of the payee's regular business operations." Lychuk, 116 T.C. at 409.

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[180] The change in litigation position announced in Chief Counsel Notice CC-2002-021, 2002 WL 32813480 (March 15, 2002), citing Lychuk, addressed employee compensation, fixed overhead and *de minmis* transaction costs, expenditures not addressed in this advice.

All of the legal fees at issue herein have a sufficiently direct connection with the creation of intangible assets that they are capital in origin. G's generic version of Drug B was developed in reliance on the Hatch Waxman Act exception to infringement when one develops a generic drug to obtain FDA approval to sell the drug in the United States prior to patent expiration. G sought FDA approval to sell its generic version prior to the expiration of the patents on Drug B by filing an ANDA with a ¶ IV certification. G could have submitted an ANDA with a ¶ III certification, but did not. When an ANDA with a ¶ IV certification is submitted to the FDA, the FDA cannot accept the ANDA for filing to determine if the new generic drug is bioequivalent to the referenced FDA-approved branded drug if the generic has not certified that the patents are invalid or not infringed. Thus, to obtain pre-patent expiration approval of its generic form of Drug B, G had to make a good faith certification that the patents were invalid or were not infringed in order for the FDA to be able to file the application.

G took these steps knowing 35 U.S.C. § 271(e)(2) litigation might follow. Since 1984, when the Hatch-Waxman Act was passed, submitting an application for FDA approval effective prior to the expiration of the patents covering a referenced branded drug, *i.e.*, an ANDA with a ¶ IV certification, is an act of infringement. 35 U.S.C. § 271(e)(2). See FTC v. Actavis, Inc., 133 S.Ct. 2223, 2228 (2013) ("Taking this . . . route (called the 'paragraph IV' route), automatically counts as patent infringement, see 35 U.S.C. § 271(e)(2)(A) (2006 ed., Supp. V), and often 'means provoking litigation.'"). Moreover, G cannot credibly argue that the 35 U.S.C. § 271(e)(2) suit that B filed originated in G's intent to infringe, rather than in obtaining a new capital asset, because G certified to the FDA that its generic product would not infringe the patents on Drug B – either because the patents were invalid or not infringed.

In addition, B's claims of infringement all asserted infringement based on G's filing of an ANDA with a ¶ IV certification. There was no claim that G commercialized its generic version of Drug B. While the parties contested the validity of the patents for the purpose of delaying or accelerating the effective date of the FDA approval, lost profits were not at issue, nor were other damages, such as reasonable royalties, at issue.

The facts and circumstances, including G's reliance on the Hatch-Waxman enacted law to develop its generic version of Drug B before all the patents expired, establish the origin was to obtain an FDA-approved ANDA with a ¶ IV certification. G had to defend itself in the 35 U.S.C.§ 271(e)(2) suit brought by B in order to obtain FDA approval of Drug B effective prior to the expiration of the patents.[181]

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[181] Even though G requested declaratory relief in its answer, B retained the burden to prove both the validity of the patents and that all the patents would be infringed if G's generic drug was commercialized prior to the expiration of the patents. Cf. Medtronic v. Mirowski Family Ventures, LLC., 34 S. Ct. 843, 846 (2014)("when a licensee seeks a declaratory judgment against a patentee to establish that there is no infringement, the burden of proving infringement remains with the patentee. We reverse the Federal Circuit's determination to the contrary.").

The remedies requested by the parties confirm the analysis. See Wellpoint, Inc. v. Commissioner, 599 F.3d 641, 648 (7th Cir. 2010)(While the origin of the claim test does not look to the consequences, the relief sought can provide clues to the origin). B requested that the court order the effective dates of the ANDA be no earlier than when the patents expired. G requested that the court order that the FDA may approve its ANDA with a ¶ IV certification effective immediately. While B sought declarations its patents were valid and G sought declarations the patents were not valid, the patents mattered in this case because valid, infringed patents could delay the effective date of G's ANDA.

Just the recital of the facts and circumstances, including the fact that an ANDA with a ¶ IV certification and an award of 180 days of exclusivity are separately transferrable commodities,[182] provides an "adverse answer" to G deducting its legal fees. See Lincoln Savings, 403 U.S. 345 at 354 (1971) (holding the expenditure at issue was not deductible as an ordinary and necessary business expense because it created or enhanced an "additional asset and that, as an inevitable consequence, the payment is capital in nature . . . . ").[183]

The two events, the filing of an ANDA with a ¶ IV certification and the defense of the lawsuits, cannot be separated because they are a part of a series of steps taken by G as part of a single plan to obtain an FDA-approved ANDA with a ¶ IV certification effective prior to the expiration of the patents that covered Drug B. While the 35 U.S.C. § 271(e)(2) action is classified as an infringement action, the substance, not the form, determines the origin of the claim. The suit is explicitly part of an overall statutory scheme of regulation put in place to allow G to obtain regulatory approval to market and sell its generic drug, as a bioequivalent of Drug B, prior to expiration of B's patents on Drug B.

That the two events cannot be separated is clear from the fact that the Hatch-Waxman Act made changes to not only the Federal Food, Drug and Cosmetic Act (FDCA), but to patent laws, in order to balance the competing interests of the generic and branded drug manufacturers.[184] The Supreme Court noted that "[i]t seems probable that Congress – for the reasons we discuss in text – would have regarded § 201 [patent law

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[182] 21 C.F.R. § 314.72 (providing an applicant can transfer ownership of its ANDA and setting forth the necessary steps to transfer title).

[183] The payment at issue in Lincoln Savings was the additional premium paid to the Federal Savings and Loan Insurance corporation (FSLIC) for a secondary reserve maintained by the FSLIC, with Lincoln Savings pro rata share transferable and refundable under certain circumstances, one of the key facts for treating the secondary reserve expenditure as paid to create or enhance an asset.

[184] Mylan Laboratories, Inc. v. Thompson, 332 F. Supp. 2d 106, 110 (DDC), aff'd 389 F.3d 1272 (D.C. Cir. 2004)("'Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to the market.'").

changes] and § 202 [FDCA law changes] as related parts of a single legislative package, as we do." Eli Lilly v. Medtronic, 496 U.S. 661, 670 n. 3 (1990).

The text that the Supreme Court referenced clearly establishes that the Hatch-Waxman Act is an integrated regulatory regime that cannot be bifurcated to treat the 35 U.S.C. § 271(e)(2) litigation as separate and unrelated to the application for FDA approval to market and sell a generic drug effective prior to the expiration of the patents covering the referenced branded drug.

