

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

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date: September 14, 2011

to: Technical Advisor
(Pharmaceuticals and Biotech)

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

subject: Attorney Fees Incurred to Defend Against Patent Infringement Claims and to Investigate Patents

This memorandum responds to your request for assistance. This advice may not be used or cited as precedent.

LEGEND

Corporation X =
Corporation Y =
Corporation Z =
Entity Y =
Entity Z =
ANDA One =
ANDA Two =
ANDA Three =
License Y =
License Z =
Drug #1 =
Drug #2 =
Drug #3 =
Drug #4 =
IDR #1 =

IDR #2 =

ISSUES

1. Whether attorney fees must be capitalized pursuant to I. R.C. § 263 when incurred to defend actions for patent infringement pursuant to 35 U.S.C. § 271(e)(2) for filing Abbreviated New Drug Applications (ANDAs) with the Food and Drug Administration (FDA) to obtain FDA approval to commercialize generic drugs before the expiration of the listed patents.
2. Whether attorney fees must be capitalized pursuant to I.R.C. § 263 when incurred for investigatory patent research relative to certifications to the FDA on the scope and validity of the patents in ANDAs with paragraph IV certifications.

CONCLUSIONS

1. The attorney fees incurred to defend actions for patent infringement pursuant to 35 U.S.C. § 271(e)(2) for submitting ANDAs to market and sell generic drugs before the expirations of the listed patents must be capitalized.
2. The attorney fees incurred for investigatory patent research relative to filing ANDAs before the expiration of the patents must be capitalized.

The questions posed with respect to cost recovery of the capitalized attorney fees will be addressed in a separate memorandum.

FACTS

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Legal Fees Incurred

Corporation X's Position

Corporation X asserts all litigation fees are deductible as ordinary business expenditures under IRC. § 162, with Treas. Reg. §1.263(a)-4(d)(9) not applicable because "Corporation X did not hold, nor was it seeking title to [,] any intangible as part of the litigation process." Corporation X's Response to Question 1, IDR #1.

Corporation X further asserts¹⁵ (footnotes in original, renumbered to be consecutive within this document):

The legal expenses and costs of defending a lawsuit can be deducted by a corporation conducting a trade or business if the suit arises in the ordinary course of the business.¹⁶ In Industrial Aggregate, the taxpayer-lessee was sued by its landlord for allegedly violating terms of the operating covenants. The U.S. Court of Appeals ruled that although the suit involved the taxpayer's title to a lease extension, the primary purpose of the suit was to collect damages for that taxpayer's alleged violation of the operating covenants of the lease. As such, the professional fees incurred in the suit were deductible. In Corporation X's case, the primary purpose of Corporation Y's lawsuit was to attempt to defend its own exclusivity over the Drug #1 and Drug #2 products. As the primary purpose of the suit surrounded the validity of Corporation Y's exclusivity, the professional fees incurred by Corporation X to defend against this exclusivity should not fall under the purview of §1.263(a)-4(d)(9).

Lawsuits brought about by the brand Company are a regular occurrence in the pharmaceutical industry, and as such, the professional fees related to this litigation should be deductible. In Urquahart [sic] v. Commissioner¹⁷, the Court held that the legal expenses incurred in an infringement litigation suit were directly connected to and 'peculiarly normal' to the taxpayer's business and were therefore deductible. In its litigation with Corporation Y, Corporation X was neither seeking to create or acquire an intangible, but rather was attempting to demonstrate that it had not infringed in any of the brand company's patents.

Generally, an expenditure must be "directly connected" with, have "proximately resulted from," the taxpayer's trade or business activity in order to be deductible under § 162. The Supreme Court first considered the causation question in Kornhauser v. U.S., 276 U.S. 145 (1928) which involved the deductibility of legal and accounting fees incurred by the taxpayer in defending against a suit brought by the taxpayer's former partner after the partnership dissolved. The

¹⁵ While Corporation X's position is stated with respect to the Corporation Y litigation, it is understood that the position applies to all legal fees the subject of this advice.

¹⁶ "See e.g. Industrial Aggregate Co. v. US, 284 F.2d 639 (8th Cir. 1960) (fees paid in defense of action by taxpayer's landlord alleging breach of operating covenants of four leases were deductible because they arose in ordinary course of business)." (id., quoting n.1)

¹⁷ "Urquahart [sic] v. Commissioner, 215 F. 2d 17 (3d Cir. 1954)." (id., quoting n.2)

Supreme Court held that it did not matter that the suit was not brought until after the partnership had terminated; the suit was still "directly connected with" or "proximately resulted from" the business. Therefore, the attorneys' fees in question were currently deductible. In Corporation X's case, the professional fees incurred with respect to the Corporation Y lawsuit were directly tied to Corporation X's core business. The Company's ability to defend its position that it is not infringing on existing patents is part of its normal course of business, and as such, the expenditures shall be deductible under IRC §162 (a).

