Office of Chief Counsel
Internal Revenue Service
Memorandum

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subject: Capitalization of Litigation Fees Incurred Relative to
New Drug Applications and Abbreviated New Drug Applications

This memorandum responds to your request for assistance in addressing Corporation X's response to certain proposed adjustments for year 1, year 2, and year 3. This advice may not be used or cited as precedent.

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Corporation X =
Corporation Y =
Entity Y =
Entity Z =
Entity AA =
Entity AB =
Entity AC =
Entity AD =
Entity AE =
Entity AF =

Entity AG =
Entity AH =

Entity AI =
Patent One =
Patent Two =
Patent Three =
Patent Four =
Patent Five =
ANDA One =
Drug #1 =
Drug #2 =
Drug #3 =
Drug #4 =
Drug #5 =
Drug #6 =
Drug #7 =
Drug #8 =
Drug #9 =
Year 1 =
Year 2 =
Year 3 =
Year 4 =
Year 5 =
Year 6 =
Year 7 =
Year 8 =

ISSUES

1. Whether legal fees incurred to obtain Food and Drug Administration ("FDA") approval to market and sell new generic drugs must be capitalized under Treas. Reg. § 1.263-4(d)(1).

2. Whether legal fees incurred to prevent the marketing and sale of a competing generic drug must be capitalized under Treas. Reg. § 1.263(a)-4(d)(9) as protecting and perfecting title to the patents.

3. Whether Urquhart v. Commissioner, 215 F.2d 17 (3rd Cir. 1954), applies to permit an I.R.C. § 162 deduction for any of the legal fees at issue.

4. Whether the cost recovery of capitalized attorney fees incurred to obtain a FDA-approved Abbreviated New Drug Application ("ANDA") must be suspended until the FDA approves the ANDA then recovered pursuant to I.R.C. § 197 on a straight line basis over 15 years.

5. Whether capitalized attorney fees incurred to protect or perfect patents and a FDA-approved New Drug Application ("NDA"):

   A. Are capitalized to the NDA and recovered pursuant to I.R.C. § 197, or capitalized to the patents and recovered under I.R.C. § 167.

   B. Can be recovered immediately over the remaining basis of the applicable asset; and

   C. Are impacted by the fact a license is granted to the generic drug company under the patents that cover the branded drug.

6. When annual cost recovery of the capitalized attorney fees commences, whether the annual amount recovered must be capitalized pursuant to I.R.C. § 263A.

7. For the legal fees incurred with respect to Corporation X's ANDAs and protecting or perfecting patents relating to FDA-approved NDAs:

   A. Whether the Internal Revenue Service ("Service") can change the method of accounting on an ANDA-by-ANDA and patent-by-patent basis and, if so, may the Service defer the year of change for attorney fees for those ANDAs and patents not specifically addressed herein to the next audit cycle.

   B. If the foregoing question is answered in the affirmative, in order to preserve its right to impose Commissioner-initiated changes in the method of accounting in the next audit cycle, whether the Service must provide

written notice that the audit of legal fees relative to ANDAs and patents not specifically addressed herein is being placed in suspense until the next audit cycle at which time the Service intends to initiate a Commissioner-imposed change of method of accounting and I.R.C. § 481(a) adjustments on an ANDA-by-ANDA and patent-by-patent basis.

CONCLUSIONS

1. Legal fees incurred to obtain FDA approval to market and sell new generic drugs must be capitalized pursuant to Treas. Reg. § 1.263-4(d)(1).

2. Legal fees incurred to defend title to patents and prevent the marketing and sale of a competing generic drug must be capitalized to the patents whose validity is at issue pursuant to Treas. Reg. § 1.263(a)-4(d)(9). Fees that are allocable to resolving whether valid patents would be infringed by the generic drug are not required to be capitalized.

3. Urquhart does not apply to the legal fees at issue in this case because they were incurred to obtain FDA approval to market or sell new generic drugs or to defend the exclusivity provided by the patents and not to recover lost profits, and Corporation X is not in the business of patent licensing as was the taxpayer in Urquhart.

4. FDA-approved ANDAs are amortizable Section 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 is met.

5. For the cost recovery of the legal fees incurred to protect both patents and a FDA-approved NDA:

   A. The fees are recovered by (1) dividing the fees pro rata among, and capitalizing these fees into, the basis of the patents, and (2) depreciating the patents under I.R.C. § 167 and Treas. Reg. § 1.167(a)-14(c)(4).

   B. Cost recovery commences beginning with the months in which the legal fees were incurred, with the recovery pro rata over the remaining useful lives of the assets to which the fees are capitalizable.

   C. The NDA holder’s grant of a license under the patents to the defendant generic drug company does not impact the cost recovery of the legal fees.

6. The annual cost recovery of the attorney fees that are capitalized to the ANDAs must also be capitalized pursuant to I.R.C. § 263A.

7. For the legal fees incurred with respect to Corporation X's ANDAs and protecting or perfecting patents relating to FDA-approved NDAs:

   A. The Service can change the method of accounting for attorney fees on an ANDA-by-ANDA and patent-by-patent basis, and the Service may defer the year of change for attorney fees for those ANDAs and patents not specifically addressed herein to the next audit cycle.

   B. In order to preserve its right to initiate changes in the method of accounting in the next audit cycle for attorney fees for the ANDAs and patents not specifically addressed herein, the Service must provide written notice that the audit of such attorney fees is being placed in suspense until the next audit cycle at which time the Service intends to initiate a change in method of accounting for all attorney fees incurred with respect to such ANDAs and patents with Commissioner-initiated I.R.C. § 481(a) adjustments.

FACTS

Corporation X is a pharmaceutical company engaged in developing, manufacturing, marketing, selling and distributing generic and brand name pharmaceutical products. During the fiscal years at issue, Corporation X and its subsidiary, Corporation Y incurred substantial amounts of attorney fees to obtain ANDAs and to protect its NDAs.

A. Marketing and Selling New Pharmaceutical Drugs in the United States

Before Corporation X can market and sell new pioneer drugs[1] in the United States, Corporation X must have FDA-approved NDAs. Similarly, to market generic versions of FDA-approved NDAs in the United States, Corporation X must have FDA-approved ANDAs.

1. NDA and ANDA Procedures and Paragraph IV Certification

In order to market or sell a new pioneer drug in the United States, significant safety and efficacy studies must be completed and a NDA must be submitted to and approved by the FDA. See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(a) (2012). The NDA application is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S. The goals of the NDA are to provide enough information to permit a FDA reviewer to determine whether the drug is safe and effective in its proposed use(s), whether the benefits of the drug

[1] Pioneer drugs refer to drugs "that have never before received FDA approval." FTC v. Watson Pharms., Inc., 677 F.3d 1298, 1302 (11th Cir. 2012), *cert. granted,* 81 U.S.L.W. 3216 (Dec. 07, 2012).

outweigh the risks, whether the drug's proposed labeling (package insert) is appropriate (and what it should contain), and whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.[2] The NDA must disclose all patents that cover the drug, with the NDA holder required to notify the FDA of all new patents that subsequently cover the drug after the filing of the NDA. 21 C.F.R. § 314.53 (2011). If the FDA approves a NDA, "it publishes the drug and patent information in a book called 'Approved Drug Products with Therapeutic Equivalence and Evaluations,' commonly referred to as the 'Orange Book.'" FTC v. Watson Pharms., Inc., 677 F.3d 1298, 1302 (11th Cir. 2012), *cert. granted,* 81 U.S.L.W. 3216 (Dec. 07, 2012).

To market a generic version of an already approved drug, the maker of that generic drug must submit an ANDA to the FDA. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j) (2012). ANDAs are subject to a streamlined process which allows the ANDA applicant to piggyback on the safety and efficacy studies conducted for the pioneer drug, and obtain FDA approval by showing that its generic drug is bioequivalent to a pioneer drug already approved by the FDA. FTC v. Watson Pharms., Inc., 677 F. 3d at 1302. Once approved, the ANDA applicant may manufacture and sell the generic drug.[3]

21 U.S.C. § 355(j)(2)(A)(vii) requires an ANDA applicant to provide certification that the ANDA will not infringe on the patent rights of a third party. The four types of certifications set forth in 21 U.S.C. §§ 355(j)(2)(A)(vii)(I) through (IV) are as follows:

Paragraph I: Certain patent information on the drug has not been filed.

Paragraph II: The original patent has expired.

Paragraph III: The generic drug will not enter the market until the date on which the patent will expire.

Paragraph IV: The applicant believes its product or the use of its product does not infringe on the third party's patents or such patents are not valid or enforceable.

Assuming an ANDA meets all other requirements for FDA approval, an ANDA applicant's certification under paragraph (I) or (II) of 21 U.S.C. § 355(j)(2)(A)(vii) allows

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2 http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm (last visited December 21, 2012).

3 http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/default.htm (last visited December 18, 2012).

the FDA to approve the ANDA immediately. A certification under paragraph III of 21 U.S.C. § 355(j)(2)(A)(vii) means that the FDA "approval may be made effective on the date certified under subclause (III)," which refers to the certified date of patent expiration. 21 U.S.C. § 355(j)(5)(B)(ii).

Where an ANDA applicant relies on a certification under paragraph IV of 21 U.S.C. § 355(j)(2)(A)(vii) (hereinafter referred to as a "paragraph IV certification"), the FDA may approve the ANDA after the following requirements have been met:

- The ANDA applicant provides the required notice to the NDA holder for the referenced drug and all patentees of record for the listed patents that the applicant has filed an ANDA application with a paragraph IV certification (the "paragraph IV notice") within 20 days of being notified by the FDA that the ANDA has been accepted for filing. 21 U.S.C. § 355(j)(2)(B).

- If neither the patent holders nor the NDA holders bring an infringement suit within 45 days from the date of the paragraph IV notice, the FDA may approve the ANDA. 21 U.S.C. § 355(j)(5)(B)(3).

- If a patent holder or NDA holder files a patent infringement lawsuit within 45 days, as set forth in 35 U.S.C. § 271, against the ANDA applicant, a stay generally prevents the FDA from approving the ANDA for 30 months. 21 U.S.C. § 355(j)(5)(B)(3).

- If the court rules on the validity of the patent before the expiration of the 30-month period, the ruling will determine whether the FDA approves the ANDA prior to the thirty months. 21 U.S.C. §§ 355(j)(5)(B)(3)(I) and (II).

- If the patent infringement litigation is still ongoing after the 30 months, the FDA may approve the ANDA, and both parties can market their product.

Therefore, if the NDA holder timely files a lawsuit, the FDA cannot approve the ANDA until the earliest of the following occurs: (1) all patents covering the drug have expired; (2) there is a final determination all patents are invalid or not infringed by a court; or (3) the 30-month stay expires. See Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study, p. 39 (July 2002) (source of paraphrased summation).

2. 180-Day Exclusivity

Federal law encourages drug manufacturers to file ANDAs with paragraph IV certifications by providing a 180-day "exclusivity period" set forth in 21 U.S.C. § 355(j)(5)(B)(iv). See F.T.C. v. Watson Pharms., Inc., 677 F.3d at 1303.

21 U.S.C. § 355(j)(5)(B)(iv) provides that the first generic drug applicant to file an ANDA containing a paragraph IV certification is awarded 180 days of marketing exclusivity. During that time, the FDA may not approve a subsequently filed ANDA that challenges a patent for the same drug product. Only the first ANDA applicant may market or sell the generic product during the 180-day exclusivity period. The 180-day exclusivity period commences on the earlier of: (1) when the generic manufacturer commences commercial marketing; or (2) when a court decision finds the patents have not been infringed or are invalid.

The 180-day exclusivity period provided in 21 U.S.C. § 355(j)(5)(B)(iv) is a significant incentive for an ANDA applicant to file a paragraph IV certification. An ANDA applicant who successfully obtains 180-day exclusivity is able to gain dramatic financial benefits and market share because their generic version of the patented drug is the only one on the market.

B. Fees Incurred with Respect to Certain Lawsuits

The Service plans to issue a revised notice of proposed adjustments (NOPA) to Corporation X, proposing to change Corporation X's method of accounting for the ANDAs and one NDA addressed herein by disallowing deductions for the attorney fees incurred, and requiring the fees be capitalized on an ANDA-by-ANDA and patent-by-patent basis. The Service plans to suspend the audit of the attorney fees incurred for all other ANDAs and NDAs, and to propose Commissioner-initiated changes to Corporation X's method of accounting in the next cycle on an ANDA-by-ANDA and patent-by-patent basis, as discussed further in the Law and Analysis section, below.

The ANDAs and the NDA addressed herein, and the lawsuits relative to said applications that gave rise to the fees that will be the subject of the revised NOPA are addressed below, grouped by the name of the primary third party in the lawsuits. In the first six groups, patent and NDA holders sued Corporation X because Corporation X filed ANDAs with paragraph IV certifications ("ANDA fees"). In the last lawsuit, Corporation X, as an NDA holder, sued an ANDA applicant who filed an ANDA with a paragraph IV certification ("NDA fees").

1. Entity Y v. Corporation X

a. Short Summary Re: Entity Y

Corporation X developed a generic drug to compete with the branded pioneer drug called Drug #1. Entity Y holds the FDA-approved NDA for Drug #1 and owns the patents cited in the Orange Book relative to Drug #1 .

After Corporation X submitted its ANDA requesting FDA approval to sell a generic version of Drug #1 prior to the expiration of the patents covering Drug #1, Entity Y sued Corporation X based on the patents listed in the Orange Book. Entity Y later filed a

second suit against Corporation X
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None of the counts in any of the Entity Y v. Corporation X pleadings alleged lost profits; and none alleged Corporation X commercialized its ANDA product. Rather, pursuant to 35 U.S.C. § 271(e)(2)(A), based on Corporation X's filing an ANDA with a Paragraph IV certification, the parties placed at issue whether Entity Y's patents were valid and, if they were, whether Corporation X infringed those patents. Entity Y requested, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of Corporation X's ANDA be moved back until the last of Entity Y's patents expired. Entity Y's pleadings also requested a declaration pursuant to 28 U.S.C. § 2201 that Corporation X would infringe Entity Y's patents if it commercialized its generic version of Drug #1. Both parties requested relief under 35 U.S.C. § 285, which permits the court to award reasonable attorneys' fees to the prevailing party.