> The function of [litigation under § 271(e)(2), and the remedies available under § 271(e)(4),] is to define a new (and somewhat artificial) **act of infringement for a very limited and technical purpose that relates only to certain drug applications.** As an additional means of eliminating the *de facto* extension at the end of the patent term in the case of drugs, and to enable new drugs to be marketed more cheaply and quickly, § 101 of the 1984 Act amended § 505 of the FDCA, 21 U.S.C. § 355, to authorize abbreviated new drug applications (ANDAs), which would substantially shorten the time and effort needed to obtain marketing approval. An ANDA may be filed for a generic drug that is the same as a so-called "pioneer drug" previously approved, see 21 U.S.C. § 355(j)(2)(A)....
>
> These abbreviated drug-application provisions incorporated an important new mechanism designed to guard against infringement of patents relating to pioneer drugs. Pioneer drug applicants are required to file with the FDA the number and expiration date of any patent which claims the drug that is the subject of the application, or a method of using such drug. See [21 U.S.C.] § 355(b)(1). ANDA's . . . are required to contain one of four certifications with respect to each patent named in the pioneer drug application: (1) "that such patent information has not been filed," (2) "that such patent has expired," (3) "the date on which such patent will expire," or (4) "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." [21 U.S.C.] §§ 355(b)(2)(A), 355(j)(2)(A)(vii).
>
> This certification is significant, in that it determines the date on which approval of an ANDA . . . can be made effective, and hence the date on which commercial marketing may commence. . . . **If the applicant makes the fourth certification,. . .the effective date must depend on the outcome of further events triggered by the Act.** An applicant who makes the fourth certification is required to give notice to the holder of the patent alleged to be invalid or not infringed, stating that an application has been filed seeking approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent, and setting forth a detailed statement of the factual and legal basis for the applicant's

> opinion that the patent is not valid or will not be infringed. See 21 U.S.C. §§ 355(b)(3)(B), 355(j)(2)(B)(ii). Approval of an ANDA . . . containing the fourth certification may become effective immediately only if the patent owner has not initiated a lawsuit for infringement within 45 days of receiving notice of the certification. If the owner brings such a suit, then approval may not be made effective until the court rules that the patent is not infringed or until the expiration of (in general) 30 months, whichever first occurs. See [21 U.S.C.] §§ 355(c)(3)(C), 355(j)(4)(B)(iii).
>
> This scheme will not work, of course, if the holder of the patent pertaining to the pioneer drug is disabled from establishing in court that there has been an act of infringement. And that was precisely the disability that the new 35 U.S.C. § 271(e)(1) imposed with regard to use of his patented invention only for the purpose of obtaining premarketing approval. **Thus, an act of infringement had to be created for these ANDA . . . proceedings. That is what is achieved by § 271(e)(2)-the creation of a highly artificial act of infringement that consists of submitting an ANDA . . . containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent. Not only is the defined act of infringement artificial, so are the specified consequences,** as set forth in subsection (e)(4). Monetary damages are permitted only if there has been "commercial manufacture, use, or sale." [35 U.S.C.] § 271(e)(4)(C). **Quite obviously, the purpose of subsections (e)(2) and (e)(4) is to enable the judicial adjudication upon which the ANDA . . . schemes depend.**

Eli Lilly v. Medtronic, 496 U.S. at 676-678 (emphasis added).

The patent litigation under 35 U.S.C. § 271(e)(2) exists as part of the process put in place to speed entry of generic drugs into the market, without abrogating the branded drug makers' patents. Clearly, the origin of the claim as to the legal fees incurred to make the ¶ IV certification, and to defend the 35 U.S.C § 271(e)(2) litigation, is the ANDA with a ¶ IV certification filed by G to obtain regulatory approval to market and sell its generic drug in the United States prior to the expiration of the patents covering the referenced branded drug Drug B .

Finally, even though G may seek to create an ANDA with a ¶ IV certification for the primary purpose of generating future profits from selling its drug before the patents on Drug B expire, that is not relevant. Nor are the consequences from losing the lawsuit relevant. See Gilmore, 372 U.S. at 49; Woodward, 397 U.S. at 578. Similarly, the fact that the litigation delayed G from obtaining its ANDA with a ¶ IV certification is a consequence of the litigation, with consequences irrelevant under Gilmore and Woodward.

B. Capitalization of Intangible Regulations

1. Overview[185]

It is uncontested that direct costs incurred to obtain approval to market and sell a generic drug must be capitalized. Under § 1.263(a)-4(d)(5)(i), a taxpayer must capitalize amounts paid to a governmental agency to obtain, renew, renegotiate, or upgrade its rights under a license, permit, franchise, or other similar right granted by that governmental agency. A generic drug manufacturer must obtain FDA approval to market and sell its generic drug and must file an ANDA (or NDA) in order to obtain such approval. FDA approval of an ANDA creates for the applicant an intangible identified in § 1.263(a)-4(d)(5)(i). Thus, the application fees incurred in pursuit of FDA approval for an ANDA must be capitalized as part of the acquisition costs for the approval to market and sell a generic drug.

Patent infringement defense costs incurred in the ANDA process are not amounts paid directly to the FDA to obtain a right to market and sell. If the costs are to be capitalized, it is because they are "transaction costs" that facilitate the acquisition or creation of a right to market or sell under § 1.263(a)-4(d)(5)(i). The facilitation standard under § 1.263(a)-4(e)(1)(i) is intentionally broad in scope (all costs paid in the process of investigating or otherwise pursuing the transaction), as is the definition of "transaction" (all of the factual elements comprising an acquisition or creation of an intangible, including a series of steps carried out as part of a single plan). Pursuit of a transaction does not require the successful completion of a transaction; it merely requires a taxpayer to attempt to gain or accomplish the transaction.

Under the statutory scheme established by the Hatch-Waxman Act, resolution of the patent claims is an integral step in the process of pursuing FDA approval of an ANDA with a ¶ IV certification. An applicant must certify not only that the generic drug is biologically equivalent to one or more drugs for which a patent exists, but that the patent is (or patents are) invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the application is submitted. As part of this certification process, the applicant must provide notice to the drug patent holder that an ANDA with a ¶ IV certification has been filed and, if the drug patent holder files an infringement suit against the ANDA applicant within 45 days of the ANDA ¶ IV notice, the FDA is prohibited from approving the ANDA for 30 months. Further, the effective date of FDA approval becomes dependent on how the patent infringement litigation is resolved and the nature of any court order. See 35 U.S.C. § 271(e)(4) and 21 U.S.C. § 355(j)(5)(B)(iii). Even if a patent infringement suit is filed after the 45-day window has expired, the effective date of FDA approval may still be altered if the ANDA applicant loses the patent infringement case. See Mylan Labs v. Thompson, 389 F.3d 1272 (D.C. Cir. 2004). The effective date of FDA approval is therefore dependent on

[185] Section from 2014 GLAM.

the outcome of any patent infringement litigation that arises as a direct result of the filing of an ANDA with a ¶ IV certification.

The infringement suit pursuant to an ANDA with a ¶ IV certification is so integral to the process by which generic drug manufacturers obtain approval to market and sell a generic version of a drug that the litigation costs to defend the suit are incurred "in the process of pursuing" such approval. A patent infringement suit following an ANDA with a ¶ IV certification is distinguishable from the typical non-ANDA patent infringement suits brought outside of the Hatch-Waxman framework. The deemed act of infringement created by filing an ANDA with a ¶ IV certification is uniquely designed to permit patent issues to be resolved without actual acts of infringement (*e.g.*, manufacturing, using, or selling) that are generally required in order for infringement to exist, and the outcome of that patent resolution can affect the rights the FDA will grant to the applicant (*e.g.*, the date of FDA approval; a potential 180-day exclusivity period). Under the Hatch-Waxman Act, the two events, the filing of an ANDA with a ¶ IV certification and the defense of the patent infringement suit, are elements of a unified statutory scheme for obtaining FDA approval to market and sell a generic drug.

2. Specifics of Regulatory Provisions

Treas. Reg. § 1.263(a)-4 identifies the categories of intangibles that must be capitalized as follows:

> (b) Capitalization with respect to intangibles--(1) In general. Except as otherwise provided in this section, a taxpayer must capitalize--
>
> (i) An amount paid to acquire an intangible (see paragraph (c) of this section)[[186]];
>
> (ii) An amount paid to create an intangible described in paragraph (d) of this section;
>
> (iii) An amount paid to create or enhance a separate and distinct intangible asset within the meaning of paragraph (b)(3) of this section;
>
> (iv) An amount paid to create or enhance a future benefit identified in published guidance in the Federal Register or in the Internal Revenue Bulletin (see § 601.601(d)(2)(ii) of

[186] To be an acquired intangible, the taxpayer must have acquired the intangible in a "purchase or similar transaction." Treas. Reg. § 1.263(a)-4(c)(1). While "purchase or similar transaction" is not defined in the regulations, reading the -4 regulations as a whole, the regulatory scheme would treat the ANDAs at issue as created, not acquired, because the ANDAs were not acquired from another for consideration.

this chapter) as an intangible for which capitalization is required under this section; [187] and

(v) An amount paid to facilitate (within the meaning of paragraph (e)(1) of this section) an acquisition or creation of an intangible described in paragraph (b)(1)(i), (ii), (iii) or (iv) of this section.