Corporation X's Response to IDR #1 (emphasis added).

In its response to Question 1, IDR #2, Corporation X stated that the litigation fees were "costs primarily associated with litigation to protect profits Corporation X would receive from the sales of the future products." (emphasis added) Corporation X stated relative to the Development/Pre-filing Investigation fees that "[t]his category represents costs for the pre-filing research and documentation of non-infringement positions with respect to the formulation of the drugs that the Company was developing and does not contribute to the ANDA being filed." Corporation X did not provide any other facts relative to these fees. Corporation X has not raised any other arguments to support deducting, rather than capitalizing, the attorney fees.

LAW AND ANALYSIS

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

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

503 U.S. at 84 (1992) (citations omitted, emphasis added).

The Indopco Court, in holding the expenditure at issue was not deductible, rejected the argument that the expenditure could be deducted because it did not create or enhance a separate asset, clarifying its opinion in Commissioner v. Lincoln Savings & Loan Ass'n, 403 U.S. 345 (1971), as follows:

Nor does our statement in Lincoln Savings that “the presence of an ensuing benefit that may have some future aspect is not controlling” prohibit reliance on future benefit as a means of distinguishing an ordinary business expense from a capital expenditure. Although the mere presence of an incidental future benefit - “some future aspect” - may not warrant capitalization, a taxpayer's realization of benefits beyond the year in which the expenditure is incurred is undeniably important in determining whether the appropriate tax treatment is immediate deduction or capitalization.

Indopco, 503 U.S. at 87 (citations and footnote omitted)(emphasis added).

Accordingly, based on general capitalization principles articulated in Lincoln Savings and Indopco, an expenditure that creates or enhances a separate and distinct asset is capitalizable, but the expenditure may still be capitalizable even if it does not create or enhance a separate and distinct asset.

Determining whether the expenditures at issue must be capitalized as within I.R.C. § 263 (rather than deducted under § 162¹⁸ or excluded from capitalization under I.R.C. § 174¹⁹) requires a two step analysis. In the first step, addressed in Section I, below,

¹⁸ I.R.C. § 162(a) allows a deduction for ordinary and necessary expenses paid or incurred during a taxable year in carrying on a trade or business. “To qualify as an allowable deduction under § 162(a), an item must be: (1) ‘be paid or incurred during the taxable year’; (2) be for ‘carrying on any trade or business’; (3) be an ‘expense’; (4) be a ‘necessary’ expense; and (5) be an ‘ordinary expense’.” Commissioner v. Lincoln Savings & Loan Ass'n, 403 U.S. 345, 352 (1971) (citations omitted). However, the Lincoln Savings Court cautioned that “[i]t is not enough, in order that an expenditure qualify as an income tax deduction, that it merely be . . . paid by all similarly [situated taxpayers], or that it serves to fortify . . . purpose and operation.” 403 U.S. at 354. The Court then held that the expenditure at issue was not deductible as an ordinary and necessary business expense because it created or enhanced an “additional asset and that, as an inevitable consequence, the payment is capital in nature.” 403 U.S. at 354 (emphasis added).

¹⁹ 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 Corporation X'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 (paragraph IV certifications are explained in Addendum A) 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

the origin of the claim test must be applied, considering the relevant facts and circumstances. A key fact is that the attorney fees at issue were incurred to obtain the right to market and sell new generic drugs in the United States. An overview of the statutes, regulations, and case law that governs obtaining the right to market and sell new generic drugs in the United States is set forth in Addendum A, attached hereto and incorporated herein. In the second step, addressed in Section II, below, whether the fees are within § 263 must be analyzed, specifically considering the 2004 capitalization of intangibles regulations.²⁰

Section I. Origin of the Claim

The characterization of the attorney fees at issue as deductible expenses within I.R.C. § 162 or as capital expenditures within I.R.C. § 263 must first be analyzed using the origin of the claim test. United States v. Gilmore, 372 U.S. 39, 49 (1963) (“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. . .”). See Deputy v. DuPont, 308 U.S. 488, 494 (1940) (“It is the origin of the liability out of which the expense accrues which is material.”)