The lawsuits were ongoing as of the end of Year 3, the last year at issue herein. Both cases were decided in Year 5.

For the lawsuits with Entity Y, Corporation X incurred attorneys' fees of $xxx in Year 2 and $xxx in Year 3.

b. FDA Approval and ANDA Product Launch Re: Entity Y

The Service does not know whether the FDA approved Corporation X's ANDA, or whether Corporation X launched its ANDA product.

2. Entity Z v. Corporation X

Corporation X developed a generic drug to compete with the branded pioneer drug called Drug #2. Entity Z is the owner of the NDA for Drug #2 and Entity AA is the owner of Patent One, . After Corporation X submitted its ANDA requesting FDA approval to sell a generic version of Drug #2 prior to the expiration of the patents covering Drug #2, Entity AA and Entity Z sued Corporation X.

None of the counts in any of the Entity AA and Entity Z v. Corporation X pleadings alleged lost profits; and none alleged Corporation X commercialized its ANDA product. Rather, pursuant to 35 U.S.C. § 271(e)(2)(A), based on Corporation X's filing an ANDA with a Paragraph IV certification, the parties placed at issue whether Entity AA's patent was valid and, if it was, whether Corporation X infringed that patent. Entity AA and

Entity Z requested, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of Corporation X's ANDA be moved back until Entity AA's patent expired. Both plaintiffs and Corporation X invoked 35 U.S.C. § 285 and requested attorney fees, costs and expenses of each other.

The case was ongoing as of Year 3, the last year at issue herein. The parties reached a settlement in Year 6

. The Service has not been provided a copy of the settlement agreement.

Corporation X incurred attorneys' fees of $xxx in Year 2 and $xxx in Year 3 for the litigation with Entity AA and Entity Z. The Service does not know whether the FDA has approved Corporation X's ANDA

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3. Entity AB v. Corporation X

Corporation X developed a generic drug to compete with the branded pioneer drug called Drug #3, . Entity AB is the owner of Patent Two, one of the patents cited in the NDA for Drug #3. After Corporation X submitted its ANDA requesting FDA approval to sell a generic version of Drug #3 prior to the expiration of Patent Two, Entity AB sued Corporation X.

None of the counts in any of the pleadings alleged lost profits; and none alleged Corporation X commercialized its ANDA product. Rather, pursuant to 35 U.S.C. § 271(e)(2)(A), based on Corporation X's filing an ANDA with a Paragraph IV certification, the parties placed at issue whether Entity AB's patent was valid and, if it was, whether Corporation X infringed that patent. Entity AB requested, pursuant to § 271(e)(4)(A), that the effective date of Corporation X's ANDA be moved back until Entity AB's patent expired.

The FDA approved Corporation X's ANDA for a generic version of Drug #3 in Year 5. Corporation X incurred attorneys' fees of $xxx in Year 2 and $xxx in Year 3 for its litigation with Entity AB.

4. Entity AC v. Corporation X ( )

Corporation X developed a generic drug to compete with the branded pioneer drug called Drug #4. Entity AC holds the FDA-approved NDA for Drug #4. Entity AD owns Patent Three, a patent cited in the Orange Book relative to Drug #4.

After Corporation X submitted its ANDA requesting FDA approval to sell a generic version of Drug #4 before the expiration of the patents covering Drug #4, Entity AC and Entity AD sued Corporation X based on the patents listed in the Orange Book.

None of the counts in any of the pleadings alleged lost profits; and none alleged Corporation X commercialized its ANDA product. Rather, pursuant to 35 U.S.C. § 271(e)(2)(A), based on Corporation X's filing an ANDA with a Paragraph IV certification, the parties placed at issue whether Entity AC's patents were valid and, if they were, whether Corporation X infringed those patents. Entity AC requested, pursuant to § 271(e)(4)(A), that the effective date of Corporation X's ANDA be moved back until Entity AC's patents expired. Both the plaintiff and Corporation X invoked 35 U.S.C. § 285 and requested attorney fees, costs and expenses of each other.

Corporation X incurred attorneys' fees of $xxx for the Entity AC litigation in Year 3. The lawsuit was ongoing as of the end of Year 3.

5. Entity AF v. Corporation X (three cases)

Entity AF and Corporation X were involved in three lawsuits in Year 2 and Year 3. Corporation X incurred total attorneys' fees of $xxx in Year 2 and $xxx in Year 3 for the three lawsuits. The Service does not have sufficient information to allocate the fees to the individual lawsuits.

a. Entity AF v. Corporation X Civil Action 1
Re: Entity AF's Drug #5

Corporation X developed a generic drug to compete with the branded pioneer drug called Drug #5. Entity AF holds the FDA-approved NDA for Drug #5 and own the patents cited in the Orange Book relative to Drug #5. After Corporation X submitted its ANDA requesting FDA approval to sell a generic version of Drug #5 prior to the expiration of the patents covering Drug #5, Entity AF sued Corporation X based on one of the patents listed in the Orange Book in the NDA for Drug #5.

None of the counts in any of the pleadings alleged lost profits; and none alleged Corporation X commercialized its ANDA product. Rather, pursuant to 35 U.S.C. § 271(e)(2)(A), based on Corporation X's filing an ANDA with a Paragraph IV certification, the parties placed at issue whether Entity AF's patent was valid and, if it

was, whether Corporation X infringed that patent. Entity AF requested, pursuant to § 271(e)(4)(A), that the effective date of Corporation X's ANDA be moved back until Entity AF's patent expired. Entity AF also requested a declaratory judgment pursuant to 28 U.S.C. § 2201, that if Corporation X marketed its generic version of Drug #5 it would infringe Entity AF's patent. Both parties invoked 35 U.S.C. § 285 and requested attorney fees, costs and expenses of each other.

The lawsuit was ongoing as of the end of Year 3.

b. Entity AF v. Corporation X Civil Action No. 2
Re: Entity AF's Drug #6 (Year 2 Suit)

Corporation X developed a generic drug to compete with the branded pioneer drug called Drug #6. Entity AF holds the FDA-approved NDA for Drug #6 and own the patents cited in the Orange Book relative to Drug #6. After Corporation X submitted its ANDA requesting FDA approval to sell a generic version of Drug #6 prior to the expiration of the patents covering Drug #6, Entity AF sued Corporation X

based on Patent Four, one of the patents listed in the Orange Book for Drug #6.

None of the counts in any of the pleadings alleged lost profits; and none alleged Corporation X commercialized its ANDA product. Rather, pursuant to 35 U.S.C. § 271(e)(2)(A), based on Corporation X's filing an ANDA with a Paragraph IV certification, the parties placed at issue whether Entity AF's patent was valid and, if it was, whether Corporation X infringed that patent. Entity AF requested, pursuant to § 271(e)(4)(A), that the effective date of Corporation X's ANDA be moved back until Entity AF's patent expired. Entity AF also requested a declaration pursuant to 28 U.S.C. § 2201 that if Corporation X marketed its generic version of Drug #6 it would infringe Entity AF's patent. Both parties invoked 35 U.S.C. § 285 and requested attorney fees, costs and expenses of each other.

The lawsuit was ongoing as of the end of Year 3.

c. Entity AF v. Corporation X Civil Action No. 3
Re: Entity AF's Drug #6 (Year 1 Suit)

Corporation X developed a generic drug to compete with the branded pioneer drug called Drug #6. Entity AF holds the FDA-approved NDA for Drug #6 and owns the patents cited in the Orange Book relative to Drug #6. After Corporation X submitted its ANDA requesting FDA approval to sell a generic version of Drug #6 prior to the expiration of the patents covering Drug #6, Entity AF sued Corporation X

based on the patents listed in the Orange Book.

None of the counts in any of the Entity AF v. Corporation X pleadings alleged lost profits; and none alleged Corporation X commercialized its ANDA product. Rather, pursuant to 35 U.S.C. § 271(e)(2)(A), based on Corporation X's filing an ANDA with a

Paragraph IV certification, the parties placed at issue whether Entity AF's patents were valid and, if they were, whether Corporation X infringed those patents. Entity AF requested, pursuant to § 271(e)(4)(A), that the effective date of Corporation X's ANDA be moved back until the last of Entity AF's patents expired. Entity AF also requested a declaration pursuant to 28 U.S.C. § 2201 that if Corporation X marketed its generic version of Drug #6 it would infringe Entity AF's patents. Both parties invoked 35 U.S.C. § 285 and requested attorney fees, costs and expenses of each other.

The lawsuit was ongoing as of the end of Year 3.

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d. FDA Approval and Launch Re: Entity AF

The Drug #5 litigation is ongoing. The Service does not know if the FDA approved Corporation X's generic version of Drug #5, or if it was launched. The Drug #6 lawsuits are also ongoing

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6. Entity AH v. Corporation X

a. Short Summary Re: Entity AH

Corporation X developed a generic drug to compete with the branded pioneer drug called Drug #7. Entity AH holds the FDA-approved NDA for Drug #7 and owns Patent Five, one of the patents cited in the Orange Book relative to Drug #7. After Corporation X submitted its ANDA for a generic version of Drug #7, it notified Entity AH of the submission. In response, Entity AH sued Corporation X for filing the ANDA to obtain FDA approval to market and sell its generic drug in competition with Drug #7.

None of the counts in any of the Entity AH v. Corporation X pleadings alleged lost profits; and none alleged Corporation X commercialized its ANDA product. Rather, pursuant to 35 U.S.C. § 271(e)(2)(A), based on Corporation X's filing an ANDA with a Paragraph IV certification, the parties placed at issue whether Entity AH's patent was valid and, if it was, whether Corporation X infringed that patent. Entity AH requested, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of Corporation X's ANDA be moved back until Entity AH's patent expired. Entity AH also requested a declaration pursuant to 28 U.S.C. § 2201 that if Corporation X marketed its generic version of Drug #7 it would infringe Entity AH's patent. Both parties invoked 35 U.S.C. § 285 and requested attorney fees, costs and expenses of each other.

The lawsuit was ongoing as of the end of Year 3.

Corporation X incurred attorneys' fees of $xxx in Year 1 and $xxx in Year 2 on account of Entity AH's lawsuit.

7. Corporation X v Entity AI

Some of the attorney fees at issue in this case were incurred in ANDA litigation regarding the branded drug Drug #8. Drug #8, like other pioneer drugs, cannot be sold in the United States without a FDA-approved NDA. Pharmaceutical companies invest significant time and resources to develop brand name drugs, test them for safety and efficacy, and market them to the public. The FDA approved Corporation X's NDA for Drug #8 in Year 8, and Corporation X began production of the drug.

In Year 2, Entity AI notified Corporation X that Entity AI filed ANDA One with a paragraph IV certification to obtain FDA approval to market and sell a generic version of Drug #8 prior to the expiration of the relevant patents. Entity AI's notice asserted that Corporation X's patents listed in the Orange Book for Drug #8 were invalid, and that the older patents so listed were not infringed.

Within forty five days of the paragraph IV notice, in Year 2, Corporation X sued Entity AI to protect its exclusive right to sell Drug #8 pursuant to the FDA-approved NDA until all patents expired. Corporation X automatically obtained a 30-month stay barring the FDA from approving Entity AI's ANDA

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The complaint did not include any counts that alleged lost profits, and none of the counts alleged Entity AI commercialized its ANDA product. Rather, pursuant to 35 U.S.C. § 271(e)(2)(A), the counts of Corporation X's Complaint and Amended Complaint were all based on Entity AI filing an ANDA with a paragraph IV certification. Corporation X's prayers for relief were limited to (i) requesting a declaration its patents were valid, (ii) requesting that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission of Entity AI's ANDA with a paragraph IV certification be declared an act of infringement, (iii) requesting the court declare Entity AI's ANDA could not be approved earlier than the date the last patent expired, and (iv) requiring Entity AI to amend its ANDA to convert to an ANDA with a paragraph III certification. Protectively, Corporation X requested damages if Entity AI commercialized its ANDA. Both parties invoked 35 U.S.C. § 285 and requested attorney fees, costs and expenses of each other.

The case was settled a year later, in Year 3

Corporation X incurred attorneys' fees of $xxx in Year 2 and $xxx in Year 3 in the Corporation X v. Entity AI litigation.

C. Corporation X's Arguments that the Legal Fees at Issue Are Deductible

1. ANDA Attorney Fees

Corporation X asserts that "[t]he defense fees [it] incurred to defend actions for patent infringement did not facilitate obtaining an ANDA and thus are deductible as ordinary and necessary business expenses under section 162." Corporation X's Year 6 letter in response to the Form 5701 on capitalization of attorney fees ("Corporation X's Position Letter"), p. 4. Corporation X makes three arguments in support of its assertion. First, Corporation X argues that "the defense attorney fees did not have their origin in facilitating the creation of an ANDA" so are not capitalizable. Id. p. 6. Second, Corporation X argues that legal fees are deductible and that Urquhart v. Commissioner, 215 F.2d 17 (3rd. Cir. 1954), establishes that legal fees incurred relative to patent infringement litigation are deductible. Id., p. 4. Third, Corporation X argues "the Service incorrectly analyzes the facilitative test [in Treas. Reg. § 1.263(a)-4(e)]". Id., p. 7.

a. Origin of the Claim

Corporation X argues:

> The origin of the patent infringement litigation is not the filing of an ANDA, but rather the infringement or intent to infringe on another's patent through manufacturing, selling or marketing a generic product.

Id., p. 4.

Corporation X contends that the infringement is "not related to the ANDA submission." Id., p. 6. Corporation X asserts infringement cases "are similar to patent litigation lawsuits before the Hatch-Waxman Act of 1984 . . . . The only difference is in timing. . . ." Id.

Corporation X further contends that

> the approval of an ANDA is *not contingent* on the outcome of any patent infringement litigation. Rather, the ANDA submission is mutually exclusive from the patent infringement litigation. A Taxpayer may lose the patent infringement lawsuit and still receive approval from the FDA for its ANDA

> (albeit with a delayed effective date). Or, the FDA may approve the ANDA after the expiration of the 30-month stay even if the patent infringement litigation is still ongoing and the generic manufacturer has the option of launching the product "at risk" of losing the patent infringement lawsuit.

Id., pp. 7-8.