Treas. Reg. § 1.263(a)-4(b)(1).

Thus, the regulations require capitalization of expenditures that are within the categories identified in Treas. Reg. § 1.263(a)-4(b)(1) (*i.e.,* amounts paid to acquire or create an intangible, amounts paid to create or enhance a separate and distinct intangible and amounts paid to facilitate an acquisition or the creation of an intangible, if within the subsections cross-referenced by Treas. Reg. § 1.263(a)-4(b)(1)) and not specifically exempted from capitalization.

These identified categories of expenditures are construed broadly to comply with the regulatory regime of capitalization reflected in the regulations. T.D. 9107, 2004-1 C.B. 447, § II. D. The legal fees incurred to defend actions for patent infringement pursuant to 35 U.S.C. § 271(e)(2) for filing an ANDA with a ¶ IV certification are within one or more of the identified categories of expenditures that must be capitalized. The amounts were paid to create intangible assets and/or paid to create or enhance separate and distinct intangibles, or to facilitate the creation of an intangible.

a. Amounts Paid to Create an Intangible or Facilitate the Creation of an Intangible

Treas. Reg. § 1.263(a)-4(d) (hereinafter the "-4(d) regulations") addresses the treatment of created intangibles, with other sections of the intangible regulations addressing the treatment of amounts paid to facilitate the creation of an intangible. As explained further below, amounts paid to obtain an ANDA with a ¶ IV certification are paid to create intangibles within the meaning of Treas. Reg. § 1.263(a)-4(d), with the legal fees at issue paid to facilitate the creation of G's ANDA with a ¶ IV certification.

Treas. Reg. § 1.263(a)-4(d)(5)(i) requires the capitalization of amounts paid to obtain rights from a government, treating such payments as being paid to create an intangible. Specifically, Treas. Reg. § 1.263(a)-4(d)(5)(i)(emphasis added) provides, inter alia:

> In general. – A taxpayer must capitalize amounts paid to a governmental agency **to obtain**, renew, renegotiate, or upgrade its rights under a

[187] To date, no guidance has been published requiring the capitalization of expenditures with respect to intangibles that must be capitalized based solely on future benefit.

> trademark, trade name, copyright, **license, permit, franchise, or other similar right granted by that governmental agency**.

Payments to the FDA (a government agency) to obtain the right to market and sell a new drug in the United States (obtained via FDA approval of a NDA or an ANDA, as addressed above) would be within Treas. Reg. § 1.263(a)-4(d)(5)(i). See § III.A., below (While an ANDA fits within more than one category of assets listed in Treas. Reg. § 1.263(a)-4(d)(5)(i), an ANDA as a franchise is addressed with specificity in the cost recovery advice).

Legal fees that facilitate the creation of the ANDA are also required to be capitalized. Treas. Reg. § 1.263(a)-4(b)(1)(v). The scope of the word "facilitate" as used in Treas. Reg. § 1.263(a)-4 is described in Treas. Reg. § 1.263(a)-4(e)(1)(i), which states:

> Except as otherwise provided in this section, an amount is paid to facilitate the acquisition or creation of an intangible (**the transaction**) if the amount is paid in the process of investigating or **otherwise pursuing the transaction**. 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. An amount paid to determine the value or price of an intangible is an amount paid in the process of investigating or otherwise pursuing the transaction.

Treas. Reg. § 1.263(a)-4(e)(1)(i) (emphasis added).

The term "transaction," as used above, is also clearly defined in the regulations, as follows:

> (3) Transaction. For purposes of this section, **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**. Thus, a transaction can involve more than one invoice and more than one intangible. For example, a purchase of intangibles under one purchase agreement constitutes a single transaction, notwithstanding the fact that the acquisition involves multiple intangibles and the amounts paid to facilitate the acquisition are capable of being allocated. . . .

Treas. Reg. § 1.263(a)-4(e)(3)(emphasis added).

Collectively, the two above-quoted regulations and the other portions of Treas. Reg. § 1.263(a)-4(e) are referred to herein as the "-4(e) regulations."

The costs of defending the lawsuits at issue would be considered facilitative under the -4(e) regulations. The costs were incurred "in the process" or "otherwise pursuing" not simply FDA approval of ANDAs, but FDA approval of an ANDA with a ¶I V certification – a right to market and sell a generic drug before the expiration of the patents covering the referenced branded drug, and, by filing early, possibly with a 180-day (6-month) exclusivity period.

The entire patent litigation takes place within a framework created by the FDA regulations, which unequivocally confer standing[188] on the patent holder, and require that the applicant for an ANDA with a ¶ IV certification advise the patent holder of the filing of an ANDA with a ¶ IV certification application. Because the legal fees were incurred in taking one of the customary or expected steps in the process of acquiring an ANDA with a ¶ IV certification, *i.e.*, defending a lawsuit brought pursuant to the artificial act of infringement of filing an ANDA with a ¶ IV certification with the FDA, the fees are costs paid in otherwise pursuing the transaction. Accordingly, the legal fees facilitate creation of an intangible asset and must be capitalized.

To the extent G argues that its fees did not facilitate obtaining an ANDA with a ¶ IV certification because G did not need to defend itself if it filed a different type of ANDA and G could have commercialized its generic drugs after the 30-month stay expired regardless of the outcome of the lawsuits, G errs for, among other reasons, the following reasons:

First, such an argument fails to acknowledge that G was not merely seeking FDA approval of an ANDA; G was seeking to obtain an ANDA with a ¶ IV certification to market and sell its generic version of Drug B prior to the patents on Drug B expiring and, if it did win the proverbial "race to the court-house steps", market and sell the generic version without competition from other generic drugs for six months. The actions (steps) that G took that gave rise to the fees at issue were all part of the required process – a single transaction under Treas. Reg. § 1.263(a)- 4(e)(3), which provides that for purposes of Treas. Reg. § 1.263(a)-4 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."

Second, while it is true that "but for" filing an ANDA with a ¶ IV certification (*e.g.*, if G, *instead, had* filed an ANDA with a ¶ III certification), G would not have incurred the fees at issue, that says nothing about what G did do, or the fact G did incur the legal fees at issue. The fees must be capitalized just because they facilitated the creation of a new capital asset. See American Stores Co. v. Commissioner, 114 T.C. 458, 473 (2000) (holding that legal fees incurred in defending against anti-trust had their origin in the taxpayer's acquisition transaction). Moreover, the result of a "but for" test in this situation is not dispositive. Treas. Reg. § 1.263(a)-4(e)(1)(i) specifically states that "[i]n

[188] We have no opinion on whether standing would exist otherwise. The point is merely that the litigation is part of the ANDA application process.

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." Thus, even if G's argument was well-taken, which it is not, that would not resolve the issue.

