**Office of Chief Counsel**
**Internal Revenue Service**
# Memorandum

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to: Technical Advisor
(Pharmaceuticals and Biotech)

from: Industry Counsel (Pharmaceuticals and Biotech)
Large Business & International

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subject: Cost Recovery of Capitalized Attorney Fees Incurred to Defend Against Patent Infringement Claims and to Investigate Patents.

On September 14, 2011, a memorandum with the subject line "Attorney Fees Incurred to Defend Against Patent Infringement Claims and to Investigate Patents" was issued to you, hereinafter referred to as the September 14, 2011 Memorandum. The September 14, 2011 Memorandum opined that attorney fees incurred to defend actions for patent infringement pursuant to 35 U.S.C. § 271(e)(2) for submitting Abbreviated New Drug Applications (ANDAs) to the Food and Drug Administration (FDA) seeking to market and sell generic drugs before the expirations of the listed patents must be capitalized. The September 14, 2011 Memorandum also opined that the investigatory patent research fees must be capitalized. The questions relative to the cost recovery of the capitalized attorney fees were reserved.

This memorandum responds to your request for assistance on the cost recovery of the capitalized attorney fees. This advice may not be used or cited as precedent.

LEGEND

Corporation X =

Entity Y =
Entity Z =
ANDA One =
ANDA Two =
ANDA Three =

License Y =
License Z =
Drug #3 =
Drug #4 =

ISSUES

1. Whether the cost recovery of capitalized attorney fees incurred by Corporation X when investigating patents and defending against infringement suits to obtain FDA-approved ANDA One must be suspended until the ANDA is amortizable and, if so, when is an ANDA amortizable.

2. When ANDA infringement litigation settles with the ANDA holder receiving a license, whether the cost recovery of capitalized attorney fees incurred when investigating patents and defending against infringement suits should be capitalized to the license obtained in settlement of the ANDA infringement litigation.

3. Whether the annual cost recovery of attorney fees capitalized to ANDAs and licenses are subject to I.R.C. § 263A.

CONCLUSIONS

1. As franchises, FDA-approved ANDAs are amortizable I.R.C. § 197 intangibles, that are amortizable ratably over a 15-year period beginning on the first day of the month the FDA-approved ANDA is acquired, provided all applicable exclusionary periods have expired and provided that the trade or business requirement of § 197 is met. Section 197 prohibits amortizable § 197 intangibles from being depreciated or amortized under any other provision, with treating ANDA One as a franchise for cost recovery purposes the primary position. Alternately, as government-granted rights within Treas. Reg. § 1.263(a)-4(d)(5)(i), rights granted pursuant to ANDAs are licenses or other similar government-granted rights within the meaning of I.R.C § 197(d)(1)(D), with the cost recovery the same as for franchises.

2. When ANDA infringement litigation settlements result in the plaintiffs granting the ANDA holders licenses to market and sell the drugs the subject of the ANDAs, the fees incurred to investigate the patents and to defend against the infringement suits would be capitalized to the basis of the licenses and suspended until the licenses are amortizable or depreciable. If the licenses are for the use of § 197 intangibles, the attorney fees would be recovered pursuant to § 197. Until provided with sufficient facts and copies of the license agreements, no further opinion can be provided on the cost recovery of the attorney fees

capitalized to the licenses. Because Corporation X declined to provide sufficient facts and copies of the licenses, Corporation X has failed to substantiate that it is entitled to commence cost recovery of the capitalized fees that relate to the drugs marketed and sold pursuant to the licenses.

3. The annual cost recovery of the attorney fees capitalized to ANDAs and licenses are subject to § 263A.

FACTS

The facts are the same as set forth in the September 14, 2011 Memorandum.

LAW AND ANALYSIS[1]

The September 14, 2011 Memorandum, in applying the origin of the claim test, opined as follows:

> Based on the facts and circumstances of this case it is clear that the infringement litigation originated from Corporation X's actions to obtain assets, FDA-approved ANDAs, which can be sold or used in its trade or business until such time, if ever, the FDA withdraws its approval of the ANDAs. . . . Accordingly, the character of the claims is capital since all claims are proximately related to, and have a direct nexus with, Corporation X's actions to obtain new assets, *i.e.*, FDA-approved ANDAs with paragraph IV certifications.