Corporation X also asserts that the FDA considers only bioequivalence before approving an ANDA with a paragraph IV certification. Thus, it concludes the legal fees cannot facilitate the FDA approval of the ANDA. Id., p. 8.

As further support, Corporation X also argues the origin cannot be the ANDA because that would be the result from looking at the first event in time, in disregard of Boagni v. Commissioner, 59 T.C. 708 (1973), *acq.* 1973-2 C.B. 1, and Santa Fe Pacific Gold Co. and Subsidiaries v. Commissioner, 132 T.C. 240 (2009).

b. Deductibility Notwithstanding the Capital Origin

Corporation X argues that legal fees are generally deductible, relying on Commissioner v. Tellier, 383 U.S. 687 (1965) and Kornhauser v. Commissioner, 276 U.S. 145 (1928). Corporation X asserts that

> as long as legal fees paid in connection with litigation arise out of the operation of a taxpayer's trade or business, they should generally be deductible . . . . See, *e.g.*, Vanderbilt v. Commissioner, T.C. Memo 1957-235, . . . Helvering v. Hampton, 79 F.2d 358 (9th Cir. 1935) . . . .

Id. p. 5.

Corporation X further argues that attorney fees resulting from patent infringement litigation are specifically deductible, relying on Urquhart, supra. Id., p.4.

c. the -4(e) regulation

Corporation X agrees that Treas. Reg. § 1.263(a)-4(e)(1)(I) requires that amounts paid to facilitate the creation of an intangible must be capitalized "if the amount is paid in the process of investigating or otherwise pursuing the transaction." Id., p.6. Corporation X does not address the meaning of "facilitate" in the context of separate and distinct intangibles.

However, Corporation X argues "the Service incorrectly analyzed the facilitative test", by applying a "but for" test. Id., p. 7. Corporation X argues that "because FDA approval of an ANDA is not contingent on the patent infringement litigation, the attorney fees incurred in the litigation process are not facilitative to obtaining the ANDA and are not required to be capitalized under section 263(a)." Id., p. 4.

2. NDA Attorney Fees

Corporation X asserts "The plaintiff attorney fees incurred in the *Corporation X v Entity AI* litigation were not incurred to defend or perfect title to the Taxpayer's patent and thus are deductible as ordinary and necessary expenses under section 162." Id., p. 4.

Corporation X argues the origin of the claim was not capital, but relies primarily on Urquhart. Id., p. 8. Corporation X argues the example in Treas. Reg. § 1.263(a)-4(d)(9)(i) where "U" claimed "R" stole technology from "U" narrows the regulation so that it cannot apply, relying on J.I. Case Co. v. U.S., 91 Ct. Cl. 144 (1940). Corporation X also argues that a claim of invalidity is not a challenge to ownership, again citing Urquhart.

LAW AND ANALYSIS

I.R.C § 162(a) provides, in general, that "[t]here shall be allowed as a deduction all the ordinary and necessary expenses paid or incurred during the taxable year in carrying on any trade of business, . . ." However, I.R.C. § 263(a) provides, in general, that no deduction shall be allowed for any amount paid out for new buildings or for permanent improvements or betterments made to increase the value of any property or estate. Treas. Reg. § 1.263(a)-4 provides rules for determining when costs relating to intangible assets must be capitalized.

Indopco specifically addressed the interplay between the general rules of §§ 162 and 263 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 (1992) (citations omitted, emphasis added).

Based on general capitalization principles articulated in Lincoln Savings and Indopco, capitalization is the norm, with an expenditure that creates an asset or enhances a separate and distinct asset specifically capitalizable. However, an

expenditure may still be capitalizable even if it does not create or enhance a separate and distinct asset.

The treatment of legal fees is determined based upon the nature and character of the underlying claim. Whether the nature and character of an expense related to an intangible asset results in capitalization is determined under Treas. Reg. 1.263(a)-4.

United States v. Gilmore, 372 U.S. 39, 49 (1963), states that "the 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** . . .". (emphasis added). See Deputy v. Dupont, 308 U.S. 488, 494 (1940) ("[I]t is the origin of the liability out of which the expense accrues which is material.")

Under the origin of the claim test, the origin and character of the claims for which legal fees were incurred are examined to determine whether the fees arose from a capital transaction or whether the fees are related to day-to-day business or profit-seeking activities. Woodward v. Commissioner, 397 U.S. 572 (1970). The Woodward Court explained that Gilmore "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, ... " 397 U.S. at 578. The origin of the claim test is an objective inquiry to determine the origin and character of the claim from which the litigation proximately resulted, taking into account all of the facts and circumstances; it is not a test dependent on the formal titles to pleadings.

I. ANDA Applicant Legal Fees

The legal fees at issue originated in Corporation X's actions to create capital assets, FDA-approved ANDAs with paragraph IV certifications to allow Corporation X to market and sell its generic drugs before the expiration of the patents covering the FDA-approved brand name drugs. The ANDA fees at issue originated in Corporation X's attempts to enhance or create separate and distinct intangibles because ANDAs with paragraph IV certifications are separately transferrable. A FDA-approved ANDA with a paragraph IV certification is more valuable than the other types of ANDAs, *e.g.*, an ANDA with a paragraph III certification. ANDAs with paragraph IV certifications that are awarded a 180-day period of exclusivity are more valuable than ANDAs with paragraph IV certifications without such exclusivity. See Addendum A, § 2, attached (addressing the regulatory rules that establish ANDAs and the180-Day exclusivity periods are separately transferrable, and that a 180-day period of exclusivity can provide a return on investment of 1000%).

Corporation X argues such determinations should not be made because the origin of the fees is the litigation, itself, not the creation of new assets. However, this view is not complete. The attorneys' fees spent on litigation are part of a larger process of

Corporation X's pursuit of FDA-approved ANDAs, approval needed to market and sell its generic drugs in the United States. This approval is an intangible asset under the regulations. The fees facilitate the creation of this intangible asset and thus are required to be capitalized.

Corporation X further argues to support its assertion that the origin is the litigation that the only difference between patent infringement suits where plaintiffs seek to recover lost profits and the lawsuits at issue is mere timing, so the origin cannot be Corporation X's actions to obtain new assets. However, timing for generic drugs determines the value the FDA approval brings – the earlier filed the more valuable, especially if Corporation X obtains first filer status so it gets a 180-Day exclusivity award. If timing was not important, Corporation X would have waited rather than incur the fees at issue.

And, while timing is not the only difference between the lawsuits at issue and infringement lawsuits that originate in recovering lost profits, even if timing was the only difference, Corporation X cannot credibly argue timing has no value.

Corporation X asserts Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562 (Fed. Cir. 1997), supports Corporation X's position that the origin is the infringement. Corporation X errs. Glaxo confirms "an action brought under § 271(e)(2)(A) is based solely upon the filing of an ANDA. . . ." 110 F.3d at 1567. In the cases in which Corporation X is pursuing an ANDA, each claim in each lawsuit at issue asserted patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A). Thus, Glaxo supports the Service's position the claims originated in the creation of new ANDAs with paragraph IV certifications.

Corporation X also argues that because the patent holder bears the burden of proving infringement, that such, somehow, changes the origin of the claim analysis as if Corporation X was being sued for lost profits so the fees are deductible. Who bears the burden of proof does not alter the origin of the claim analysis. Moreover, "[w]hile persons challenging the validity of a patent in litigation bear the burden of defeating a presumption of validity, this presumption is intended merely as a procedural devise and is not a substantive right. . . ." In re K-DUR Antitrust Litigation, 686 F.3d 197, 214 (3rd Cir. 2012).

Corporation X argues that, if the 30-month stay expired, it could commercialize its ANDA if approved by the FDA so the origin of its lawsuits cannot be creating ANDAs. That defies reason; Corporation X was seeking FDA approval prior to patent expiration, with delay until patent expiration a bad result. But, the result (consequence) does not impact the origin. Woodward, 397 U.S. at 578.

Corporation X also argues the FDA is not a party to the lawsuits and can approve the ANDAs regardless of the outcomes so that the origin cannot be the ANDA. Corporation X ignores the broader transaction and the other possible outcomes. While it is possible that an ANDA could be granted subject a protracted patent litigation, what is certain is that in every case, under the FDA regulations that apply, once the lawsuits were filed within 45 days, the FDA cannot approve the ANDAs until the 30-month stay is up, subject to the outcome of the litigation. Delaying approval allows the NDA holder to have a longer period of exclusive marketing, and frustrates what Corporation X seeks – immediate entry into the marketplace.

The ANDA fees at issue originate in Corporation X's actions to obtain/create new FDA-approved ANDAs with paragraph IV certifications to use in its business. The next step is to determine whether the fees expended in litigation to pursue creation of an ANDA are an ordinary or capital expense.

Treas. Reg. § 1.263(a)-4(b)(1) 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)[4];
>
> (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 this chapter) as an intangible for which capitalization is required under this section; [5] and

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[4] Amounts paid to acquire intangibles are not addressed herein since the regulations set forth that 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, for example, not acquired from another pharmaceutical company for consideration.

[5] 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.

> (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 (*e.g*., the 12-month rule). 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 ANDAs with paragraph IV certifications 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 ANDAs are paid to create intangibles within the meaning of Treas. Reg. § 1.263(a)-4(d), with the professional fees at issue paid to facilitate the creation of the ANDAs.

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:

> (i) In general. – A taxpayer must capitalize amounts paid to a government agency **to obtain**, renew, renegotiate, or upgrade its rights under a trademark, trade name, copyright, **license, permit, franchise, or other similar right granted by that governmental agency**.

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). Professional 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:

> (e) Transaction costs--(1) Scope of facilitate--(i) In general. 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 unquoted 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" of "otherwise pursuing" not simply FDA approval of ANDAs, but FDA approval of ANDAs with paragraph IV

certifications – a right to market and sell an approved generic drug before the expiration of the patents covering the branded drugs, and by filing early, possibly with a 180-day (six-month) exclusivity period. The entire patent litigation takes place within a framework created by the FDA regulations, which unequivocally confer standing[6] on the patent holder, and require that the ANDA applicant advise the patent holder of the pending ANDA application. Because the legal fees were incurred in taking one of the customary or expected steps in the process of acquiring such ANDAs, *i.e*., defending a lawsuit brought pursuant to the artificial act of infringement of filing an ANDA with a paragraph IV certification with the FDA, the fees are costs paid in otherwise pursuing the transaction. Accordingly, the ANDA fees facilitate creation of an intangible asset and must be capitalized.

Corporation X's Position Letter argues that its fees did not facilitate obtaining ANDAs with paragraph IV certifications because it did not need to defend itself if it filed a different type of ANDA and/or Corporation X could have commercialized its generic drugs after the 30-month stay expired regardless of the outcome of the lawsuits.

First, Corporation X's argument fails to acknowledge that Corporation X was not merely seeking FDA approval of ANDAs; Corporation X was creating/obtaining ANDAs with paragraph IV certifications to market and sell approved generic drug prior to the patents on the branded drugs expiring and, if it did win the proverbial "race to the court-house steps", market and sell the drugs without competition from other generic drugs for six-months. The actions (steps) that Corporation X 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, Corporation X appears to be applying a reverse "but-for" test. Corporation X argues "but for" its paragraph IV certifications, it would not have been sued, so its fees did not facilitate acquiring its ANDAs with paragraph IV certifications. However, Corporation X was trying to obtain ANDAs with paragraph IV certifications. Thus, while it is true that if Corporation X did not obtain new assets it would not incur the cost of obtaining new assets, that says nothing about what Corporation X did do, or the fact Corporation X 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, 471 (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 determining whether an amount is paid to facilitate a transaction, the fact that the amount would (or would not) have been paid

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

but for the transaction is relevant, but is not determinative. Thus, even if the taxpayer's argument was well-taken, it would not resolve the issue.

Third, the argument that the ANDA fees were not necessary to create the intangible, and that therefore 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, they are part of the series of steps that are taken in pursuit of the intangible, 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 paragraph (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 the ANDAs with paragraph IV certifications and the defense of the patent infringement lawsuit, cannot be separated because they were 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 Corporation X 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 ANDAs with paragraph IV certifications. Accordingly, the attorney fees Corporation X incurred that are the subject of this advice must be capitalized because they were incurred to facilitate Corporation X obtaining the FDA-approved ANDAs that granted it the right to market and sell its ANDA products in the United States. 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 intangible 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)(iii)(IV) (2010). An entire profitable industry, the generic pharmaceutical industry, has evolved around the value of ANDAs.[7] 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 "an amount paid to facilitate . . . creation of an intangible described in paragraph (b)(1). . . . (iii) . . . of this section" must be capitalized. Paragraph (b)(1)(iii) of the section addresses amounts "paid to create or enhance a separate or distinct intangible". The legal fees paid to enhance or facilitate the creation of these separate and distinct assets ought to be capitalized. Treas. Reg. §§ 1.263(a)-4(b)(1)(v) and -4(b)(3)(i).

II. NDA Holder Legal Fees

In one instance, Corporation X engaged in ANDA related litigation as the NDA/patent holder. Entity AI sought to obtain FDA-approved ANDAs with paragraph IV certifications to compete with Corporation X's FDA-approved NDA drug. In Corporation X v. Entity AI, Corporation X sued Entity AI to protect its NDA drug by delaying FDA approval of Entity AI's ANDA. While the origin of the claims in Corporation X v. Entity AI is not determined by the results, the relief sought in the litigation sheds light on the origin. In Corporation X v. Entity AI, Corporation X sought to delay the FDA's approval of Entity AI's ANDA until all patents expired, requesting the ANDA be amended to an ANDA with paragraph III certification in lieu of a paragraph IV certification. Corporation X also requested a declaration that Corporation X's patents were valid. Corporation X did not seek lost profits and could not given it relied upon 35 U.S.C. § 271(e)(2)(A), which bars such relief if the generic drug was not commercialized. Entity AI did not commercialize its generic drug.