Third, any argument that the litigation fees at issue were not necessary to create an ANDA, so they do not have to be capitalized, is meritless. If costs are incurred to pay for a reasonable step taken in pursuit of the intangible, here an ANDA with a ¶ IV certification, they are part of the series of steps that comprise the transaction described in Treas. Reg. § 1.263(a)-4(e)(3), and must be capitalized. For example, the buyer of a warehouse to hold inventory need not obtain an appraisal of the warehouse before purchasing it. But if the buyer does get an appraisal in order to determine the amount of money it is willing to pay for the warehouse, then the cost of the appraisal must be added to the cost of acquiring the warehouse and capitalized. In the present case, the defense of the infringement lawsuits predictably prompted by the filing of a ¶ IV certification ANDA are steps customarily taken by seekers of intangible rights obtained through the ANDA process, and thus must be capitalized.

The two events, the filing of an ANDA with a ¶ IV certification and the defense of the patent infringement lawsuit, cannot be separated because they are a part of a series of steps described in Treas. Reg. § 1.263(a)-4(e)(3) undertaken in the pursuit of a single plan to create an intangible. Because the attorneys' fees incurred by G were directly associated with, and were incurred in pursuit of, the intangibles sought, the fees facilitate the creation of the intangible and must be capitalized under I.R.C. § 263(a).

Accordingly, based on the facts and circumstances, the fees facilitated the creation of an ANDA with a ¶ IV certification. Therefore, the attorney fees G incurred that are the subject of this advice must be capitalized because they were incurred to facilitate G obtaining the FDA-approved ANDA with a ¶ IV certification that would grant the right to market and sell G's generic version of Drug B in the United States before the patents on Drug B expired. See also Treas. Reg. § 1.263(a)-4(e)(5), Example 3.

b. Amounts Paid to Create or Enhance a Separate and Distinct Intangible

The capitalization of intangibles regulations provide that amounts paid to create or enhance a separate and distinct intangible must be capitalized. Treas. Reg. § 1.263(a)-4(b)(1)(iii). Treas. Reg. § 1.263(a)-4(b)(3)(i) defines separate and distinct asset, as follows:

> The term separate and distinct intangible asset means a property interest of ascertainable and measurable value in money's worth that is subject to protection under applicable State, Federal or foreign law and the possession and control of which **is intrinsically capable of being sold, transferred or pledged** (ignoring any restrictions imposed on

> assignability) **separate and apart from a trade or business**. . . . The determination of whether a payment creates a separate and distinct intangible asset is made based on all of the facts and circumstances existing during the taxable year in which the payment is made.

Treas. Reg. § 1.263(a)-4(b)(3)(i)(emphasis added).

ANDAs are within the definition of separate and distinct intangible assets. ANDAs can be transferred from the sponsor (original applicant) to another, separate and apart from a trade or business. 21 C.F.R. § 314.72(a). ANDAs are subject to protection under Federal law. For example, when an ANDA holder has 180 days of exclusivity, federal law precludes any other generic for the referenced NDA from being approved during the period of exclusivity. 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2014). An entire profitable industry, the generic pharmaceutical industry, has evolved around the value of ANDAs.[189] While it would take an expert, the expected stream of income from each ANDA could be projected and then valued at its net present value. Accordingly, each ANDA is a separate and distinct asset. Treas. Reg. § 1.263(a)-4(b)(1)(v) provides "[a]n amount paid to facilitate . . . creation of an intangible described in paragraph (b)(1). . . . (iii) . . . of this section" must be capitalized. The legal fees paid to enhance or facilitate the creation of these separate and distinct assets must be capitalized. Treas. Reg. §§ 1.263(a)-4(b)(1)(v) and -4(b)(3)(i).

c. Treas. Reg. §1.263(a)-4(f)(1) 12 Month Rule

If G is awarded 180 days of exclusivity for its generic version of Drug B, the 180-day period of exclusivity would not be within the 12 month rule of Treas. Reg. § 1.263(a)-4(f) because the exclusivity was obtained as part of one transaction to obtain FDA approval of an ANDA with a ¶ IV certification, notwithstanding the fact the 180 days of exclusivity can be separately sold. See Facts § 2.B., above (180-day period can be separately transferred through a waiver).

The steps that must be followed to obtain an FDA-approved ANDA with a ¶ IV certification effective before the patents on Drug B expire must be followed whether or not 180 days of exclusivity is awarded, with the 180 days of exclusivity automatically awarded to the "first applicant" to file a substantially complete ANDA, as described in

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[189] See Generic Pharmaceutical Association, The Industry, http://www.gphaonline.org/about/the-industry/ ("It wasn't until passage of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as Hatch-Waxman, that the generic industry truly blossomed. This landmark law created the regulatory mechanism under which the Food and Drug Administration can approve affordable pharmaceuticals. . . .

Over nearly three decades, President Reagan's prediction has proven to be true. The generic industry has grown dramatically and use of generic drugs has saved the U.S. health care system approximately $1.07 trillion over the past decade alone (2002 through Year Eight) with $192.8 billion in savings achieved in Year Eight alone. From a modest beginning, today nearly 80% of all prescriptions are filled with generic medicines.)(last viewed July 14, 2015).

more detail in the Facts, § 2, above. Thus, none of the fees can be separately allocated to the 180 days of exclusivity since the fees are incurred for the ANDA with a ¶ IV certification, with or without the 180 days of exclusivity. The period of exclusivity was intended by Congress to be an incentive to file ANDAs with ¶ IV certifications (see Facts, § 2.B., above), not an asset that requires separate payments to the FDA or additional steps separate and apart from the steps to obtain the ANDA with a ¶ IV certification. No separate payments or steps are required to be awarded the 180 days of exclusivity; rather, the exclusivity period is generally awarded to the first to file a substantially complete ANDA ¶ IV.

The fact that the 180 days of exclusivity can be separately transferred, apart from the ANDA, does not allow the costs, if any, for the 180 days of exclusivity to be exempt from capitalization under the 12 month rule. The primary reason is that the ANDA with a ¶ IV certification and its 180 days of exclusivity constitute one transaction. See Treas. Reg. § 1.263(a)-4(e) (quoted and discussed).

Alternatively, the benefits of the 180-day period are not limited to the first 180 days; the benefits have an indefinite duration since G would have garnered market share in the 180 days that had lingering effect, and may have become the generic drug stocked by pharmacies, which provides continuing benefits to G. If the 180 days of exclusivity is transferred by G, G would presumably obtain consideration commensurate with the continuing benefit that was transferred, whether paid as a lump sum, over a period of years, or as a percentage of the future sales. Thus, whether retained or transferred, Treas. Reg. § 1.263(a)-4(f)(4) would apply to make the 12 month rule inapplicable to the 180 days of exclusivity since the benefits of the 180 day exclusivity period have an indefinite duration.

> Paragraph (f)(1) of this section does not apply to amounts paid to create (or facilitate the creation of) an intangible of indefinite duration. A right has an indefinite duration if it has no period of duration fixed by agreement or by law, or if it is not based on a period of time, such as a right attributable to an agreement to provide or receive a fixed amount of goods or services. For example, a license granted by a governmental agency that permits the taxpayer to operate a business conveys a right of indefinite duration if the license may be revoked only upon the taxpayer's violation of the terms of the license.

Treas. Reg. § 1.263(a)-4(f)(4)(emphasis added).

Accordingly, the 12 month rule would not be applicable to the 180-day period of exclusivity since the ANDA with a ¶ IV certification, along with any exclusivity awarded, is a single transaction. Treas. Reg. § 1.263(a)-4(e)(3). Alternatively, the 12-month rule would not apply because the benefit of the 180 days of exclusivity has an indefinite duration. Treas. Reg. § 1.263(a)-4(f)(4). However, for the alternative position, if the fact

that exclusivity technically ends after 180 days trumps the fact that the benefits extend indefinitely, G would still not be entitled to any deduction until G established the amount, if any, of the legal fees could be allocated solely to the 180 days of exclusivity.

