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Memorandum

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

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

LEGEND

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

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

ISSUES

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

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

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

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

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

CONCLUSIONS

1. Where a drug manufacturer files an ANDA with a ¶ IV certification, the legal fees the drug manufacturer incurs to defend against a 35 U.S.C. § 271(e)(2) patent infringement suit are required to be capitalized under § 263(a) of the Code and §§ 1.263(a)-4(d)(5) and 1.263(a)-4(b)(1)(v) of the regulations.

2. The legal fees incurred for regulatory matters before the FDA in connection with obtaining an FDA-approved ANDA with a ¶ IV certification are required to be capitalized under § 263(a) of the Code and §§ 1.263(a)-4(d)(5) and 1.263(a)-4(b)(1)(v) of the regulations.

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

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

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

FACTS

1. **Taxpayer's Business**

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

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

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

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

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

Whether the fees must be capitalized, rather than

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

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

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

2. Sales of New Drugs in the United States

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

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

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

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

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

A. Innovator Drugs

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

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

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

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

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

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

[9] 35 U.S.C. § 154(a)(1).

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

B. Generic Drugs

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

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

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[11] Id.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Paragraph II: The original patent has expired.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4. Litigation, and Filings

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

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

A. Year Five Lawsuit

i. Complaint

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

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[29] Id.

[30]

[31]

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[35]

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

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

The prayer for relief requested that:

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

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38 Id.

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

[45]

, Year Five, G filed its Answer,

- [46]
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[47]

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

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- The 'C Patent would not be infringed by commercialization of G's generic version of Drug B.[49]
- The 'D Patent would not be infringed by commercialization of G's generic version of Drug B [50]
- The 'D and 'C Patents are invalid .[51]
- [52]
- [53] :
-

For the 'D Patent, G relied solely on invalidity; but, for the 'C Patent, G relied on invalidity and non-infringement.

G's prayer for relief requested that:

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

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

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

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59 Id.

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[60]

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[61]

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[62]

[63]

[64]

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[60]

[61] Id.

[62] Id.

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[64]

ii. Amended Complaint[65]

The amended complaint mirrored the complaint,

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

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- [77]

- [78]

[79]

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

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

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[84]

[85]

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,[86] ,[87] [88]

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

[90] :

1. ;

2. ,

3. .[91]

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

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

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

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

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[86]

[87]

[88]

[89]

[90]

[91]

[92] Id.

[93]

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G

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

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

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C. Year Six and Year Seven Proceedings

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, Year Seven, B filed amendments

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D. **Year Seven Lawsuit**

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

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

[108]

[109]

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

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

B's prayer for relief requested

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

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

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

- [116]

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G
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, requested the Court:[120]

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

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- ; and
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B did not raise any new claims.

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

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

G , pointing out it spent over in discovery

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

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144 Id.

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[160]

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

E. Year Nine Lawsuit

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

[162]

[163]

[164]

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

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

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[160]

[161]

[162]

[163]

[164]

[165]

[166] Id.

[167]

.[168]

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

TAXPAYER'S POSITION

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

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

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

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170 Id.

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

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

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

COMMISSIONER'S POSITION

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

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