September 14, 2011 Memorandum, page 37 (footnote omitted).

The September 14, 2011 Memorandum also opined that the attorney fees incurred to investigate the listed patents[2] must be capitalized, as follows:

> The transactions at issue in this case, which generated the fees at issue, arose from Corporation X's filing of ANDAs with paragraph IV certifications to obtain FDA-approved ANDAs allowing Corporation X to market and sell generic pharmaceuticals in the territory of the United States prior to the expiration of the United States patents for the referenced NDA-approved drugs. Corporation X was pursuing obtaining each ANDA as part of one overall transaction for FDA

[1] The September 14, 2011 Memorandum is incorporated herein by reference. Selective quotations from the advice in the September 14, 2011 Memorandum should not be construed as modifying or departing from the advice contained therein, with the advice in the September 14, 2011 Memorandum confirmed and restated by this incorporation.

[2] Listed patents are defined in the September 14, 2001 Memorandum, Addendum A.

> approval of each ANDA to be able to market and sell the new drugs the subject of each ANDA in the United States (*e.g.*, license, permit, franchise or similar right to market and sell its generic drugs in the United States). On an ANDA-by-ANDA basis Corporation X was seeking to obtain FDA-approved ANDAs by carrying out the series of steps required by the statutory and regulatory regime to obtain approval of its ANDAs. The steps included notifying the NDA holders and patentees of the filing of an ANDA with a paragraph IV certification, with that certification necessitating outside counsels to research the patents. Once the NDA holders and patentees filed suit, Corporation X had to defend itself to obtain FDA approval of an ANDA effective before the expiration of the patents. Accordingly, the professional fees incurred in researching the paragraph IV certifications and infringement litigation defense fees were incurred to facilitate obtaining governmental-granted rights and thus must be capitalized.

September 14, 2011 Memorandum, pages 42-43 (emphasis added).

In applying the capitalization of intangible regulations, the September 14, 2011 Memorandum opined that ANDAs fit one or more of the categories of intangibles that are treated as created intangibles pursuant to Treas. Reg. § 1.263(a)-4(d). The September 14, 2011 Memorandum further opined that, as created intangibles, ANDAs are within Treas. Reg. § 1.263(a)-4(d)(5)(i) requiring capitalization of amounts paid to a government agency to obtain rights granted by that governmental agency, stating as follows:

> [A]n 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."

September 14, 2011 Memorandum, page 41.

The September 14, 2011 Memorandum also opined with respect to Treas. Reg. § 1.263(a)-4(d)(5)(i) that, while neither the fees to defend against the infringement litigation nor the fees to investigate the patents were paid to the FDA, the attorney fees "that are the subject of this advice must be capitalized because they were incurred to facilitate, directly or indirectly" obtaining ANDAs. September 14, 2011 Memorandum, page 44. The September 14, 2011 Memorandum further opined that the attorney fees incurred by Corporation X were capitalizable because they were paid to create or enhance separate and distinct intangibles and/or to facilitate the creation or enhancement of separate and distinct intangibles.[3]

[3] ANDAs are within the definition of separate and distinct intangible assets.

Accordingly, the September 14, 2011 Memorandum opined that whether the attorney fees at issue are incurred to facilitate, directly or indirectly, the creation of a government-granted right within Treas. Reg. § 1.263(a)-4(d)(5)(i) and/or incurred to create or enhance a separate and distinct intangible pursuant to Treas. Reg. §§ 1.263(a)-4(b)(1)(v) and -4(b)(3)(i), or facilitate such, the attorney fees incurred by Corporation X that are the subject of the September 14, 2011 Memorandum must be capitalized.

## COST RECOVERY ISSUES

### SECTION I. FDA-APPROVED ANDA One

For FDA-approved ANDA One, the attorney fees incurred relative to ANDA One should be added to the basis of the ANDA One because the costs were incurred with respect to that ANDA.

> An amount required to be capitalized by [Treas. Reg. §1.263(a)-4] is not currently deductible under section 162. Instead, the amount generally is added to the basis of the intangible acquired or created. See section 1012.