3. Urquhart Does Not Apply to the Legal Fees at Issue.

G contends that Urquhart v. Commissioner, 215 F.2d 17 (3d Cir. 1954), establishes that fees to defend patent infringement suits are *per se* deductible, so that the fees G incurred must be deductible. However, Urquhart was decided prior to significant Supreme Court decisions on capitalization and the origin of the claim, as well as prior to enactment of the capitalization of intangible regulations.

In addition, Urquhart was a participant in a joint venture engaged in the business of exploiting and licensing patents. The legal fees at issue in Urquhart were incurred to defend a lawsuit filed against Urquhart seeking a declaratory judgment that the patents at issue in Urguhart were invalid and that plaintiff's apparatus and methods did not infringe upon those patents. The legal expenses were found to be deductible because the suit arose out of, and was directly related to, the exploitation of taxpayer's patent rights: "Since the Urquharts were engaged in the business of exploiting and licensing patents, we are the more clear that the litigation expenses were incurred to prevent (and recover) damage to their business, that is, to protect, conserve and maintain their business profits." Urquhart, 215 F.2d 17, 20.

In this case, the parties to the 35 U.S.C. §271(e)(2) litigation are in the business of producing brand name and generic drugs, and the fees at issue were incurred in connection with the larger process of creating an intangible asset, an ANDA with a ¶ IV certification. Unlike Urquhart, the focus in G's litigation cases is not on damages or the recovery of lost profits. Accordingly, Urquhart is distinguishable.

Urquhart did not address capitalization of legal fees incurred to create new assets; it addressed legal fees incurred to protect profits that were being generated from existing patent licenses. G was not sued for lost profits due to infringing sales of competing drugs; rather, G was sued because it sought FDA approval to market and sell competing drugs before the expiration of the patents covering Drug B. The lawsuit does not even allege that G commercialized its generic drugs; rather, the suit sought to delay FDA approval until all patents expired. The fact that G notified the soon-to-be plaintiffs that G was seeking FDA approval of ANDA with ¶ IV certifications, as required by law, does not preclude the lawsuits from being all about G obtaining new intangible capital asset to use in its trade or business, with the litigation facilitating the transaction-obtaining an ANDA with a ¶ IV certification. Accordingly, Urquhart does not establish precedent helpful to G's position.

4. Conclusion Re Capitalization[190]

We conclude that the patent defense litigation following the filing of an ANDA with ¶ IV certification originates in a capital transaction: the application for FDA approval to market and sell a generic drug, and that the costs of such litigation facilitate that transaction and must be capitalized under § 1.263(a)-4(e)(1).

Our conclusion is consistent with the underlying purpose of the capitalization rules, which attempt to match expenses with the income generated by those expenses. In filing an ANDA with a ¶ IV certification, an applicant is seeking to obtain the right to market and sell a generic drug in advance of actually manufacturing and selling that drug. All costs the generic drug maker incurs in the process of seeking FDA approval are better matched against the income derived from future sales of a generic drug, sales that cannot commence until after FDA approval is received.

II. REGULATORY FEES

To the extent the legal fees incurred for regulatory matters, e.g. FDA filings, were incurred in the process of creating an FDA-approved ANDA with a ¶ IV certification for G's generic version of Drug B, the reasoning relative to the application of the capitalization of intangible regulation with regard to the litigation fees, is equally applicable to the fees incurred for regulatory services. See Treas. Reg. §§ 1.263(a)-4(l) Example 1(i) and (iv) (In the example, a taxpayer paid its outside counsel $4,000 for legal services relative to regulatory matters, *i.e.*, obtaining a government license to sell alcoholic beverages. The license would last indefinitely as long as the taxpayer complied with the laws relative to the sale of alcoholic beverages. The regulation example explains the fees were paid to facilitate the creation of an intangible). See also Treas. Reg. § 1.263(a)-4(e)(5) Example 3 (payment to outside counsel to negotiate five-year lease facilitated creation of lease).

To the extent legal fees incurred for regulatory matters were incurred for representation before the

to obtain an FDA-approved ANDA with a paragraph IV certification prior to the expiration of the patents listed as covering Drug B in the Orange Book. Accordingly, all of the legal fees incurred with respect to regulatory matters must be capitalized.

III. COST RECOVERY OF CAPITALIZED LEGAL FEES.

Treas. Reg. § 1.263(a)-4(g)(1) provides that "[a]n amount required to be capitalized by this section is not currently deductible under section 162. Instead, the amount generally

[190] Section from 2014 GLAM.

is added to the basis of the intangible acquired or created. See section 1012." The question at hand is how are the fees added to the basis recovered.

A. As franchises, ANDAs are amortizable § 197 Intangibles

The -4(d) regulations addressing created intangibles do not define the term "franchise". However, the term is defined within the capitalization of intangible regulations addressing acquired intangibles. "Franchise" for purpose of acquired intangibles has the same meaning the term is given in Treas. Reg. § 1.197-2(b)(10). See Treas. Reg. § 1.263(a)-4(c)(1)(viii). Specifically, Treas. Reg. § 1.197-2(b)(10) states that a "franchise has the meaning given in [I.R.C.] § 1253(b)(1) and includes any agreement that provides one of the parties to the agreement with the right to distribute, sell, or provide goods, services, or facilities, within a specified area." Section 1253(b)(1) defines a franchise to include "an agreement which gives one of the parties to the agreement the right to distribute, sell, or provide goods, services, or facilities, within a specified area." G's ANDA with a ¶ IV certification fits neatly into the § 1253(b)(1) definition of a franchise since the ANDA would give G the right to market and sell its ANDA products within the United States, a territory that encompasses the entire country. Courts have noted that Congress provided an "expansive definition" of franchise to "include" agreements to sell or distribute goods within a specified area, which does not exclude other things otherwise within the meaning of a franchise. See, *e.g.*, Jefferson-Pilot Corp. v. Commissioner, 98 T.C. 435, 441 (1992), aff'd 995 F.2d 530 (4th Cir. 1993) (FCC licenses are agreements "between the Federal Government and the licensee under which the licensee agrees to provide the service of radio broadcasting within a specified area in exchange for the right to broadcast." Id. at 443). See also, Jefferson-Pilot Corp. v. Commissioner, 995 F. 2d 530 at 531 (4th Cir. 1993) ("The definition of 'franchise' is sufficiently broad to include licenses issued by the FCC.").

That the right to market and sell came from the FDA, not the Federal Communications Commission (FCC), is a distinction without a difference – both the FDA and FCC are granting, for a territory, commercialization rights. See 21 C.F.R. § 314.80 (2009), (post-marketing reporting of adverse drug experiences, enumerating the quality controls and other restrictions imposed on the holder of an ANDA[191] to retain the rights to market and sell, with the controls similar in nature to the "strings" a franchiser would retain over its franchise, *e.g.,* quality controls). In addition, the identified categories of expenditures that must be capitalized are construed broadly, and not limited by narrow technical arguments. T.D. 9107, 2004-1 C.B. 447, § II. D. Accordingly, FDA-approved ANDAs that allow the marketing and selling of new drugs in the United States are franchises within the meaning of Treas. Reg. § 1.263(a)-4(d)(5)(i).

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[191] Except as provided in paragraph (b) of this section, "[e]ach applicant having an approved abbreviated new drug application under § 314.94 that is effective shall comply with the requirements of § 314.80 regarding the reporting and recordkeeping of adverse drug experiences.