Entity AI asserted Corporation X's patents did not exclude Entity AI from marketing and selling its generic drugs because the patents were invalid. In substance, Entity AI attacked Corporation X's ownership of the right to exclude Entity AI from marketing and selling. Entity AI's attack on the validity of Corporation X's patents is an attack on the only property interest that patents confer – the right to exclude. It is well established

[7] See generally Generic Pharmaceutical Association Providing Extraordinary Savings for Americans. http://www.gphaonline.org/ (last visited on June 14, 2011)

law that patents are federal statutorily-created monopolies allowing the patent holder to exclude others from using, making or selling. Bloomer v. McQuewan, 55 U.S. 539, 549 (1852) (A patent grants the patentee "the right to exclude everyone from making, using or vending [selling] the thing patented, without the permission of the patentee."). Thus, the origin of the claim in this lawsuit was, from Corporation X's perspective, protecting and perfecting Corporation X's patents.

Treas. Reg. § 1.263(a)-4(d)(9) (the "-4(d)(9) regulation") provides:

> (i) In general. A taxpayer must capitalize amounts paid to another party to defend or perfect title to intangible property if that other party challenges the taxpayer's title to the intangible property.
>
> * * *
>
> (iii) Example. The following example illustrates the rules of this paragraph (d)(9):
>
> Example. Defense of title. R corporation claims to own an exclusive patent on a particular technology. U corporation brings a lawsuit against R, claiming that U is the true owner of the patent and that R stole the technology from U. The sole issue in the suit involves the validity of R's patent. R chooses to settle the suit by paying U $100,000 in exchange for U's release of all future claim to the patent. R's payment to U is an amount paid to defend or perfect title to intangible property under paragraph (d)(9) of this section and must be capitalized.

Of course facilitative costs relating to the defense of title must also be capitalized. Treas. Reg. § 1.263(a)-4(b)(1)(v). Treas. Reg. § 1.263(a)-4(e)(5) Example 6 provides:

> Costs that do not facilitate. X corporation brings a legal action against Y corporation to recover lost profits resulting from Y's alleged infringement of X's copyright. Y does not challenge X's copyright, but argues that it did not infringe upon X's copyright. X pays its outside counsel $ 25,000 for legal services rendered in pursuing the suit against Y. Because X's title to its copyright is not in question, X's action against Y does not involve X's defense or perfection of title to intangible property. Thus, the amount paid to outside counsel does not facilitate the creation of an intangible described in paragraph (d)(9) of this section. Accordingly, X is not required to capitalize its $ 25,000 payment under this section.

The regulations require amounts paid to facilitate the defense of title be capitalized, but this is limited to claims resolving the validity or ownership of the intangible and do not

require that amounts paid to collect lost profits or determine whether intangible property was infringed.

Corporation X argues the -4(d)(9) regulation cannot apply to its NDA fees because the example in the -4(d)(9) regulation is not applicable to the Corporation X v. Entity AI litigation because the ownership of the patent is not disputed. First, the example is just that, an example, which does not limit the -4(d)(9) regulation to that one set of facts. Second, the claims in the Corporation X v Entity AI lawsuit parallel the example in the regulation. Corporation X claimed to own exclusive rights to the inventions the subject of the patents listed in the Orange Book for Drug #8, and Entity AI claimed Corporation X does not own exclusive rights to the inventions the subject of the patents listed in the Orange Book. The fact that Entity AI does not allege Corporation X stole its inventions, is a distinction without a difference since who owns the right to exclude is clearly at issue. Further, unlike the copyright in example Treas. Reg. § 1.263(a)-4(e)(5), Example 6, the validity of Corporation X's patent is the focus of the litigation

The exclusive rights to the inventions the subject of the patents are all the rights the patents can confer. This is because patents are statutorily-granted monopolies that just confer on the patentee the right to exclude others from the unauthorized making, using or selling of an invention. See Bloomer v. McQuewan, 55 U.S. 539, 549 (1852) (A patent grants the patentee "the right to exclude everyone from making, using or vending [selling] the thing patented, without the permission of the patentee."); Waterman v. Mackenzie, 138 U.S. 252, 255 (1891) (in order to sue an infringer the plaintiff must have the exclusive right to make, use, and vend). See also Raymond T. Nimmer and Jeff Dodd, *Modern Licensing Law*, § 9:21 (addressing the concept a nonexclusive license is merely a promise to not sue for using, making or selling a patented invention).

When Entity AI answered Corporation X's Complaint and claimed of Corporation X's patents were invalid, Entity AI was, in essence, alleging Corporation X did not own the right to exclude anyone from using, making or selling the inventions the subject of the patents. Corporation X's Complaint and Amended Complaint alleged to the contrary, claiming Corporation X did own the right to exclude others from using, making and selling. Thus, whether Corporation X owned the rights to exclude conferred by the patents that Entity AI alleged were invalid was clearly placed at issue in Corporation X v Entity AI, and none of the claims of either party alleged Corporation X suffered loss of profits. Indeed, Corporation X could not so allege because Entity AI had not commercialized its generic drug. The infringement statute Corporation X brought the suit pursuant to, 35 U.S.C. § 271(e)(2)(A), does not allow for the recovery of lost profits if the generic drug was not commercialized. Corporation X sought declaratory judgments that all patents were valid, with the counts that requested declaratory judgment confirming that the case is all about whether Corporation X owed the right to exclude others from using, making or selling its patented inventions.

The situation is different for the older patents that Entity AI did not allege were invalid, but did allege were not infringed. Corporation X claimed that the older

patents, which Corporation X acquired by assignment in Year 2,[8] were infringed by Entity AI's generic drug product. Entity AI's Answer claimed that its generic drug did not infringe the older patents, alleging, in essence, that the scope of the claims of the older patents were not broad enough to cover Entity AI's generic drug so Corporation X did not have the right to exclude Entity AI from using, making or selling Entity AI's generic drug. Thus, what was placed at issue was whether Entity AI's generic drug was within the scope of the older patents, *i.e*., did Corporation X own the right to exclude Entity AI from making, using or selling its generic drugs. Given that Corporation X was suing Entity AI pursuant to 35 U.S.C. § 271(e)(2)(A), and Entity AI had not commercialized its generic drug, Corporation X was not seeking lost profits from infringement. What Corporation X was alleging is that its right to exclude was so broad that if Entity AI commercialized it generic drugs Entity AI would infringe. Thus, the costs allocable to determining whether patents are infringed (as opposed to valid) are not required to be capitalized by 1.263(a)-4(d)(9).

Accordingly, the fees relating to defending title to the patents originated in protecting or perfecting title to the patents, the fees originated in a capital transaction and must be capitalized. However, the fees relating to determining whether valid patents have been infringed are not required to be capitalized.

III. Recurring Fees Cannot Override the Capital Origin

Corporation X argues, as an alternative, that legal fees are deductible as ordinary and necessary expenses regardless of the capital origin, apparently because they recur. Treas. Reg. § 1.263(a)-4 contains exceptions for de minimis expenditures, short lived assets, and employee compensation, but does not contain an exception for recurring expenditures that are otherwise required to be capitalized. This argument is without merit.

This position was clearly rejected in Lincoln 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.") Moreover, it has long been established that the norm is capitalization. Indopco, 503 U.S. 79, 84 (1992).

Nevertheless, Corporation X alleges that Commissioner v. Tellier, 383 U.S. 687 (1966), Kornhauser v. Commissioner, 276 U.S. 145 (1928), Vanderbilt v. Commissioner, T.C. Memo 1957-235, and Helvering v. Hampton, 79 F.2d 358 (9th Cir. 1935) establish a contrary rule for legal expenses. Corporation X errs.

Tellier declined to disallow an otherwise allowable deduction on public policy grounds; it says nothing about legal fees incurred to create assets and does not hold that legal fees should be presumed to be deductible. Likewise, Kornhauser did not establish a presumption that all legal fees are deductible. Rather, the fees at issue in Kornhauser

[8] It is not known what amount, if any, Corporation X paid to acquire ownership of these patents.

were incurred in the defense of a suit for an accounting of businesses earnings, an ordinary and necessary aspect of a business; not the creation or enhancement of a separate asset. Thus, Kornhauser does not apply to Corporation X's facts, just as it did not apply in Safety Tube Corp. v Commissioner, 168 F.2d 787, 790 (6th Cir.1948) (distinguished Kornhauser as a case not applicable when the litigation "struck at the very ownership of the patent itself").

In Vanderbilt, the taxpayer failed to carry its burden to prove part of the legal fees at issue were deductible. The court found that the remainder of the legal fees were not incurred in investigating a new business. Thus, the case did not hold that legal fees are presumed deductible. Hampton also says nothing about fees incurred to create an intangible or to create or enhance a separate and distinct asset. The case, like the others, does not change the norm of capitalization just for legal fees.

As stated in Lychuk v. Commissioner, 116 T.C. 374, 393-416 (2001),[9] 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 expenses are made in the course of the payee's regular business operations." Lychuk, 116 T.C. at 409. All of the legal fees at issue herein have a sufficiently direct connection with the creation of intangible assets and/or the protection or perfection of title that they must be capitalized.

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

A. ANDA Fees

To the extent Corporation X contends Urquhart v. Commissioner, 215 F.2d 17 (3rd Cir. 1954), establishes that fees to defend patent infringement suits are *per se* deductible, Corporation X errs. Urquhart is a 1954 case that predates the more recent Supreme Court cases that confirm the norm is still capitalization when considering whether expenditures are deductible or capitalizable. See Indopco, 503 U.S. 79, 84 (1992) (addressing the strong foundation supporting the norm of capitalization), and the regulations under Treas. Reg. § 1.263(a)-4. Urquhart was decided a decade before United States v. Gilmore, 372 U.S. 39 (1963), the landmark Supreme Court case addressing the origin of the claim test.[10] Also, Urquhart was decided decades before

[9] The change in litigation position announced in 2002 that cited Lychuk, Chief Counsel Notice CC-2002-021, 2002 WL 32813480, addressed employee compensation, fixed overhead and de mimis transaction costs, expenditures not addressed in this advice.

[10] As of November 27, 2012, Westlaw listed ten positive cases relying on Urquhart, with all predating Gilmore, except for three: Nickerson v. Kutschera, 390 F. 2d 812, 815, n.9 (3rd Cir. 1968), *opinion after remand*, 419 F. 2d 983 (3rd Cir. 1969) (a patent case stating "we do not reach the problem of whether language in . . .; or Urquhart . . . , must be overruled . . . ."); Technograph Printed Circuits, Ltd. v. U.S. 178 Ct. Cl. 543 (1967) (a patent case citing Urquhart relative to mutuality of estoppel); and Clark v

the regulations required costs that facilitate the creation of intangibles to be capitalized.

In addition, Urquhart did not address capitalization of legal fees incurred to create new assets, it addressed legal fees incurred to protect profits. Corporation X was not sued for lost profits due to infringing sales of competing drugs; rather, Corporation X was sued because it sought FDA approval to market and sell competing drugs before the expiration of the patents covering the branded drugs. None of the lawsuits even allege Corporation X commercialized its generic drugs; rather, all sought to delay FDA approval until all patents expired. The fact that Corporation X notified the soon-to-be plaintiffs that Corporation X was seeking FDA approval of ANDAs with paragraph IV certifications, as required by law, does not preclude the lawsuits from being all about Corporation X obtaining new intangible capital assets to use in its trade or business. For the litigation arising from Corporation X's ANDA applications, the litigation facilitated the transaction—obtaining an ANDA.

Finally, the taxpayer in Urquhart was in the business of patent licensing. The parties to ANDA litigation are in the business of producing brand name and generic drugs. The taxpayer's infringement litigation in Urquhart was of an ordinary and regular occurrence focused on the royalties; in the cases at issue, the litigation is part of a larger process of creating an intangible asset, the ANDA.

Because of these distinctions, Urquhart is not dispositive of Corporation X's ANDA fees, and any arguments based upon the case do not advance the cause of the proponent.

B. NDA Fees

Likewise, Urquhart is not authority for a case where title is at issue because, in Urquhart, at the appellate level, it was "**conceded that no question of title was involved**." 215 F.2d at 19 (emphasis added). Urquhart is the quintessential example of a case that does not involve title since it was conceded that the case did not involve title. The joint venture that deducted the fees in Urquhart was merely protecting its royalties from licensing two patents that it did not own. See Urquhart v. Commissioner, 20 T.C. 944, 945 (1953), rev'd, 215 F.2d 17 (3rd Cir. 1954) ("Although title to these two patents was retained by Radcliffe M. Urquhart and George Gordon Urquhart, they invested the joint venture with power to make arrangements for the administration and licensing of these patents and to receive the royalties earned therefrom."). The joint venture's sole business income consisted of royalties generated by patents it did not

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Commissioner, 1989 WL 145988 (1989) *aff'd* 455 N.W. 2d 480 (1990) (citing Urquhart for the proposition deductibility does not depend on winning the lawsuit). Of the six cases listed in Westlaw as mentioning Urquhart, only one post-dated 1963, Rust-Oleum v. US, 280 F. Supp 796 (N.D. Ill, 1967), *action on dec*., 1968 WL 16312 (March 4, 1968) (protection of title predominated, disagreeing with the allocation, in part, to deductible expenditures).

own. Id. ("From 1942 through 1946 [the years at issue] the sole business conducted by the joint venture was the licensing of the two patents.").

In addition, because the Urquharts had sued a customer of the plaintiff, the plaintiff's action against Urquhart took the form of a declaratory judgment action, with the Third Circuit stating "[t]he declaratory judgment remedy merely enabled a turn about of parties. Mere forms of action is immaterial." 215 F.2d at 20. The Urquhart court then found the "purpose and intent are the same whether the Urquharts commenced the action, or maneuvered Pyrene into taking the initial litigative step." Id. Thus, arguably, Urquhart applied the primary purpose test, as one court has so found. Rust-Oleum v. US, 280 F. Supp 796, 801 (N.D. Ill, 1967), *action on dec*., 1968 WL 16312 (March 4, 1965)(protection of title predominated, disagreeing with the allocation, in part, to deductible expenditures). The primary purpose test has been repudiated by the Supreme Court. See Woodward v. Commissioner, 397 U.S. 572, 578 (1970) (stating Gilmore "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"). See also American Stores v. Commissioner, 114 T.C. 458, 470 (2000) (reiterates that the primary purpose test has been rejected); 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).