Treas. Reg. § 1.263(a)-4(g)(1).

All capitalized attorney fees relative to ANDA One would be suspended (along with other expenditures for the ANDA that are not within I.R.C. § 174) until the ANDA is amortizable or depreciable.

#### A. ANDAs as Franchises

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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)(iii)(IV)(2010). An entire profitable industry, the generic pharmaceutical industry, has evolved around the value of the ANDAs. 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 with the professional fees paid to enhance or facilitate the creation of these separate and distinct assets capitalized. Treas. Reg. §§ 1.263(a)-4(b)(1)(v) and -4(b)(3)(i).

September 14, 2011 Memorandum, pages 44-45 (footnote omitted).

The September 14, 2011 Memorandum pointed out the following as an example to illustrate that ANDAs are within the non-exclusive list of types of government-granted rights in Treas. Reg. § 1.263(a)-4(d)(5)(i), and are government granted franchises.

> While the -4(d) regulations addressing created intangibles do not define the term "franchise," 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). Treas. Reg. § 1.263(a)-4(c)(1)(viii). 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." Treas. Reg. § 1.197-2(b)(10). 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."
>
> Corporation X's ANDAs fit neatly into the I.R.C. § 1253(b)(1) definition since the ANDAs give Corporation X 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, 443 (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"). See also, Jefferson-Pilot Corp. v. Commissioner, 995 F. 2d 530 at 531 (4th Cir. 1993) ("The definition of term '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 also Addendum A, [attached to the September 14, 2011 Memorandum] last 3 pages (enumerating the quality controls and other restrictions imposed on the ANDA holder 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).

September 14, 2011 Memorandum, page 41, n. 61.

The question not addressed in the September 14, 2011 Memorandum is whether, as franchises, ANDAs are amortizable § 197 intangibles.

To determine if ANDAs are amortizable § 197 intangibles, the first inquiry is whether ANDAs are § 197 intangibles and the second inquiry is whether ANDAs are amortizable § 197 intangibles. If ANDAs are amortizable § 197 intangibles, § 197 prohibits any other depreciation or amortization with respect to the ANDAs.

> 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)(1) (emphasis added).

1. As Franchises, ANDAs are § 197 Intangibles

I.R.C. § 197(d) defines what constitutes a "section 197 intangible" and provides generally, *inter alia*, that a § 197 intangible includes any franchise and any license, permit, or other right granted by a governmental unit or an agency. The corresponding Treasury Regulations elaborate on what a franchise is for purposes of I.R.C. § 197(d), including when a government granted right is a franchise, as follows:

> Section 197 intangibles include any franchise, trademark, or trade name. The term franchise has the meaning given in section 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… A license, permit, or other right granted by a governmental unit is a franchise if it otherwise meets the definition of a franchise. A trademark or trade name includes any trademark or trade name arising under statute or applicable common law, and any similar right granted by contract. The renewal of a franchise, trademark, or trade name is treated as an acquisition of the franchise, trademark, or trade name.

Treas. Reg. § 1.197-2(b)(10) (emphasis added).

I.R.C. § 1253(b)(1) provides the term "franchise" includes 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. This is the same code section relied upon for the definition of franchise by the § 263 regulations.[4]

As opined in the September 14, 2011 Memorandum, 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 § 197 intangible. An approved ANDA provides the applicant (or current holder)[5] 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 franchise. See September 14, 2011 Memorandum, Addendum A, last 3 pages (reporting, investigatory and production requirements imposed on an ANDA holder). See also Jefferson-Pilot Corp. v. Commissioner, 98 T.C. 435 at 443 (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") and Jefferson-Pilot Corp. v. Commissioner, 995 F. 2d 530 at 531 (4th Cir. 993) ("The definition of 'franchise' is sufficiently broad to include licenses issued by the FCC."). Thus ANDAs satisfy the § 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 the 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 § 197 intangible.

2. As Franchises, ANDAs are Amortizable § 197 Intangibles

I.R.C. § 197(c)(1) defines "amortizable 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

[4] Treas. Reg. § 1.263(a)-4(c)(1)(viii) provides that "franchise" has the same meaning that the term is given in Treas. Reg. § 1.197-2(b)(10). 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." Treas. Reg. § 1.197-2(b)(10).