"Each applicant must make the reports required under § 314.81 and section 505(k) of the [Act] for each of its approved abbreviated applications." 21 C.F.R. § 314.98 (a) and (b).

The first inquiry is whether ANDAs are amortizable section 197 intangibles. Specifically, the regulations provide as follows:

> Section 197 allows an amortization deduction for the capitalized costs of an **amortizable section 197 intangible** and **prohibits** any other depreciation or amortization with respect to that property.

Treas. Reg. § 1.197-2(a)(emphasis added).

As opined above, an ANDA granted by the FDA is a franchise for purposes of the Treas. Reg. § 1.263(a)-4(d) regulations. For the same reasons, an ANDA is also a section 197 intangible. An approved ANDA provides the applicant (or current holder) a right granted by the FDA to sell specific generic pharmaceutical products in the territory of the United States, subject to complying with the reporting requirements of the FDA, which are in the nature of quality controls a franchisor would typically have over a franchisee (reporting, investigatory and production requirements imposed on an ANDA holder). Thus ANDAs satisfy the I.R.C. § 1253(b)(1) definition because ANDAs are agreements which provide a taxpayer with the right to distribute and sell a specific product (generic pharmaceuticals) within a specific area (the United States). Because the FDA is a governmental unit that approves the right to sell, market, and distribute drugs subject to ANDAs, an approved ANDA also meets the definition of a franchise under Treas. Reg. § 1.197-2(b)(10). Accordingly, for the reasons stated above, an FDA-approved ANDA is a section 197 intangible.

I.R.C. § 197(c)(1) defines "[a]mortizable section 197 intangible," stating:

> Except as otherwise provided in this section, the term "amortizable section 197 intangible" means any section 197 intangible—
>
> (A) which is acquired by the taxpayer after the date of the enactment of this section [August 10, 1993], and
>
> (B) which is held in connection with the conduct of a trade or business or an activity described in section 212.

In Broz [II] v. Commissioner, 137 T.C. 46 (2011), [192] aff'd 727 F. 3d 621 (6th Cir. 2013), the Tax Court addressed the interpretation of the "in connection with the conduct of a trade or business" requirement set forth in I.R.C. § 197(c)(1)(B). In that case, the taxpayer contended that an FCC license could be amortized upon acquisition, regardless of whether the entity holding the FCC licenses had commenced a trade or business. The Commissioner contended the FCC license could not be amortized until

[192] Broz [I] v. Commissioner, 137 T.C. 25 (2011), aff'd, 727 F. 3d 621 (6th Cir. 2013), decided other issues of first impression.

commencement of a trade or business to which the license related. The Tax Court found for the Commissioner, interpreting the phrase "in connection with the conduct of a trade or business" in § 197(c)(1)(B) as follows:

> The inclusion of the word "conduct" indicates to us that the intangibles must be used in connection with a business that is being conducted. We find, therefore, that section 197 contains an active trade or business requirement similar to the requirement imposed by section 162.

Broz [II] v. Commissioner, 137 T.C. at 69 (footnote omitted).

The Broz [II] Court then found that, because the entity holding the FCC license was not engaged in an active trade or business, the entity was not entitled to any amortization deductions for the FCC license.

The facts of this case clearly establish that G was engaged in the trade or business of developing, producing, marketing and selling generic drugs prior to incurring the attorney fees at issue in order to market and sell generic drugs,

Therefore, unless otherwise excluded from being an amortizable § 197 intangible, G's ANDA with a ¶ IV certification will qualify as an amortizable § 197 Intangible.

I.R.C. § 197 excludes certain self-created intangibles from the category of amortizable §197 intangibles, stating:

> The term "amortizable section 197 intangible" shall not include any section 197 intangible—
>
> (A) which is not described in subparagraph (D), (E), or (F) of subsection (d)(1), and
> (B) which is created by the taxpayer.

I.R.C. § 197(c)(2)(emphasis added).

Pursuant to I.R.C. § 197(c)(2), amortizable § 197 intangibles **do include** self-created intangibles described in § 197(d)(1)(D) (relating to licenses, permits or other rights granted by a government unit), § 197(d)(1)(E) (relating to covenant not to complete) or § 197(d)(1)(F)(relating to franchises, trademarks, and trade names). For example, costs incurred relative to a franchise or a government-granted right **are not excepted** from the amortizable § 197 category because franchises are excepted from the self-

created exception by § 197(d)(1)(F) and government-granted rights are excepted from the self-created exception by § 197(d)(1)(E).[193]

Treas. Reg. § 1.197-2(d)(2) reiterates the statute and clarifies the status of created intangibles, stating:

> Except as provided in paragraph (d)(2)(iii) of this section, amortizable section 197 intangibles do not include any section 197 intangible created by the taxpayer (a self-created intangible).

Treas. Reg. § 1.197-2(d)(2)(iii) confirms franchises are not excluded from amortizable section 197 intangibles, citing I.R.C. § 197(d)(1)(F).

As discussed above, an approved ANDA is a government granted franchise within both I.R.C. § 197(d)(1)(F) and Treas. Reg. § 1.197-2(b)(10). The self-created exception only applies to any section 197 intangible ***NOT*** described in I.R.C. § 197(d)(1)(D), (E), and (F). Therefore, the exception provided in I.R.C. § 197(c)(2) is inapplicable to FDA-approved ANDAs. Accordingly, FDA-approved ANDAs are amortizable section 197 intangibles.

The Internal Revenue Code ("Code") provides a taxpayer shall be entitled to an amortization deduction with respect to any amortizable section 197 intangible. I.R.C. § 197(a). The Code further provides that the amount of such deduction shall be determined by amortizing the adjusted basis of such intangible ratably over the "15-year period beginning with the month in which such intangible was acquired." Id; see Frontier Chevrolet Company v. Commissioner, 329 F.3d 1131 (9th Cir. 2003) (an amortizable section 197 intangible must use the 15-year period for amortization, not some other life that the taxpayer asserts.)

The Treasury Regulations further elaborate on the computation of the amortization deduction by providing:

> [T]he amortization deduction allowable under section 197(a) is computed as follows:
>
> (i) The basis of an amortizable section 197 intangible is amortized ratably over the 15-year period beginning on the later of—
>
> (A) The first day of the month in which the property is acquired; or

[193] While I.R.C. § 197(c)(2) does not apply if the intangible is created in connection with a transaction (or a series of transactions) involving the acquisition of assets constituting a trade or business or substantial portion thereof, there was no purchase of a trade or business by G in this case. Further, because G created, rather than acquired, its franchises, Treas. Reg. § 1.197-2(e)(2) does not impact the treatment of G's ANDA as amortizable section 197 intangibles.

(B) In the case of property held in connection with the conduct of a trade or business or in an activity described in section 212, the first day of the month in which the conduct of the trade or business or the activity begins.

Treas. Reg. § 1.197-2(f)(1)(i).

An FDA-approved ANDA is acquired for purposes of I.R.C. § 197 on the effective date of the final FDA approval, provided all applicable exclusionary periods have expired. *e.g.*, the effective date is not subject to a condition precedent such as the expiration of the period of exclusivity barring the ANDA holder from immediately commencing marketing and selling of the drugs the subject of the ANDA in the United States. ANDAs are treated as acquired on said date because that is the date the holder of an ANDA can begin to market and sell the generic drugs that are the subject of the ANDA in the United States.

Applying the rule set forth in Treas. Reg. § 1.197-2(f)(1) to the matter at hand, G's 15-year amortization period for recovering the attorney fees associated with its ANDA would begin the first day of the month in which the FDA finally approves the ANDA as effective with no exclusionary periods barring the immediate marketing and selling of drug the subject of the ANDA, since that is the later date of when G enters into a trade or business or when the amortizable § 197 intangibles are acquired.