Again, the litigation at issue in Corporation X v. Entity AI, unlike that in Urquhart, is not about recovering lost profits, but about preventing commercialization of a generic drug and protecting Corporation X's title to its patent. The reliance on Urquhart in the preamble to the Notice of Proposed Rule Making ("NPRM") merely reflects the fact that title was not at issue in Urquhart, and confirms that legal fees incurred to recover lost profits are not capitalizable.[11] Accordingly, Urquhart does not establish precedent for cases where the litigation is, in whole or part, to protect or perfect title.

V. Cost Recovery of ANDA Fees

A. As Franchises, ANDAs are Amortizable § 197 Intangibles

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

[11] See § IV. H. (December 19, 2003) Guidance Regarding Deduction and Capitalization of Expenditures, 67 Fed. Reg. 77701("The rule is not intended to require capitalization of amounts paid to protect the property against infringement and to recover profits and damages as a result of an infringement. As under current law, these costs are generally deductible. See, *e.g.,* Urquhart v. Commissioner, 215 F.2d 17 (3rd Cir. 1954) (expenditures made by a licensor of patents to protect against infringement and to recover profits and damages were made to protect, conserve, and maintain business profits, and not to defend or perfect title to property. Whether an amount is paid to defend or perfect title, on the one hand, or to protect against infringement, on the other, is a factual matter.").

1. ANDAs are Franchises

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."

Corporation X’s ANDAs fit neatly into the § 1253(b)(1) definition of a franchise 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, 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 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, § 3 (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).

2. As Franchises, ANDAs are Section 197 Intangibles

The second 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 franchise. See Addendum A, § 3 (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.

3. As Franchises, ANDAs are Amortizable Section 197 Intangibles

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),[12] the Tax Court addressed the interpretation of the "in connection with 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 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:

[12] Broz I v. Commissioner, 137 T.C. 46 (2011), decided other issues of first impression.

> 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 Corporation X was engaged in the trade or business of developing, producing, marketing and selling generic and brand name drugs prior to incurring the attorney fees at issue in order to market and sell generic and brand name drugs. Therefore, unless otherwise excluded from being an amortizable section 197 intangible, ANDAs that were approved by the FDA after August 10, 1993, such as those for which the professional fees in dispute were incurred, will qualify as amortizable section 197 intangibles of the trade or business to which the ANDAs relate.

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

> [T]he 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). 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. However, because Corporation X created,

rather than acquired, its franchises, Treas. Reg. § 1.197-2(e)(2) does not impact the treatment of Corporation X's ANDAs as amortizable section 197 intangibles.[13]

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.

4. 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 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—

[13] As a matter of fact, there were no purchases of a trade or business by Corporation X in this case. While Treas. Reg. § 1.197-2(e)(2) provides, in general, that "[t]he acquisition of a franchise . . . constitutes the acquisition of a trade or business or substantial portion thereof," because Corporation X created, not acquired, the franchises, Treas. Reg. § 1.197-2(e)(2) does not impact the treatment of ANDAs as franchises.

> (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) (emphasis added)

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.[14] 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, Corporation X's 15-year amortization period for recovering the attorney fees associated with its approved ANDAs would begin the first day of the month in which the FDA finally approves the ANDAs as effective with no exclusionary periods barring the immediate marketing and selling of drugs the subject of the ANDAs, since that is the later date of when Corporation X 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 under the subheading "Amounts Paid to Create an Intangible or Facilitate the Creation of an Intangible," an ANDA fits one of 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. § 1.263-4(d)(5). Thus, ANDAs constitute licenses and other similar

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

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.

VI. Cost Recovery of the Fees to Protect or Perfect Patents

A. Fees Incurred to Protect or Perfect Patents Are Recovered Under Treas. Reg. § 1.167(a)-14

1. Patents At Issue Are Not Section 197 Intangibles

According to I.R.C. § 197(d)(1)(C)(iii), a section 197 intangible includes any patent, copyright, formula, process, design, pattern, knowhow, format, or other similar item.

I.R.C. § 197(e)(4)(C) provides an exception to the general rule of I.R.C. § 197(d)(1)(C)(iii), stating that if an interest in a patent or copyright is not acquired in a transaction (or a series of related transactions) involving the acquisition of assets constituting a trade or business or substantial portion thereof, then the patent or copyright shall not be included in the definition "section 197 intangible." See also Treas. Reg. § 1.197-2(c)(7).

Since there is no indication that the patents listed in the Orange Book for Drug #8 were acquired by Corporation X as part of the acquisition of assets constituting a trade or business, or substantial part thereof, the patents do not qualify as section 197 intangibles. Treas. Reg. § 1.197-2(c)(7) indicates that the applicable rules for interests in patents not acquired as part of a trade or business are set forth in Treas. Reg. § 1.167(a)-14(c)(4) (governing depreciation deductions for interests in patents (other than such interests acquired as part of a purchase of a trade or business) described in I.R.C. § 167(f)(2) and Treas. Reg. § 1.197-2(c)(7)).

2. Fees Incurred to Protect or Perfect Patents, Because They Are Capitalized to the Patents, Are Depreciable Ratably Over The Patents' Useful Lives Under I.R.C. § 167

I.R.C. § 167(f)(2) provides that [i]f a depreciation deduction is allowable under [I.R.C. § 167(a)] with respect to any property described in [I.R.C. § 197(e)(4)(C)] (any interest in a patent or copyright), such deduction shall be computed in accordance with regulations.

If an intangible asset is not included among the intangibles subject to I.R.C. § 197, the intangible asset may be subject to depreciation in accordance with I.R.C. § 167. I.R.C. § 167(f)(2). Under I.R.C. § 167, a patent, which has been placed in service, is subject to depreciation. See Treas. Reg. § 1.167(a)-3(a); Treas. Reg. § 1.167(a) -10(b); and Treas. Reg. 1.167(a)-14. Pursuant to Treas. Reg. § 1.167(a)-14(c)(4), the basis of a patent may be depreciated using one of the following methods, as appropriate:

(1) Ratably over the remaining useful life of the patent;

(2) Under the income forecast method provided by I.R.C. § 167(g); or

(3) If the purchase price of a patent is payable at least annually as a fixed amount per use or a fixed percentage of revenue generated from use of the patent, the amount paid or incurred during the taxable year can be treated as the depreciation deduction for such taxable year.

Consequently, Treas. Reg. § 1.167(a)-14(c)(4) governs the depreciation of the patents for Drug #8 commencing with the dates when they were placed in service. Here, Corporation X is not making payments to purchase the patents in question and there is no indication that it has applied the income forecast method. Accordingly, the bases of the patents are depreciable ratably over their useful lives.

3. Fees Incurred to Protect and Perfect Patents Would Be Recovered over the Remaining Lives of the Patents, After the Fees Are Divided Pro Rata Among the Patents

Treas. Reg. § 1.167(a)-14(c)(5) provides that rules similar to those in Treas. Reg. § 1.197-2(f)(2) apply for purposes of Treas. Reg. § 1.167(a)-14(c). Treas. Reg. § 1.197-2(f)(2)(i) provides that any amount that is properly included in the basis of an amortizable section 197 intangible after the first month of the 15-year period described in Treas. Reg. § 1.197-2(f)(1) and before the expiration of that period is amortized ratably over the remainder of the 15-year period. Thus, the legal fees incurred by Corporation X associated with protecting its patent for Drug #8 are depreciable ratably over the remaining useful lives of the patents listed in the Orange Book for Drug #8, after dividing such fees pro rata among the patents and so increasing the bases of such patents.

B. Corporation X's Grant of A License to Entity AI Does Not Impact the Cost Recovery of the Legal Fees

Corporation X granted Entity AI a valuable asset (a license) to settle the Corporation X v. Entity AI lawsuit.

. That
does not impact the cost recovery of the fees relating to protecting and perfecting patents - they are capitalized to the patents.

VII. Section 263A Applies to the Annual Cost Recovery Deductions related to the ANDAs

Once Corporation X commences production of its generic drugs, Corporation X's annual cost recovery of the capitalized attorney fees relating to the ANDAs 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 Corporation X's drug manufacturing operations. Further, Corporation X's drugs would not be produced if they could not be marketed and sold. Thus, the ANDAs directly benefit, and/or were obtained to enable, the production of the generic drugs and the annual cost recovery (amortization or depreciation) is an indirect cost that is properly allocable to the generic 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 ANDAs, which are otherwise deductible, must be capitalized pursuant to the uniform capitalization rules of I.R.C. § 263A.

VIII. The Commissioner May Change Corporation X's Method of Accounting On an ANDA-by-ANDA and Patent-by-Patent Basis

A. A change in Corporation X's treatment of attorney fees for an ANDA or for protecting and perfecting patents is a change in method of accounting under §§ 446 and 481

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.[15]

An accounting practice that involves the timing of when 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 (1999); 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 section 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." [16]

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[15] See Treas. Reg. § 1.481-1(a)(1); Treas. Reg. § 1.446-1(e)(2)(ii)(a); Graf 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 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.

[16] 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).

The treatment of Corporation X's attorney fees for each ANDA or patent as either deductible or capitalizable is a "material item" used in Corporation X's overall plan of accounting because such treatment involves the proper time for the taking of deductions for such attorney fees. Further, such treatment does not permanently affect Corporation X's lifetime income. Accordingly, the change in the treatment of Corporation X's attorney fees for each ANDA or patent from immediately deductible (when incurred) to capitalizable (when incurred) is a change in a material item used in Corporation X's overall plan of accounting for gross income and deductions. Thus, it constitutes a change in method of accounting under Treas. Reg. § 1.446-1(e)(2)(ii)(a). Accordingly, the Commissioner may change Corporation X's method of accounting for attorney fees on an ANDA-by-ANDA and a patent-by-patent basis.

B. The Service May Change Taxpayer's Treatment of Attorney Fees for ANDAs and Patents by Imposing Changes in Method of Accounting, Either in a Taxable Year Currently under Examination or in a Subsequent Taxable Year

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 section 1.446-1(b)(1) of the Income Tax Regulations.

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.[17] 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.[18]

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

[17] 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).

[18] 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).

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, 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 on the date of the agreement finalizing the change. See Rev. Proc. 2002-18, section 5.04(1).

An examining agent changing a taxpayer's method of accounting ordinarily will impose a section 481(a) adjustment, subject to a computation of tax under section 481(b) (if applicable). The section 481(a) adjustment, whether positive or negative, will be taken into account entirely in the year of change. See section 1.448-1(c)(3); Rev. Proc. 2002-18, 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 section 1.448-1(a).

A change in method of accounting to which section 481(a) applies includes a change in treatment of a single material item.[19] Once the Commissioner has imposed a change in method of accounting, the application of section 481(a) to such change is mandatory.[20] An adjustment under section 481(a) can include amounts attributable to taxable years that are closed by the statute of limitations.[21]

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[19] See Treas. Reg. § 1.481-1(a)(1); Graf 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).

[20] Primo Pants Co. v. Commissioner, 78 T.C. 705, 720 (1982); Emert v. Commissioner, T.C.Memo. 1999-175; Hitachi Sales Corp. of America v. Commissioner, T.C.Memo. 1994-159, supp. T.C.Memo. 1995-84.

[21] 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.2d 357, 363-4 (6th Cir. 2008); Graff Chevrolet Co. v. Campbell, 343 F.2d at 571-572; Rankin v. Commissioner, 138 F.3d 1286, 1288 (9th Cir. 1998);

Because a change in treatment of attorney fees of an ANDA or a patent is an accounting method change, the Service may propose adjustments to Corporation X's treatments of attorney fees for ANDAs and patents only by imposing an involuntary method change to a proper method of accounting and imposing an adjustment under section 481(a). Accordingly, the Service will impose accounting method changes and section 481(a) adjustments for most of the ANDAs and patents pursuant to the terms of Rev. Proc. 2002-18. However, the Service does not have sufficient time in the current audit cycle to compute I.R.C. § 481(a) adjustments for any ANDAs or patents for which attorney fees may have been incurred before Year 1. Accordingly, the Service will defer the imposition of accounting method changes for such ANDAs and patents to a year beyond the years under audit. Section 481(a) adjustments will be computed and proposed in the later year(s) of change.

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).

C. The Service Should Preserve the Commissioner's Right to Make Service-Initiated Changes in Method of Accounting for certain ANDAs and patents in Subsequent Taxable Years by Giving Corporation X Written Notice that Such Methods of Accounting are Issues Placed in Suspense Within the Meaning of Revenue Procedure 97-72

The general rule (i.e., scope limitation) is that a taxpayer may not request a voluntary accounting method change while under examination for any year. However, this rule has the following exceptions:

a. *90-day window* - The taxpayer may file a Form 3115 (Application for Change in Accounting Method) within the first 90 days of a taxable year if (1) the taxpayer has been under examination for at least 12 consecutive months as of the first day of the taxable year; and (2) the method which the taxpayer seeks to change is not an issue under consideration or an issue that has been placed in suspense;[22] and,

b. *120-day window* - The taxpayer may file a Form 3115 within the 120-day period following the date an examination ends, provided the change requested is not an issue under consideration or an issue that has been placed in suspense at the time the form is filed.

See Rev. Proc. 2011-14, 2011-4 I.R.B. 330, Section 6.03; Rev. Proc. 97-27, 1997-1 C.B. 680; and I.R.M. 4.11.6.6.5(3).

An issue is placed in suspense if an issue has been under consideration in an examination cycle or tax year, and the Service makes a decision not to propose an adjustment to the issue in that cycle or tax year, but the Service intends to examine the issue in the immediately subsequent examination cycle and the Service has given the taxpayer written notification of its intent. Neither the Internal Revenue Manual nor the applicable revenue procedures provide specific detail regarding the nature or timing of the written notification that Service must furnish to a taxpayer in this regard. Supplemental advice will be provided on the content and timing of the written notification required to preserve the Service's ability to make Service-initiated accounting changes with regard to attorney fees for all ANDAs and patents not specifically addressed herein (on an ANDA-by-ANDA and patent-by-patent basis), the audit of which will be suspended until the next audit cycle.

CASE DEVELOPMENT, HAZARDS AND OTHER CONSIDERATIONS

The audit of the ANDAs and NDAs/patents at issue herein did not extend to investigatory patent attorney fees. While not legal precedent, a previously issued CSLA that addressed investigatory patent fee issues, 2011 IRS NSAR 4901F, 2011 WL

[22] This window allows taxpayers under continuous examination an opportunity to use the voluntary change procedures.