[5] The term "holder" is explained in Addendum A to the September 14, 2011 Memorandum.

> (B) which is held in connection with the conduct of a trade or business or an activity described in section 212.

In Broz v. Commissioner, 137 T.C. No. 5, 2011 WL 3875059 (September 1, 2011) [Broz II],[6] the Tax Court addressed an issue of first impression, the interpretation of the "in connection with a trade or business" requirement in § 197(c)(1)(B). 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 commencement of a trade or business to which the license related. In finding for the Commissioner, the Tax Court interpreted 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.

2011 WL 3875059 at *16 (footnotes omitted).

The Broz II Court 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.

Based on the facts of this case, Corporation X was engaged in the trade or business prior to incurring the attorney fees at issue in order to market and sell generic drugs.

Further, Corporation X held ANDA One in connection with the conduct of its trade or business. Thus, unless otherwise excluded from being an amortizable § 197 intangible, ANDA One will qualify as an amortizable § 197 intangible.

Section 197 excludes certain self-created § 197 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.

[6] Broz v. Commissioner, 137 T.C. No. 3, 2011 WL 2670569 (July 7, 2011) [Broz I] decided other issues of first impression.

I.R.C. § 197(c)(2) (emphasis added).

Pursuant to I.R.C. § 197(c)(2), amortizable § 197 intangibles do include self-created § 197 intangibles within § 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) and § 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 I.R.C. § 197(d)(1)(F) and government-granted rights are excepted from the self-created exception by I.R.C. § 197(d)(1)(E). Furthermore, it is noteworthy that, although 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 Corporation X in this case. Treas. Reg. § 1.197-2(e)(2) provides that, in general, "[t]he acquisition of a franchise . . . constitutes the acquisition of a trade or business or substantial portion thereof." However, because Corporation X created, rather than acquired, its franchise, Treas. Reg. § 1.197-2(e)(2) does not impact the treatment of Corporation X's ANDA One as an amortizable § 197 intangible.

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(d)(2)(iii) confirms franchises are not excluded from amortizable § 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 § 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 ANDA One is an amortizable § 197 intangible.

3. As Franchises, FDA-Approved ANDAs Must Be Amortized Over a 15-Year Period

The Internal Revenue Code (Code) provides a taxpayer shall be entitled to an amortization deduction with respect to any amortizable § 197 intangible. § 197(a). The Code also 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, 1135 (9th Cir. 2003) (an amortizable § 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
>
> (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) (emphasis added). See Broz II, above (the § 197 regulations support the determination that a § 197 intangible cannot be amortized if the trade or business or activity to which it relates has yet to commence).

An FDA-approved ANDA is acquired for purposes of § 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 period of exclusivity barring the ANDA holder from immediately commencing the marketing and selling of the drugs that are the subject of the ANDA in the United States.[7] 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 of Treas. Reg. § 1.197-2(f)(1) to Corporation X, Corporation X's 15-year amortization period for amortizing the attorney fees associated with its FDA-approved ANDA One would begin the first day of the month in which the FDA finally approved the ANDA as effective with no exclusionary periods barring the immediate marketing and selling of a drug that is the subject of the ANDA, since that is the later date of when the Corporation X entered into a trade or business or when the amortizable § 197 intangible was acquired.

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[7] See, September 14, 2011 Memorandum, Addendum A (explanations of exclusionary periods and final approval as opposed to tentative FDA approval).

B. ANDAs as Other Government-Granted Rights that are Not Franchises

The September 14, 2011 Memorandum opined:

> 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 in Addendum A) would be within Treas. Reg. § 1.263(a)-4(d)(5)(i). Specifically, 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."

September 14, 2011 Memorandum, page 41 (footnote omitted).

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 § 263.