Accordingly, all capitalized attorney fees relative to an ANDA would be placed into suspense (along with other expenditures for the ANDA that are not within I.R.C. § 174) until the ANDA is amortizable.

B. **ANDAs as other Government-Granted Rights that are not Franchises**

As stated above, an ANDA fits one or more of the non-exclusive list of types of government-granted rights that are treated as created intangibles, *e.g.*, "license, permit, franchise or other similar right granted by that governmental agency" within Treas. Reg. § 1.263(a)-4(d)(5). Thus, ANDAs constitute licenses and other similar government granted rights, with franchises just one of the government granted rights that an ANDA falls within for purposes of capitalization pursuant to I.R.C. § 263.

Treas. Reg. § 1.197-2(d)(2)(iii) and I.R.C. § 197(c)(2) do not exclude licenses, permits or other rights granted by a governmental unit from amortizable section 197 intangibles. Thus, as government granted rights other than franchises, ANDAs are still amortizable section 197 Intangibles. Accordingly, ANDAs as other government granted rights would be amortized just as would franchises, with treatment as other government-granted rights an alternative position for purposes of determining cost recovery issues.

IV. SECTION 263A APPLICABILITY TO THE ANNUAL COST RECOVERY DEDUCTIONS

Once G commences production of generic Drug B, the annual cost recovery of the capitalized attorney fees will be subject to I.R.C. § 263A.

Treas. Reg. § 1.263A-2(a)(3) requires that indirect production costs properly allocable to property produced be capitalized. Treas. Reg. § 1.263A-1(e)(3)(i) provides that indirect costs are properly allocable to property produced when the costs directly benefit or are incurred by reason of the performance of production activities. Treas. Reg. § 1.263A-1(e)(3)(ii) provides examples of indirect costs that must be capitalized to the extent they are properly allocable to property produced. One example in Treas. Reg. § 1.263A-1(e)(3)(ii)(I) is cost recovery, including depreciation, amortization, and cost recovery allowances on equipment and facilities (including depreciation or amortization of self-constructed assets or other previously produced or acquired property to which I.R.C. § 263A or I.R.C. § 263 applies). Another example in particular, found at Treas. Reg. § 1.263A-1(e)(3)(ii)(U), emphasizes how the otherwise deductible portion (*e.g.,* amortization) of the initial fees incurred to obtain a license or franchise and any minimum annual payments and royalties that are incurred by a licensee or a franchisee ought to be capitalized.

Obtaining FDA approval of the generic drugs and complying with FDA manufacturing guidelines are incident and necessary for G's drug manufacturing operations. Further, G's generic drug would not be produced if it could not be marketed and sold. Thus, the ANDA directly benefits, and/or was obtained to enable, the production of the generic drug and the annual cost recovery (amortization or depreciation) is an indirect cost that is properly allocable to the generic drugs and must be capitalized. Treas. Reg. § 1.263A-1(e)(3)(i). Accordingly, G's annual cost recovery for its ANDA must be capitalized pursuant to the uniform capitalization rules of I.R.C. § 263A.

V. CAPITALIZING LEGAL FEES INCURRED TO OBTAIN AN ANDA CONSTITUTES A CHANGE IN METHOD OF ACCOUNTING UNDER I.R.C. § 446 WITH § 481 REQUIRING A § 481(A) ADJUSTMENT

A change in method of accounting includes a change in the treatment of any material item used in an overall method of accounting. A "material item" includes "any item that involves the proper time for the inclusion of the item in income or the taking of a deduction." Treas. Reg. § 1.446-1(e)(2)(ii)(a). In determining whether timing is involved, generally the pertinent inquiry is whether the accounting practice permanently affects the taxpayer's lifetime income or merely changes the taxable year in which taxable income is reported.[194] An accounting practice that involves the timing of when

[194] See Treas. Reg. § 1.481-1(a)(1); Treas. Reg. § 1.446-1(e)(2)(ii)(a); Graff Chevrolet v. Campbell, 343 F.2d 568, 570-571 (5th Cir. 1965); Knight-Ridder Newspapers, Inc. v. United States, 743 F.2d 781, 798 (11th Cir. 1984); Peoples Bank & Trust v. Commissioner, 415 F.2d 1341, 1344 (7th Cir. 1969); Primo

an item is included in income or when it is deducted is considered a method of accounting. General Motors Corp. v. Commissioner, 112 T.C. 270, 296 (Year One); Color Arts, Inc. v. Commissioner, T.C. Memo. 2003-95.

Under the foregoing principles, a change from deducting an expense when paid or incurred to capitalizing such expense, or vice versa, generally constitutes a change in method of accounting. Expensing and capitalization generally result in the same cumulative taxable income over the lifetime of the taxpayer. For example, an expenditure of $1,000 that is deducted in full when it is paid or incurred reduces a taxpayer's lifetime taxable income by $1,000. If the same expenditure is capitalized, taxpayer's lifetime taxable income will also be reduced by $1,000 through deductions for depreciation or amortization, recognition of basis resulting in a reduction of gain (or an increase of loss) on sale or disposition of the asset, or a combination of the foregoing.

Treating changes between expensing and capitalization as changes in method of accounting is supported by Treas. Reg. § 1.446-1(e)(2)(ii)(*d*)(*2*), which provides that "a correction to require depreciation or amortization in lieu of a deduction for the cost of depreciable or amortizable assets that had been consistently treated as an expense in the year of purchase, or vice versa, is a change in method of accounting." [195]

The treatment of G's attorney fees incurred to obtain an ANDA with a ¶ IV certification as either deductible or capitalizable is a "material item" used in G's overall plan of accounting because such treatment involves the proper time for taking deductions for such attorney fees. Further, such treatment does not permanently affect G's lifetime income. Accordingly, the change in the treatment of G's attorney fees at issue from immediately deductible to capitalizable is a change in a material item used in G's overall plan of accounting for gross income and deductions.[196] Thus, it constitutes a change in

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Pants Co. v. Commissioner, 78 T.C. 705, 723 (1982); Rev. Proc. 97-27, 1997-1 C.B. 680, § 2.01(1); Rev. Proc. 2002-9, 2002-1 C.B. 327, § 2.01(1); and Rev. Proc. 91-31,1991-1 C.B. 566, § 3.02.

[195] See also Exxon Mobil v. Commissioner, 114 T.C. 293, 321-323 (2000) (change in treatment of 'dismantlement, removal and restoration costs' from deduction when work is performed to capitalization constituted accounting method change); Pelaez and Sons, Inc. v. Commissioner, 114 T.C. 473, 487-489 (2000), aff'd 253 F.3d 711 (11th Cir. 2001) (change in treatment of preproductive citrus growing costs from deduction to capitalization); FPL Group, Inc. v. Commissioner, 115 T.C. 554 (2000) (change in treatment of asset costs from capitalizing and depreciating to deducting when incurred constituted accounting method change); Sunoco, Inc. v. Commissioner, T.C. Memo. 2004-29 (change in treatment of miner's 'overburden removal costs' from developmental costs (spread as deductions) to production costs (included in cost of goods sold) constituted a change in method of accounting); and Southern Pacific Transportation Co. v. Commissioner, 75 T.C. 497, 680-687 (1980), supplemented by 82 T.C. 122 (1984) (change in treatment of certain railway maintenance expenses from capitalization into embankments to deduction as work is performed constitutes a change in method of accounting).