6284624, n. 19, opined:

> Expenditures within the twelve code sections listed in I.R.C. § 263(a)(1) are not within the mandate of capitalization in I.R.C. § 263(a), with one of the listed code sections I.R.C. § 174. The fees at issue are not within § 174 because the fees were incurred to acquire the right to market and sell [said corporation's] generic drugs prior to the expiration of the patents on the branded drugs the generic drugs "mimic." The substantial fees incurred to prepare for a paragraph IV certification . . . and to defend the paragraph IV certification in infringement litigation in order to expedite commercialization of the already developed generic drugs are not minor costs incurred in "connection with inventions or improvements from research and development in the experimental or laboratory sense undertaken directly by the taxpayer or carried on in his behalf by another person or organization," as required to be within § 174. Rev. Rul. 66-30, 1966-1 CB 55, applying Treas. Reg. § 1.174-2. None of the fees at issue were incurred in obtaining a patent for any research and development previously undertaken to develop the generic drugs and/or to establish their bioequivalence with the branded drugs, so none of the fees are within Treas. Reg. § 1.174-2(a)(1). See Rev. Rul. 67-401, 1967-2 C.B. 123 ("The expenses for legal and accounting work incurred by the taxpayer in applying for a Federal income tax ruling in connection with a research and development project and a determination of a regulatory commission with respect to the effect of the project on the taxpayer's rate structure are not deductible as research and experimental expenditures under section 174(a) of [the Code]"). . . .]

It is advised that in the next cycle, when changing Corporation X's method of accounting for legal fees incurred to obtain ANDAs, the investigatory legal fees prior to litigation be ascertained and the relevant Issue Practice Groups and Local Counsel be contacted for assistance.

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.

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Attachment:

Addendum A: Obtaining Approval to Market and Sell New Drugs in the United States

Addendum A

Obtaining Approval to Market and Sell
New Drugs in the United States

In order to market or sell a new drug in the United States, the new drug must be approved by the Food and Drug Administration (FDA). Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(a)(2012) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug."). The term "new drug" in § 355(a) includes generic drugs. United States v. Generix Drug Corporation, 460 U.S. 453, 461 (1983) ("In summary, a generic drug product is a 'drug' within the meaning of § 201(g)(1) of the Act.").

§ 1. New Drug Applications

The 2007 Coordinated Issue Paper on taxation of drug development agreements summarizes the process for developing a new (non-generic) drug for FDA approval.

> The pharmaceutical/biotech drug development process is generally composed of four stages: Preclinical or discovery research, clinical development, regulatory approval, and post marketing. These stages take approximately 10 to 12 years to complete.
>
> In the preclinical or discovery research stage (typically the first two years of the discovery/development process), a compound is tested on animals and non-human systems. If the compound/molecule looks promising at this stage, it is patented. The patent prevents other companies from freely using the same compound/molecule for 20 years (life span of a patent). The Food and Drug Administration (FDA) established a set of standards (called "Good Laboratory Practice") for this stage of development to ensure quality of animal testing and the resultant data for an Investigational New Drug Application (IND). If the IND is approved by the FDA, testing of the compound/molecule in humans can begin.
>
> Th[e] second stage is known as clinical development. Clinical development (typically spans 5 to 7 years or years 3 through 10 of the discovery/development process) is normally conducted in three phases. In Phase I, the first trials in humans are conducted for safety, tolerance and pharmacokinetics. In Phase II, testing is done to evaluate effectiveness, dosage and safety in selected populations of patients with the disease or condition to be treated, diagnosed or prevented. In Phase III, expanded clinical trials are conducted to gather additional evidence to verify dosage and effectiveness for specific indications and to better understand safety and adverse effects. These are large-scale trials

> typically involving thousands of patients to prove effectiveness against a specific disease or condition.
>
> The third stage, known as the regulatory approval stage, begins after Phase III trials have been completed (typically spans 12 to 18 months or years 11 and 12 of the discovery/development process). Sponsors file a New Drug Application (NDA) with the FDA to obtain authorization to market a new pharmaceutical product. The NDA consists of clinical and nonclinical data on the product's safety and effectiveness and a full description of the methods, facilities, and quality controls employed in manufacturing and packaging. Until the FDA grants authorization, a drug sponsor cannot market the drug in the United States.
>
> The final stage, post-marketing studies (also called Phase IV), occurs after the product has received FDA approval. These studies are performed to determine the incidence of adverse reactions, to determine the long-term effect of a drug, to study a patient population not previously studied, and to conduct marketing comparisons against other products and other uses.

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.

See Josephine C. Babiarz and Douglas J. Pisano, Overview of FDA and Drug Development, FDA Regulatory Affairs, A Guide for Prescription Drugs, Medical Devices and Biologics, 1-32. (Douglas J. Pisano and David S. Mantus, eds., 2nd Ed., 2008) (Summarizing the statutory and regulatory regime for New Drug Applications, with citations).

New Drug Applications (NDAs) can be transferred from the original sponsor (entity that submitted the application for the NDA) to another, provided the requirements imposed by the FDA are met.[23] The entity that holds the rights to the NDA is referred to as the holder of the NDA. See aaiPharma, Inc., v. Thompson, 296 F.3d 227 (4th Cir. 2002) (referring to the current owner of an FDA-approved NDA as the NDA holder when addressing the FDA's role in ensuring the accuracy of patent information).

The NDA must disclose all patents that cover the drug, with the NDA holder required to notify the FDA of all new patents that subsequently cover the drug after the filing of the NDA. 21 C.F.R. § 314.53 (2012). The FDA posts the patent information provided by the NDA holder to its publication called "Approved Drug Products With Therapeutic

[23] 21 C.F.R. § 314.72(a) (2012) ("An applicant may transfer ownership of its application. At the time of transfer the new and former owners are required to submit information to the Food and Drug Administration . . . . ").

Equivalence Evaluations," also known as the "Orange Book," available in hard copy or electronically on the FDA website.[24]

The term "pioneer drug" was used in early case law to refer to a new drug with an FDA-approved NDA. See United States v. Generix Drug Corporation, 460 U.S. 453, 454-55 (1983)("The term 'generic drug' is used to describe a product that contains the same active ingredients but not necessarily the same excipients as a so-called "pioneer drug" that is marketed under a brand name."); Actavis Elizabeth LLC v United States, 625 F.3d 760, 761 (D.C. Cir. 2010) ("So-called 'new drug applications' - required for 'pioneer' drugs that have never before received FDA approval - must be supported by full reports of investigations showing the drug is safe and effective."). See also FTC v. Watson Pharms. Inc., 677 F.3d 1298, 1302 (11th Cir. 2012), *petition for Writ of Certiorari granted*, 2012 U.S. LEXIS 9415 (Dec. 7, 2012)(Pioneer drugs refer to drugs "that have never before received FDA approval."). Current literature sometimes uses the term "innovator drug" without specifying if the term "innovator drug" means the same as "pioneer drug" or refers only to innovator drugs that have extended exclusivity. Pioneer drugs that can be marketed and sold in the United States pursuant to an approved NDA are likely to have a trademarked name, and are generally referred to as "branded drugs" whether or not the patents covering the drugs have expired.

Some FDA-approved pioneer drugs qualify for regulatory exclusivity, which is sometimes called "marketing exclusivity" and/or "data exclusivity".[25] Currently the regulatory exclusivity periods that a FDA-approved NDA may qualify for include:

1. Five-year exclusivity for new chemical compounds. 21 U.S.C. § 355(c)(3)(E)(ii). But see 21 U.S.C. § 355(j)(5)(F)(ii) (ANDA can be submitted to FDA in four years).

2. 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).

3. Seven-year exclusivity for drugs that treat certain rare diseases. Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983) (codified at 21 U.S.C. §§ 360 and 42 U.S.C. § 236).

4. Thirty-month exclusivity for timely filing an infringement suit when notified that an Abbreviated New Drug Application (ANDA) with a paragraph IV certification has been accepted for filing by the FDA. "The 30-month stay provision provides the brand-name company an additional exclusionary

[24] Orange Book Publications, U.S. Food and Drug Administration, http://www.accessdata.fda.gov/scripts/cder/ob/eclink.cfm (last visited on May 20, 2011).

[25] Wendy H. Schacht and John R. Thomas, Follow-On Biologics: Intellectual Property and Innovation Issues, Congressional Research Service RL33901, p. 13 (March 20, 2009).

> right beyond those granted by the patent system." Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study, p. 39 (July 2002), p. 42 (July 2002).

Regulatory exclusivity can run concurrently with patent exclusivity or extend beyond the patent exclusivity, depending on the timing, facts and circumstances.

There are separate provisions that can extend patent exclusivity for patented pharmaceutical products (*e.g.*, an extension of the patent life based on the time the FDA spent reviewing the drug or the time the United States Patent Office spent reviewing the patent). 35 U.S.C. §§ 155 and 156. See Mary W. Bourke and M. Edward Danberg, Current Trends in Hatch-Waxman Patent Litigation: A System Still in Flux, Practicing Law Institute, 878 PLI/Pat 939, §§ I.C. 6, 7 and 8 (2006)(patent extensions and exclusivity).

A patent does not provide an affirmative right to market or sell a drug.[26] The separate role played by patents is summarized in a Congressional Research Service Report, as follows:

> [A]n award of marketing approval by the FDA and the grant of a patent by the U.S. Patent and Trademark Office (USPTO) are distinct events that depend upon different criteria. FDA procedures determine whether the drug is sufficiently safe and effective to be marketed. In contrast, the USPTO grants patents on inventions that fulfill requirements established by the Patent Act of 1952, including utility, novelty, and nonobviousness....
>
> Although a complete review of the patent system exceeds the scope of this report, its basic contours may be concisely stated. The Patent Act allows inventors to obtain patents on processes, machines, manufactures, and compositions of matter that are useful, novel and nonobvious. An invention is judged as useful if it is minimally operable towards some practical purpose. To be considered novel within the patent law, an invention must differ from existing references that disclose the state of the art, such as publications and other patents. The nonobviousness requirement is met if the invention is beyond the ordinary abilities of a skilled artisan knowledgeable in the appropriate field.
>
> In order to receive a patent, an inventor must file a patent application with the USPTO. Patent applications must include a specification that so completely describes the invention that skilled artisans are enabled to practice it without undue experimentation. **The patent application must**

[26] Wendy H. Schacht and John R. Thomas, Follow-On Biologics: Intellectual Property and Innovation Issues, Congressional Research Service RL33901, p. 18 (March 20, 2009).

> **also contain distinct, definite claims that set out the proprietary interest asserted by the inventor**.
>
> Trained personnel at the USPTO, known as examiners, review all applications to ensure that the invention described and claimed in the application fulfills the pertinent requirements of the patent law. If the USPTO believes that the application fulfills the statutory requirements, it will allow the application to issue as a granted patent. Each patent ordinarily enjoys a term of twenty years commencing from the date the patent application was filed. If the patent proprietor was unable to market its product for a period of the patent term due to lack of approval by the FDA, the term may be extended by a portion of the regulatory review period in some circumstances.
>
> Granted patents give the patentee the right to exclude others from making, using, selling, offering to sell, or importing into the United States the patented invention. Parties who engage in those acts without the permission of the patent proprietor during the term of the patent can be held liable for infringement. The patentee may file a civil suit in federal court in order to enjoin infringers and obtain monetary remedies. Although issued patents enjoy a presumption of validity, accused infringers may assert that the patent is invalid or unenforceable on a number of grounds.

Wendy H. Schacht and John R. Thomas, Follow-On Biologics: Intellectual Property and Innovation Issues, Congressional Research Service, RL33901, pp. 10-11 (March 20, 2009) (footnotes omitted) (emphasis added).

There are multiple types of patents, with the Federal Trade Commission ("FTC") summarizing the three basic types as follows:

> There are three basic types of patents: utility, plant, and design patents. Utility patents generally have a term of 20 years from the date on which the application for the patent was filed. Utility patents are divided into three basic categories: chemical, electrical and mechanical. Pharmaceutical patents are a subset of chemical patents and are issued over four different categories: drug substance, method of use, formulation, and process. Drug substance patents cover the compound or active ingredient in the drug product, such as fluoxetine hydrochloride, which is the active ingredient in Prozac. Method of use patents cover the use of the product to treat certain health problems, such as depression or asthma. Formulation patents cover the physical composition or delivery mechanism of the drug product, such as an extended release tablet or capsule. Process patents generally cover the procedure used to make the active ingredient.

Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration - FTC Study, p. 41, Box 4-1 (July 2012).

While not providing the necessary FDA approval to market and sell, patents protection is critical to pharmaceutical companies that develop, market and sell pioneer drugs in the United States. The critical roll of patents is summarized in one paragraph by the Congressional Research Service Report.

> **The significant costs** of pharmaceutical R&D, coupled with the uncertainty of the clinical trial process, **lend consequence to patents in [the pioneer pharmaceutical] area because "the disparity between the investment of innovators and those of imitators is particularly large in pharmaceuticals** – almost as large as when software pirates simply copy the diskettes of an innovator." While the capitalized cost of developing a new drug to the point of market approval is estimated at over $800 million, it takes only between $1 million and $2 million to obtain approval for a generic version of the chemically synthesized pharmaceutical.

Wendy H. Schacht and John R. Thomas, Follow-On Biologics: Intellectual Property and Innovation Issues, Congressional Research Service, RL33901, p. 21 (March 20, 2009) (footnotes omitted) (emphasis added).

When an FDA-approved NDA loses patent exclusivity and generic versions are commercialized, there can be a significant loss in sales.

> According to a study conducted by the FTC of the industry as a whole . . ., a branded manufacturer typically loses about 90 percent of its unit sales over the course of generic entry. . . . **Thus, a branded manufacturer can expect that, if a drug is earning $1 billion a year before generic entry, the manufacturer will only earn about $100 million** a year once generic competition has matured . . . ."

FTC v. Watson Pharms., Inc., 677 F.3d 1298, 1302, n. 2 (11th Cir. 2012), *petition for Writ of Certiorari granted*, 2012 U.S. LEXIS 9415 (Dec. 7, 2012) (emphasis added).

The Federal Trade Commission (FTC) pointed out that:

> Brand-name pharmaceutical drug manufacturers seeking to protect the sales of brand-name drugs may have an incentive and ability to enter into agreements with would-be generic competitors, or engage in other types of activities, that would slow or thwart the entry of competing generic drug products.

Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study, p. 2 (July 2002).

See J. Thomas Rosch, Commissioner, Pharmaceutical Patent Settlements and the Supreme Court, CBI's 2nd Annual Life Sciences Compliance, Legal and Regulatory Congress, 2012 WL 4363166 (September 21, 2012). ("The legal standard by which to evaluate pharmaceutical infringement settlements has been one of the most hotly litigated and debated antitrust questions over the last decade."). Commissioner Rosch quoted from the Amicus Curiae Brief in In re K-Dur Antitrust Litig, 686 F.3d 197 (3rd Cir. 2012) (No. 10-2077) as stating "'the finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as prima facia evidence of unreasonable restraint of trade, which could be rebutted . . . .'" 2012 WL 4363166 at *4 and *10. But see FTC v. Watson Pharms. Inc., 677 F.3d 1298 (11th Cir. 2012), *cert. granted*, 81 U.S.L.W. 3216 (Dec. 7, 2012).

§ 2. Abbreviated New Drug Applications

Initially, most generic drugs had to be approved pursuant to the same process applicable to pioneer drugs. See aaiPharma Incorporated v. Thompson, 296 F.3d 227, 230-231 (4th Cir. 2002) ("Prior to Hatch-Waxman's passage in 1984, both pioneer (brand name) and generic drug manufacturers who wished to bring a drug to market were required to file a New Drug Application (NDA) with the FDA.").

In 1984, an abbreviated process for approving generic drugs was established by 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)).[27] In general, under the Hatch-Waxman Act, an ANDA "piggy-backs" off an approved NDA. In lieu of replicating the time intensive and expensive studies performed to obtain an NDA, an applicant for an ANDA can establish that its generic drug is the bioequivalent[28] of the

[27] The 1984 changes did not include an abbreviated process for approving biologic drugs. See Asim Varma, Son B. Nguyen and Justin P. Hedge, The FTC Reports on Follow-On Biologics and Authorized Generics: Applying Lessons from Hatch-Waxman to Promote Competition, Antitrust Vol. 24, No. 1 at 41-42 (Fall, 2009)("Hatch-Waxman does not apply to biologic products"). A pathway for generic biologics was provided for in the "Biologics Price Competition and Innovation Act of 2009, which was enacted as part of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010), with the pathway legislation in § 7002 of Pub. L. No. 111-148, 124 stat. 119 at 816-817, 820 and 860. See 4 Health L. Prac. Guide Appendix A (May, 2011) ("The healthcare reform legislation, as amended by the reconciliation act (Publ. L. No. 111-152), creates a clear regulatory pathway for approving follow-on biologics.")

[28] "'Bioequivalence' means that the active ingredient is absorbed at the same rate and to the same extent for the generic drug as for the innovator drug." Mary W. Bourke and M. Edward Danberg, Current Trends in Hatch-Waxman Patent Litigation: A System Still in Flux, Practicing Law Institute, 878 PLI/Pat 939, § I.C.2. (2006).

drug in an approved NDA. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j).[29] See 21 C.F.R. §§ 314.1- 314.650 (2011) (Applications for FDA Approval to Market a New Drug). See also Mylan Pharmaceuticals, Inc. v. FDA, 454 F.3d 270, 271-272 (4th Cir. 2006)("The Hatch-Waxman Act made it easier to obtain FDA approval of generic drugs.").

The Hatch-Waxman Act sought to correct two distortions in the law, as explained in Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990).

> **First**, the holder of a patent relating to such products [drugs subject to FDA approval] would as a practical matter not be able to reap any financial rewards during the early years of the [patent] term. When an inventor makes a potentially useful discovery, he ordinarily protects it by applying for a patent at once. Thus, if the discovery relates to a product that cannot be marketed without substantial testing and regulatory approval, the "clock" on his patent term will be running even though he is not yet able to derive any profit from the invention.
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> The **second** distortion occurred at the other end of the patent term. In 1984, the Court of Appeals for the Federal Circuit decided that the manufacture, use, or sale of a patented invention during the term of the patent constituted an act of infringement, *see* 35 U.S.C. § 271(a), even if it was for the sole purpose of conducting tests and developing information necessary to apply for regulatory approval. Since that activity could not be commenced by those who planned to compete with the patentee until expiration of the entire patent term, the patentee's de facto monopoly would continue for an often substantial period until regulatory approval was obtained. In other words, the combined effect of the patent law and the premarket regulatory approval requirement was to create an effective extension of the patent term.
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> **The 1984 Act sought to eliminate this distortion from both ends of the patent period**. Section 201 of the Act established a patent-term extension for patents relating to certain products that were subject to lengthy regulatory delays and could not be marketed prior to regulatory approval. . . .

[29] More specifically, "[t]o obtain FDA approval, a generic manufacturer must ordinarily show, among other things, that its product has the same active ingredients as an approved brand-name drug; that 'the route of administration, the dosage form, and the strength of the new drug are the same' as the brand-name drug; and that its product is 'bioequivalent' to the brand-name drug. [21 U.S.C.] §§ 355(j)(2)(A)(ii), (iii), (iv). By eliminating the need for generic manufacturers to prove their drugs' safety and efficacy independently, the Hatch-Waxman Amendments allow generic manufacturers to bring drugs to market much less expensively." Pliva v. Mensing, 131 S. Ct. 2567, 2583 (June 23, 2011)(quoting from dissent by Justice Sotomayor).

> . . .
>
> The distortion at the other end of the patent period was addressed by § 202 of the Act. That added to the provision prohibiting patent infringement, . . . [a section] establishing that "it shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." This allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval.

496 U.S. at 669-71 (emphasis added, citations and footnotes omitted).

Thus, while prior to the Hatch-Waxman Act non-authorized generic equivalents of patented drugs could not be developed without infringing the patents that covered the drug,[30] **under the 1984 revisions the unauthorized use of a patented drug for the purposes of developing a generic drug no longer constitutes an act of infringement**.[31] 35 U.S.C. § 271(e)(2010).

However, the "safe harbor" from infringement terminates when the ANDA is filed with the FDA. The termination of the "safe harbor" occurs, as applicable, because the Hatch-Waxman Act makes filing of an ANDA prior to the expiration of the patents covering the approved NDA an act of infringement in 35 U.S.C. § 271(e)(2)(2010), which has limited remedies (35 U.S.C. § 271(e)(4)). As explained in Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990), after quoting from 35 U.S.C. § 271(e)(2) and (e)(4):

> The function of the paragraphs in question is to define a new (and somewhat **artificial**) **act of infringement** for a very limited and technical purpose . . . .

496 U.S. at 676 (emphasis added).

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[30] Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858 (Fed.Cir.), cert. denied, 469 U.S. 856 (1984).

[31] See Merck KGaA v. Integra Lifesciences I Ltd, 545 U.S. 193, 207 (2005)(interpreting the safe harbor from infringement in 35 U.S.C. § 271(e) and articulating the applicable test as follows: "At least where a drugmaker has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA, that use is 'reasonably related' to the 'development and submission of information under . . . Federal law."). See also Proveris Scientific Corp. v. Innovasystems, Inc, 536 F.3d 1256 (Fed. Cir. 2008) (exemption from infringement does not apply if the invention is not subject to FDA approval).

The Supreme Court went on to explain, with respect to the Hatch-Waxman Act regime that exempts the use of patented inventions to develop generic drugs from infringement suits then creates an artificial act of infringement[32], as follows:

> 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[s] . . . . That is what is achieved by § 271(e)(2)-the **creation of a highly artificial act of infringement** that consists of submitting an ANDA . . . . 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. It is wholly to be expected, therefore, that these provisions would apply only to applications under the sections establishing those schemes . . . .

Eli Lilly & Co., 496 U.S. at 678 (footnote omitted)(emphasis added).

While monetary damages are not permitted if the generic drug has not been commercialized, in exceptional cases, pursuant to 35 U.S.C. § 271(e)(4)(D), attorney fees can be awarded under 35 U.S.C. § 285. Yamanouchi Pharmaceutical Co., Ltd. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1345-47 (Fed. Cir. 2000).[33]

Through this exemption/infringement regime, the Hatch-Waxman Act intended to accelerate the vetting of the validity of listed patents to accelerate the approval of generic drugs. See Shashank Upadhye, Mechanics of Orange Book Patent Certifications and Notice Letters, Generic Pharmaceutical Patent and FDA Law, §10:15, Genpharma (2011) ("The crux of the Hatch Waxman generic drug approval process revolves around vetting out patent issues vis-à-vis the Paragraph IV Certification.").

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[32] The artificial act of infringement has been referred to by at least one court as "a constructive act of infringement." FTC v. Watson Pharms, 677 F.3d 1298, 1303 (11th Cir. 2012), *petition for Writ of Certiorari granted*, 2012 U.S. LEXIS 9415 (Dec. 7, 2012).

[33] See, *e.g.*, Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc., 459 F.Supp.2d 227, 245-252 (S.D.N.Y. 2006) (Sanctions Opinion) and Takeda Chem. Indust., Ltd. v. Mylan Labs, Inc., 2007 WL 840368 (S.D.N.Y. Mar. 21, 2007) ("Amount Opinion"), aff'd and rehearing en banc denied, 549 F.3d 1381 (Fed. Cir.) , cert. denied 130 S.Ct. 106 (2009) (attorney fees awarded for bad faith filing of the paragraph IV certification and misconduct during litigation).

To carryout this regulatory scheme, the sponsor (applicant) of the ANDA is required to include in the ANDA:

> **[A] certification**, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section--
>
> > **(I)** that such patent information has not been filed,
> >
> > **(II)** that such patent has expired,
> >
> > **(III)** of the date on which such patent will expire, **or**
> >
> > **(IV)** 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 (j)(2)(A)(vii) (emphasis added).

The last certification is referred to as a paragraph IV certification. See 21 C.F.R. § 314.95 (2009) (regulation addressing certification requirement). For an ANDA with a paragraph IV certification, the sponsor (applicant) must send notices within 20 days of being notified by the FDA that the ANDA is accepted for filing[34] to the NDA holder for the referenced drug[35] and all patentees of record for the listed patents[36] notifying that the applicant has filed an ANDA with a paragraph IV certification. 21 U.S.C. § 355(j)(2)(B)(i)-(iii)(2010). The notification must set forth the reasons the applicant

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[34] Notification by the FDA that an ANDA is accepted for filing does not mean it is approved by the FDA, just that the application appears to be sufficient to consider on the merits.

[35] The FDA-approved NDA drug that the generic drug "mimics" is, for convenience, referred to herein as the "referenced drug;" but, that term is not necessarily used in the technical sense of the term "reference listed drug" or "RLD." The Orange Book, Orange Book Publications, U.S. Food and Drug Administration, http://www.accessdata.fda.gov/scripts/Cder/ob/eclink.cfm (Annual ed., last visited on May 25, 2011), Introduction § 1.4, states "[a] reference listed drug (21 CFR 314.94(a)(3)) means the listed drug identified by FDA . . . " (emphasis added) Section 1.4 further explains that "[b]y designating a single reference listed drug as the standard to which all generic versions must be shown to be bioequivalent, FDA hopes to avoid possible significant variations among generic drugs and their brand name counterpart. Such variations could result if generic drugs were compared to different reference listed drugs." However, Section 1.4 explains that, in certain circumstances, another listed drug can become an additional referenced drug and, in some circumstances, two listed drugs can both be reference listed drugs, with specific terminology used for the reference listed drugs addressed in Section 1.4.

[36] The patents in the Orange Book for the referenced drugs are referred to herein as "listed."

contends the patents are invalid and/or not infringed. 21 U.S.C. § 355(j)(2)(B)(iv) (2010). Specifically, the notice must include, pursuant to 21 C.F.R. § 314.95(c)(6)(2009):

> A detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed. The applicant shall include in the detailed statement:
>
> > (i) For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed.
> >
> > (ii) For each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.

If neither the patent holders nor the NDA holder bring an infringement suit against the ANDA sponsor (applicant) with a Paragraph IV Certification within forty five days from the day after receipt of the notice, and if the application otherwise meets with approval, the FDA may approve the generic drug. **If suit is brought within said forty-five day period, the ANDA will be subject to a thirty-month stay unless the patent is earlier found to be invalid or not infringed**[37], as explained in Natalie Pous, Shifting the Balance Between Branded and Generic Pharmaceutical Companies: Amendments to Hatch-Waxman Past, Present, And Future, 19 Fed. Cir. B.J. 301 (2009):

> [i]f the patent owner chooses to bring an infringement suit against the ANDA applicant within forty-five days, the FDA is prohibited from approving the generic version of the drug for thirty months ("thirty-month stay") or until the patent is found to be invalid or not infringed. If, before the thirty-month stay expires, the court holds that the patent is invalid or would not be infringed by the ANDA application, then the FDA will approve the ANDA upon that decision. Otherwise, "the FDA will not approve the ANDA until the [original] patent expires."

19 Fed. Cir. B.J. at 305-306 (footnotes omitted)

If the patent litigation is not resolved during the thirty-month stay, the FDA will approve the ANDA if all other requirements are met, but the generic drug company proceeds at its own risk, as explained below.

> If the generic applicant makes a paragraph IV certification and suit is brought within forty-five days, final approval is stayed for thirty months or

[37] For purposes of determining whether there has been a decision of a court that terminates the 30-month stay, the FDA has "provided a 'Guidance for the Industry' that redefines 'court' to be a district court. This definition applies, however, only to ANDAs that were filed with the FDA after March, 2000." Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration - An FTC Study, p. 47 (July 2012).

> until a court decision of validity and non-infringement. If the case is resolved in favor of the patent owner, the court must order that final approval take effect no earlier than patent expiry. If the litigation is ongoing at the conclusion of the thirty months, FDA must approve the ANDA if it is otherwise approvable, and the generic applicant may market its product. In this case, however, [the ANDA holder] risks damages for patent infringement if it later loses the lawsuit. The patent owner may bring a patent infringement suit later, but if it brings suit after the forty-five day notice period, there is no thirty-month stay of generic approval.

Krista Hessler Carver, Jeffrey Elikan & Erika Lietzan, An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009, 65 Food & Drug L.J. 671, 678 (2010)(footnotes omitted).