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

## SECTION II. ANDA TWO AND ANDA THREE

As stated in the facts, Corporation X commenced marketing and selling Drug #3 and Drug #4 pursuant to a License Y and a License Z, respectively, not pursuant to FDA-approved ANDAs. While the infringement litigation was settled, the origin of the claim test applies to settlements. See 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). See also Commissioner v. Arrowsmith, 193 F.2d 734 (2nd Cir., aff'd, 344 U.S. 6 (1952), petition for rehearing denied 344 U.S. 900 (1952) (doctrine of relation back).

The Anchor Coupling Court stated, in rejecting Anchor Coupling's arguments similar to Corporation X's primary purpose arguments, as follows:

> Further, for deductibility to depend upon subjective considerations encourages schemes of tax avoidance and, as the Supreme Court

> noted in Gilmore, can lead to capricious results and a concomitant lack of uniformity in the application of our tax laws. Finally, as the Court noted in Woodward, a test based upon taxpayer's purpose in defending or settling litigation would encourage resort to 'formalisms and artificial distinctions.'

427 F.2d at 433 (emphasis added).

For Corporation X, the origin of the claim litigated, which gave rise to the attorney fees at issue, was to acquire a capital asset for all the reasons stated in the September 14, 2011 Memorandum. Also, as stated by the Anchor Coupling Court at the close of its opinion:

> The Government offers another argument which we think should be mentioned briefly to further buttress the result we have reached. It argues that the settlement and release received by Anchor in return for its settlement payment created enforceable rights in Anchor which constituted the acquisition of a capital asset. We agree that the transaction can also be viewed in this manner. Thus, if Anchor had completed the proposed sale of its assets by accepting $4,025,000 and then repurchased its assets for $4,625,000, it can hardly be doubted that the $600,000 premium would be included in the new book value of Anchor's assets. The settlement in this case accomplished an identical purpose and should be accompanied by identical tax treatment.

427 F.2d at 434 (citation omitted, emphasis added).

The litigation that gave rise to Corporation X's liability to pay the attorney fees at issue herein originated in the process of acquiring the right to market and sell generic drugs in the United States, with that fact not changed by the settlement. However, Treas. Reg. § 1.197-2(b)(8) providing that government-granted licenses are § 197 intangibles does not apply to the settlement licenses because they are not government granted; the settlement licenses are between Corporation X and the plaintiffs in the infringement actions. While the licenses may grant Corporation X the right to use patented intangibles, Treas. Reg. § 1.197-2(c)(7) provides that "[s]ection 197 intangibles do not include any interest (including an interest as a licensee) in a patent … that is not acquired as part of a purchase of a trade or business." Corporation X did not acquire the settlement licenses as part of the acquisition of a trade or business.

However, Treas. Reg. § 1.197-2(d)(2)(ii)(B) provides (emphasis added):

> Contracts for the use of intangibles. A section 197 intangible is not a self-created intangible to the extent that it results from the entry into (or renewal of) a contract for the use of an existing section 197

> intangible. Thus, for example, the exception for self-created intangibles does not apply to capitalized costs, such as legal and other professional fees, incurred by a licensee in connection with the entry into (or renewal of) a contract for the use of know-how or similar property.

So, to the extent the licenses received in the settlement of the ANDA infringement litigation relative to ANDA Two and in the settlement of the ANDA infringement litigation relative to ANDA Three were for the use of § 197 intangibles as described in Treas. Reg. § 1.197-2(b)(11), the fees are still amortizable pursuant to § 197. However, it is not known whether the licenses were for the use of the plaintiffs' New Drug Applications (NDAs), with the generic drugs Corporation X marketed and sold pursuant to the licenses authorized generics, or merely licenses to use the patents that provided patent exclusivity to the branded drugs that Corporation X's generics mimic.