[196] See Treas. Reg. § 1.481-1(a)(1); Graff Chevrolet v. Campbell, 343 F.2d 568, 570-571 (5th Cir. 1965); Knight-Ridder v. United States, 743 F.2d at 798; Peoples Bank & Trust v. Commissioner, 415 F.2d at 1344; Ryan v. Commissioner, 42 T.C. 386, 392 (1964).

method of accounting under Treas. Reg. § 1.446-1(e)(2)(ii)(a). Accordingly, the Commissioner may change G's method of accounting for attorney fees relative to its ANDA for Drug B.

Section 446(b) provides that if no method of accounting has been regularly used by the taxpayer, or if the method used does not clearly reflect income, the computation of taxable income shall be made under such method as, in the opinion of the Secretary, does clearly reflect income. See also Treas. Reg. § 1.446-1(b)(1). The Commissioner has broad discretion in determining whether a taxpayer's method of accounting clearly reflects income, and the Commissioner's determination must be upheld unless it is clearly unlawful.[197] Once the Commissioner has determined that the taxpayer's method of accounting does not clearly reflect income, the Commissioner has broad discretion in selecting a method of accounting that the Commissioner believes properly reflects the income of a taxpayer. The Commissioner's selection may be challenged only upon showing an abuse of discretion by the Commissioner.[198]

An examining agent who determines that a taxpayer's method of accounting is impermissible may propose an adjustment with respect to that method only by changing the taxpayer's method of accounting. Except as provided in section 2.06 of Rev. Proc. 2002-18, 2002-1 C.B. 678 (relating to previous accounting method changes made by a taxpayer without obtaining the requisite consent under section 446(e)), an examining agent changing a taxpayer's method of accounting will select a new method of accounting by properly applying the law to the facts determined by the agent. The method selected must be a proper method of accounting and will not be a method contrived to reflect the hazards of litigation. See Rev. Proc. 2002-18, 2002-1 C.B. 678, sections 3.01, 5.01 to 5.03.

An examining agent changing a taxpayer's method of accounting will make the change in a year under examination. Ordinarily, the change will be made in the earliest taxable year under examination, or, if later, the first taxable year the method is considered to be impermissible, although an examining agent may defer the year of change to a later taxable year in appropriate circumstances. An examining agent will not defer the year of change in order to reflect the hazards of litigation. Moreover, an examining agent will not defer the year of change to later than the most recent year under examination. See Rev. Proc. 2002-18, 2002-1 C.B. 678, section 5.04(1).

An examining agent changing a taxpayer's method of accounting ordinarily will impose a § 481(a) adjustment, subject to a computation of tax under § 481(b) (if applicable). The § 481(a) adjustment, whether positive or negative, will be taken into account entirely in

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[197] See Thor Power Tool Co. v. Commissioner, 439 U.S. 522, 532-3 (1979); RCA Corp. v. United States, 664 F.2d 881, 886 (2nd Cir. 1981), cert. denied 457 U.S. 1133 (1982).

[198] See Wilkinson-Beane, Inc. v. Commissioner, 420 F.2d 352 (1st Cir. 1970); Stephens Marine, Inc. v. Commissioner, 430 F.2d 679, 686 (9th Cir. 1970); Standard Paving Co. v. Commissioner, 190 F.2d 330, 332 (10th Cir.), cert. denied, 342 U.S. 860 (1951).

the year of change. See § 1.448-1T(c)(3); Rev. Proc. 2002-18, 2002-1 C.B. 678, section 5.04(2), (3). Section 481(a) provides that in computing the taxpayer's taxable income for any taxable year (year of change), if such computation is under a method of accounting different from the method under which the taxpayer's taxable income for the preceding taxable year was computed, then there shall be taken into account those adjustments which are determined to be necessary solely by reason of the change in order to prevent amounts from being duplicated or omitted, except there shall not be taken into account any adjustment in respect of any taxable year to which this section does not apply unless the adjustment is attributable to a change in the method of accounting initiated by the taxpayer. See also Treas. Reg. § 1.448-1T(a).

Once the Commissioner has imposed a change in method of accounting, the application of § 481(a) to such change is mandatory.[199] An adjustment under § 481(a) can include amounts attributable to taxable years that are closed by the statute of limitations.[200] Because a change in treatment of attorney fees of an ANDA is an accounting method change, the Service may propose adjustments to G's treatments of attorney fees for its legal fees only by imposing an involuntary method change to a proper method of accounting and imposing an adjustment under § 481(a). Accordingly, the Service should impose accounting method changes and a § 481(a) adjustment for the change in method pursuant to the terms of Rev. Proc. 2002-18.

The Year Five-initiated lawsuit commenced in February of Year Five. The litigation filings provided by G disclose that, as of , Year Six (Year Six is the first year under audit), G had already incurred over dollars in litigation fees.[201] To the extent these fees, and any other legal fees relative to G's actions (steps) to obtain an FDA-approved ANDA with a ¶ IV certification for Drug B were deducted in Year Four and Year Five, the aggregate amount of these fees would constitute the § 481 adjustment.[202] See Treas. Reg. § 1.263(a)-4(p)(3)(§ 481(a) adjustment computed taking into account amounts accrued on or after December 31, 2003). Since Year Six is the first year under examination, the § 481(a) adjustment would be included in G's Year Six income.

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[199] Primo Pants Co. v. Commissioner, 78 T.C. 705, 720 (1982); Emert v. Commissioner, T.C. Memo. 1999-175, aff'd 249 F. 3d 1130 (9th Cir. 2001); Hitachi Sales Corp. of America v. Commissioner, T.C. Memo. 1994-159, supp. T.C. Memo. 1995-84.

[200] Suzy's Zoo v. Commissioner, 114 T.C. 1, 12-13 (2000), aff'd 273 F.3d 875, 884 (9th Cir. 2001); Huffman v. Commissioner, 126 T.C. 322, 341-2 (2006), aff'd 518 F.3d 357, 363-4 (6th Cir. 2008); Graff Chevrolet Co., 343 F.2d at 571-572; Rankin v. Commissioner, 138 F.3d 1286, 1288 (9th Cir. 1998); Superior Coach of Florida v. Commissioner, 80 T.C. 895, 912 (1983); Weiss v. Commissioner, 395 F.2d 500 (10th Cir. 1968); Spang Industries, Inc. v. United States, 6 Cl. Ct. 38, 46 (1984), rev'd on other grounds 791 F.2d 906 (Fed. Cir. 1986).

[201]

[202] While the § 481(a) adjustment is not limited to fees incurred in Year Five, and can include prior years, the only pre-Year Six fees disclosed to date were in Year Five.

CASE DEVELOPMENT, HAZARDS AND OTHER CONSIDERATIONS

[redacted]

A. **Amount of § 481(a) adjustment**

[redacted]

B. [redacted] **claims**

[redacted]

[redacted]

[redacted]

[redacted] 203

[redacted] 204

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203 [redacted].

204 [redacted].

[redacted]

[redacted]

C. **Abandonment of ANDA**

[redacted]

D. **Limitations on Opinion**

Please be aware that this legal memorandum is limited to opining on the NOPA proposal to capitalize the legal fees incurred in Year Six and Year Seven relative to Drug B, the cost recovery of said fees, and advising that an I.R.C. § 481(a) adjustment be proposed. No opinions are expressed relative to any other aspects of G's Year Six and Year Seven tax returns or any actions thereafter.

E. **Disclosure**

This writing may contain privileged information. Any unauthorized disclosure of this writing may undermine our ability to protect the privileged information. If disclosure is determined to be necessary, please contact this office for our views.
Please call (312) 368-8730 if you have any further questions.

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