To counter the burden of being sued for infringement, the Hatch-Waxman Act provides an incentive for the generic company to expose itself to an infringement suit in order to bring a generic drug to market: a 180-day period of exclusivity for the generic product in the market.

> The fundamental goal behind 180-day exclusivity was to provide an incentive for generic drug applicants to challenge innovator patents, and the core of the concept--as it has been applied by the Food and Drug Administration (FDA) and the courts--is that the first generic drug applicant to challenge an innovator's patent is entitled to six months of exclusivity against subsequent patent challengers for the same innovator drug. 180-day exclusivity is governed by sections 505(j)(5)(B)(iv) and 505(j)(5)(D) of the FDCA.

David E. Korn, Erika Lietzan & Shaw W. Scott, A New History and Discussion of 180-Day Exclusivity, 64 Food & Drug L.J. 335 at 335 (2009).

The first to file[38] a substantially complete ANDA with a paragraph IV certification (subject to other requirements, including the applicable exclusivity periods granted to the FDA-approved NDA[39]) obtains 180 days of exclusivity over other generic drug

[38] There can be more than one first filer if multiple ANDAs are submitted on the same day. See Center for Drug Evaluation and Research, Food and Drug Administration, U.S. Dept. of Health and Human Services, Guidance for Industry, 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day (July, 2003).

[39] 21 U.S.C. § 355(j)(5)(B)(2010) provides that approvals can be made effective subject to conditions; however, the statute also provides that the FDA can send tentative approval letters. The FDA's interpretation of the definition of tentative approval letters may limit the use of tentative approval letters to situations where the exclusivity period is relative to the NDA-approved drugs (*e.g.*, new innovative drug for certain rare diseases exclusivity) - periods of exclusivity that can apply after the patents expire and are cross-referenced in the statute provision defining tentative approval, not the 180-day exclusivity of the first applicant.

ANDA filings. 21 U.S.C. § 355(j)(5)(B)(iv) (2010). **The 180 days of exclusivity is valuable to the generic drug producer**. The article by David E. Korn, Erika Lietzan and Shaw W. Scott (cited above) addresses multiple views of the value of the 180-day exclusivity,[40] with one view stated as follows (emphasis added):[41]

> In light of the average selling price of the first generic drug in the market, some have estimated that **a first filer awarded 180-day exclusivity could, in fact, "expect a 1,000 percent return on investment.**" In addition, first filers, by launching their generic drugs in the absence of other generic competitors, may have the advantage of being able to enter into long-term supply contracts with pharmacies retailing their products.

> Tentative Approval. If a generic drug product is ready for approval before the expiration of any patents or exclusivities accorded to the reference listed drug product, FDA issues a tentative approval letter to the applicant. The tentative approval letter details the circumstances associated with the tentative approval. FDA delays final approval of the generic drug product until **all** patent or exclusivity issues have been resolved. A tentative approval does not allow the applicant to market the generic drug product.

U.S. Food and Drug Administration, Glossary of Terms, www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm (last visited on 8/16/2011) (emphasis added). The article by Erika Lietzan and David E. Korn, Issues in the Interpretation of 180-Day Exclusivity, 62 Food & Drug L.J. 49, 50 (2007) may interpret the language in 21 U.S.C. § 505(j)(5)(B)(iv) as barring FDA approval (even tentative) if a prior ANDA filer may be a first applicant entitled to 180-days of exclusivity. See Teva Pharmaceutical Industries v. Crawford, FDA, 410 F.3d 51, 54 (D.C. Cir. 2005) ("The means the Congress 'deemed appropriate, and prescribed' to give generic drug makers an incentive to challenge brand-drug patents is unambiguous: The FDA may not approve a second or later ANDA containing a paragraph (IV) certification until 180 days after the first filer with such a certification begins commercially marketing the drug . . . .").

[40] 64 Food & Drug L.J. at 383-385.

[41] Id. at 384 (footnotes omitted) (emphasis added).

The exclusivity does not extend to drugs known as authorized generics (AG),[42] "generics" that are marketed and sold pursuant to a license from an NDA holder.

The 180-day exclusivity is transferable. See Mary W. Bourke and M. Edward Danberg, Current Trends in Hatch-Waxman Patent Litigation: A System Still in Flux, Practicing Law Institute 878 PLI/Pat 939, § I.C.5 (2006) ("exclusivity may be transferred separately from the ANDA [quoting Mylan Pharm. Inc. v. Shalala, 81 F. Supp.2d 30, 47-48 (D.D.C. 2000)] that 'exclusivity periods are a transferable commodity which can be waived in favor of another generic manufacturer for a substantial price.'").[43]

However, the 180-day exclusivity can be forfeited in certain circumstances.

> The court decision trigger for forfeiture states that 180-day exclusivity is **forfeited if the applicant fails to market 75 days after**, as to each patent at issue, "**a court enters a final decision** from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed"-- unless 75 days have not elapsed since the ANDA approval was effective *and* 30 months have not elapsed since the ANDA was submitted. Put another way, forfeiture occurs if: 1) every patent as to which the first applicant filed a paragraph IV certification has been declared invalid or not infringed in a final court decision, and 75 days have elapsed since the last such

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[42] See the Federal Trade Commission Study, "Authorized Generics: An Interim Report, 2009 WL 1847678 (June 2009) (discussing AG drugs). The FTC Interim Report found that "[b]etween FY2004-FY2008, 76 final patent settlement agreements were with first-filer generics. About one-quarter (20 out of 76) of those patent settlements involved (1) an explicit agreement by the brand not to launch an AG to compete against the first filer, combined with (2) an agreement by the first-filer generic to defer its entry past the settlement date by, on average, 34.7 months. With regard to these twenty settlements, branded sales of the affected products ranged from $12.6 million to $5.3 billion, with an average market size of $917 million and a median market size of $514 million. Five of the settlements covered products with annual sales of $1 billion, $1.1 billion, $2.1 billion, $2.5 billion, and $5.3 billion." See Asim Varma, Son B. Nguyen and Justin P. Hedge, The FTC Reports on Follow-On Biologics and Authorized Generics: Applying Lessons from Hatch-Waxman to Promote Competition, Antitrust Vol. 24, No.1 at 41 - 42 (Fall, 2009) (addressing two reports issued by FTC). See also J. Thomas Rosch, Federal Trade Commission, Pay-For-Delay Settlements, Authorized Generics, and Follow-on Biologics: Thoughts on the [sic] How Competition Law Can Best Protect Consumer Welfare in the Pharmaceutical Context, 2009 WL 4047975, (November 19, 2009) (presented at the World Generic Medicine Congress by an F.T.C. Commissioner).

[43] See also David E. Korn, Erika Lietzan & Shaw W. Scott, A New History and Discussion of 180-Day Exclusivity, 64 Food & Drug L.J. 335 at 348 ("After a triggering event occurred, the first generic would be permitted to waive its rights in favor of another company. FDA noted that waiver can be particularly useful when a subsequent generic wins its patent suit with the innovator before the first generic's suit goes to trial. Prior to the triggering event, however, the first generic could not waive its exclusivity rights. It could relinquish its rights--waive its exclusivity entirely--permitting FDA to approve all subsequent ANDAs, but it could not sell the exclusivity term to a particular generic manufacturer. FDA withdrew its proposed regulations in 2002, but confirmed this position two years later in response to a Pfizer citizen petition.").

> decision; *and* 2) 30 months have elapsed since the ANDA was submitted *or* FDA has granted final approval to the ANDA, and 75 days have elapsed since that approval was effective.

David E. Korn, Erika Lietzan & Shaw W. Scott, A New History and Discussion of 180-Day Exclusivity, 64 Food & Drug L.J. 335 at 362 (emphasis added).[44]

An ANDA, itself, can be transferred on a stand-alone basis from the original sponsor (entity that submitted the application for the ANDA) or current ANDA holder to another,[45] provided the requirements of 21 C.F.R. § 314.72 are met.

§ 3. Post Approval Maintenance of NDAs and ANDAs

Once an NDA or ANDA is approved, the holder of both types of approved applications is still subject to numerous FDA requirements in order to retain the right to market and sell the approved drug. But cf. Pliva v. Mensing, 131 S. Ct. 2567 (2011), *rehearing denied by*, 132 S. Ct. 56 (U.S. Aug. 15, 2011)(NDA holder not ANDA holder is responsible for labeling changes to warn of potential adverse consequences based on preemption).

If the FDA requirements to maintain approval are not met, the NDA and ANDA will no longer be effective.[46]

Some of the FDA-imposed requirements to maintain FDA approval are in 21 C.F.R. § 314.80 (2009), Postmarketing Reporting of Adverse Drug Experiences,[47] which requires that the applicant/holder[48] shall, *inter alia*:

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[44] The definition of court for the 180-day trigger remain "the court that enters final judgment from which no appeal can be or has been taken." Generic Drug Entry Prior to Patent Expiration - an FTC Study, Federal Trade Commission, p. 47 (July 2002) (quoting FDA, Guidance for Industry Court Decisions, ANDA Approvals and 180-Day Exclusivity under the Hatch Waxman Amendments to the Federal Food, Drug and Cosmetic Act (Mar., 2000)) (distinguishing the definition 'court' for the 30-month stay and for the 180-day exclusivity).

[45] "An applicant may transfer ownership of its application. At the time of transfer the new and former owners are required to submit information to the Food and Drug Administration . . . . " 21 C.F.R . § 314.72(a).

[46] See generally 21 C.F.R. § 314.150 (describes the instances in which the FDA will withdraw an approval of an NDA or an ANDA); See also 21 U.S.C.§ 355(k)(1)(2010) (states, in part, that the applicant must maintain records and reports of data relating to the clinical experience and other data or information received or obtained by the applicant with respect to such drug, and that these records may be reviewed to determine if there are grounds to invoke 21 U.S.C. § 355(e)); and 21 U.S.C. § 355(e), in which details the grounds for withdrawing the approval of either an NDA or ANDA, including scientific data showing the drug is unsafe for use under the conditions of use for which the application was approved, that the application contains untrue statements of material fact, that the applicant has failed to maintain a system of required records, or that the methods used in or the facilities and controls used for the manufacture, processing and packing of such drug are inadequate to assure and preserve its identity, strength, quality and purity or the labeling of such drug is false or misleading.

1. "[D]evelop written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA." 21 C.F.R. § 314.80(b) (2009);

2. "[R]eport each adverse drug experience that is both serious and unexpected, whether foreign or domestic, as soon as possible but in no case later than 15 calendar days of initial receipt of the information . . . ." 21 C.F.R. § 314.80(c)(1)(i) (2009);

3. "[P]romptly investigate all adverse drug experiences that are the subject of these postmarketing 15-day Alert reports and shall submit follow up reports within 15 calendar days of receipt of new information or as requested by FDA." 21 C.F.R. § 314.80(c)(1)(ii) (2009);

4. "[R]eport each adverse drug experience not reported under paragraph (c)(1)(i) of this section at quarterly intervals, for 3 years from the date of approval of the application, and then at annual intervals . . . Upon written notice, FDA may extend or reestablish the requirement that an applicant submit quarterly reports, or require that the applicant submit reports under this section at different times than those stated." 21 C.F.R. § 314.80(c)(2)(i) (2009); and

5. Provide "[a] 15-day Alert report based on information from the scientific literature . . ." 21 C.F.R. § 314.80(d)(1) (2009).

More examples of the FDA-imposed requirements can be found in 21 C.F.R. § 314.81 (2009), Other Postmarketing Reports, which requires the ANDA holder to provide, *inter alia*:

1. "Information concerning any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article." 21 C.F.R. § 314.81(b)(1)(i) (2012);

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[47] "Except as provided in paragraph (b) of this section, each 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 shall 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 (c) (emphasis added).

[48] 21 C.F.R. § 314.80(c)(1)(iii)(2009) clarifies that the requirements "shall also apply to any person other than the applicant (nonapplicant) whose name appears on the label of an approved drug product as a manufacturer, packer, or distributor." This summary does not address to what extent, if any, the applicant also has continuing responsibilities after it has sold or otherwise transferred its FDA-approved application to a third party.

2. "Information concerning any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in the distributed drug product, or any failure of one or more distributed batches of the drug product to meet the specification established for it in the application." 21 C.F.R. § 314.81(b)(1)(ii) (2012);

3. An annual report that must include, *inter alia*:

   a. "A brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product. The report is also required to contain a brief description of actions the applicant has taken or intends to take as a result of this new information, for example, submit a labeling supplement, add a warning to the labeling, or initiate a new study." 21 C.F.R. § 314.81(b)(2)(i) (2012).

   b. "Information about the quantity of the drug product distributed under the approved application . . . " 21 C.F.R. § 314.81(b)(2)(ii)(a) (2012);

4. Reports are also required on, *inter alia*:

   a. "Currently used professional labeling, patient brochures or package inserts (if any), and a representative sample of the package labels." 21 C.F.R. § 314.81(b)(2)(iii)(a) (2012).

   b. "[C]hanges in labeling that have been made since the last report listed by date in the order in which they were implemented, or if no changes, a statement of that fact." 21 C.F.R. § 314.81(b)(2)(iii)(c) (2012); and

5. Requirements to "submit specimens of mailing pieces and any other labeling or advertising devised for promotion of the drug product at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product. " 21 C.F.R. § 314.81(b)(3)(i) (2012).

See Karen L. Drake, FDA Regulation of the Advertising and Promotion of Prescription Drugs, Biologics, and Medical Devices, FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices and Biologics, 267-287 (Douglas J. Pisano and David S. Mantus, eds., 2nd Ed., 2008).

The FDA approval letter for an ANDA may subject the approval to additional requirements that must be met to maintain the ANDA, such as specific procedures for manufacturing.[49] In addition, the ANDA holder must follow the FDA's rules on good

[49] See http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm (search by ANDA or NDA number to find approval letters that are online) (last visited on June 2, 2011).

manufacturing practices and allow FDA inspections of the manufacturing facilities. See Bob Buckley and Robert Blanks, Overview of the GxPs for the Regulatory Professional, FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices and Biologics, 213-266. (Douglas J. Pisano and David S. Mantus, eds., 2nd Ed., 2008) (Summarizing numerous requirements, with citations).