Since Corporation X commenced marketing its generic drugs pursuant to the licenses when it did not have FDA-approved ANDAs, it is likely the licenses received granted use of the plaintiffs' NDAs. If the licenses were licenses to use NDAs, like ANDAs, the rights under the license may be franchises, licenses or similar rights, or contracts for the use of § 197 intangibles, and as such § 197 intangibles for some or all the reasons ANDAs are such. See Treas. Reg. § 1.197-2(b)(11). As such, NDAs are amortizable § 197 intangibles for some or all the reasons ANDAs are amortizable § 197 intangibles. Therefore the capitalized attorney fees would still be amortized pursuant to § 197, but to the basis of the licenses or other § 197 intangibles obtained in the settlements. Without more information, and copies of the licenses, no opinion can be rendered beyond this limited opinion.[8]

Because Corporation X has declined to provide more information, and copies of the licenses, no opinion can be rendered upon: (1) the length of the recovery period for the attorney fees capitalized relative to the Drug #3 and Drug #4 products, or (2) when such recovery begins to run. Thus, Corporation X has failed to substantiate that it is entitled to commence cost recovery, or the annual allowable amount of cost recovery, of the attorney fees capitalized relative to the Drug #3 and Drug #4 products for any year under consideration.

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[8] For treatment of licenses within the definition of collaboration agreements, see the Coordinated Issue Paper titled "Non Refundable Upfront Fees, Technology Access Fees, Milestone Payments, Royalties and Deferred Income under a Collaboration Agreement," Tax Notes Today, October 18, 2007, 2007 TNT 204-17 ("Collaboration agreements are agreements for joint research, experimentation or development, as well as agreements for the sharing of know-how or patents for the purpose of research, experimentation or development. Collaboration agreements can take the form of a license agreement, an alliance agreement, a co-marketing agreement or a functional equivalent of such.")

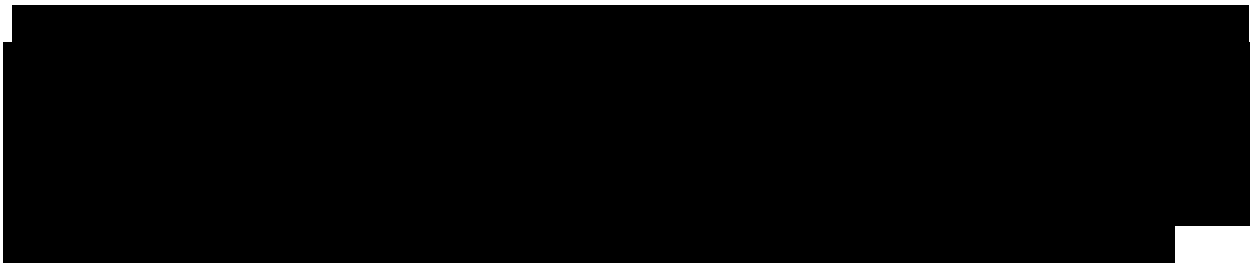
## SECTION III. SECTION 263A APPLIES TO THE ANNUAL DEDUCTIONS

Once Corporation X begins production of drugs for the first commercialization under ANDA One and under the licenses allowing Corporation X to market and sell Drug #3 and Drug #4, Corporation X's annual cost recovery of the capitalized attorney fees is 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. Treas. Reg. § 1.263A-1(e)(3)(ii)(U) provides, as one of example of indirect costs that must be capitalized, 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.

Corporation X's drugs would not be produced if they could not be marketed and sold. Thus, the ANDA and the licenses directly benefit, and/or were obtained to enable, the production of the drugs and the annual cost recovery (*e.g*., amortization) is an indirect cost that is properly allocable to the drugs that Corporation X produces and must be capitalized. Treas. Reg. § 1.263A-1(e)(3)(i). Accordingly, Corporation X's annual cost recovery for ANDA One and the licenses, which are otherwise deductible, are subject to the uniform capitalization rules of § 263A.

In closing, it is pointed out that the September 14, 2011 Memorandum concluded that the attorney fees incurred to investigate listed patents and to defend actions for patent infringement for submitting ANDAs to market and sell generic drugs before the expiration of the listed patents must be capitalized under § 263 for the reasons stated in the September 14, 2011 Memorandum. This memorandum reaches conclusions as to the cost recovery of the capitalized attorney fees, separate and apart from the reasons for capitalization under § 263.

## CASE DEVELOPMENT, HAZARDS AND OTHER CONSIDERATIONS



Please provide a copy of the 30-day letter, when issued, and provide a copy of Corporation X's Protest, if any, when received.

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.

By: _____

Marjory A. Gilbert
Industry Counsel (Pharmaceuticals and Biotech)
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