In Woodward v. Commissioner, 397 U.S. 572 (1970), the Supreme Court explained that:

A standard based on the origin of the claim litigated comports with this Court's recent ruling on the characterization of litigation expenses for tax purposes in United States v. Gilmore, 372 U.S. 39, 83 . . . (1963). This court there held that the expense of

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]”). At no time has Corporation X contended the fees addressed herein are within § 174.

²⁰ Due to the “difficulty of translating general capitalization principles into clear, consistent and administrative standards,” the capitalization of intangibles regulations were drafted because “much of the uncertainty and controversy *** has related to expenditures that create or enhance intangible assets or benefits.” Announcement 2002-9, 2002-1 C.B. 536. To reduce this uncertainty and controversy, for a specifically delineated subset of expenditures (*i.e.*, expenditures not within the scope of the intangible regulations), capitalization will not be proposed solely on the grounds that the intangible asset has a significant future benefit until further guidance is published. 2004-1 C.B. 447, T.D. 9107, § II.A., General Principle of Capitalization. The regulations did not reverse the norm of capitalization; the subset of expenditures that are not within the regulations is limited given the breadth and depth of the regulations. Moreover, the preamble to the 2004 capitalization of intangible regulations clearly states that “[t]he IRS and Treasury Department intend to construe broadly the categories of intangibles identified in the regulations in response to any narrow technical arguments that an intangible created by the taxpayer is not literally described in the categories.” T.D. 9107, 2004-1 C.B. 447 § II. D. Created Intangibles.

defending a divorce suit was a nondeductible personal expense, even though the outcome of the divorce case would affect the taxpayer's property holdings, and might affect his business reputation. The Court rejected a test that looked to the consequences of the litigation, and did not even consider the taxpayer's motives or purposes in undertaking defense of the litigation, but rather examined the origin and character of the claim against the taxpayer, and found that the claim arose out of the personal relationship of marriage.

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

In accord, United States v. Hilton Hotels Corp., 397 U.S. 580, 583 (1970) (“As we held in Woodward, supra, the expenses of litigation that arise out of the acquisition of a capital asset are capital expenses, quite apart from whether the taxpayer’s purpose in incurring them is the defense or perfection of title to property.”); McKeague v. United States, 12 Cl. Ct. 671, 675 (1987) aff’d without published opinion, 852 F.2d 1294 (Fed. Cir. 1988) (the objective in the origin of the claim test is “to find the transaction or activity from which the taxable event approximately resulted”); American Stores v. Commissioner, 114 T.C. 458, 470 (2000)(reiterates that the primary purpose test has been rejected, and states the “nature of the transaction out of which the expenditure in controversy arose governs ... regardless of the motives”); 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); Keller Street Development Company v. Commissioner, 688 F. 2d 675, 678, 680 (9th Cir. 1982)(the origin of the claim is not “based on the consequences to the taxpayer” and does not look to the primary purpose).

In general, the above cases establish that, in applying the origin of the claim test, the purpose, consequence, or result is irrelevant. 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 or subjective motives. The intangible regulations, Treas. Reg. §1.263(a)-4, also provide that determinations of whether to capitalize should be made taking into account all of the facts and circumstances, disregarding distinctions between labels. Treas. Reg. §1.263(a)-4(d)(1).

A. Applying the Origin of the Claim Test to the Facts

Before the infringement suits at issue were filed, Corporation X notified²¹ the New Drug Application (NDA) holders²² for the referenced drugs²³ and the patentees for the listed

²¹ Notifications are required by law, as explained in Addendum A, which summarizes the statutory and regulatory regime governing the marketing and selling of new drugs in the United States.

patents²⁴ that Corporation X had filed applications with the Federal Food and Drug Administration (FDA) to obtain the right to market and sell its new generic drugs before the expiration of their listed patents.²⁵ The notifications specifically stated Corporation X had filed Abbreviated New Drug Applications (ANDAs) with paragraph IV certifications,²⁶ certifying that the listed patents were either invalid or not infringed by Corporation X's new generic drugs. To support its good faith in certifying that the patents were invalid or not infringed, Corporation X paid patent attorneys to research the listed patents for the referenced drugs.

For each drug, in each notification letter, Corporation X detailed its grounds for contending the listed patents were not infringed. Additionally, in each notification letter, Corporation X specifically reserved the right to assert the patents were invalid if the NDA holders or patentees brought infringement suits. Each lawsuit filed against Corporation X was filed within 45 days of receiving Corporation X's notification letters, the time period for commencing suit for the NDA holders to obtain a 30-month stay. The stay precludes the FDA from approving Corporation X's ANDAs for 30 months unless Corporation X prevails in the infringement litigation. On an ANDA-by-ANDA basis, if no infringement suits had been filed within the 45 day window, subject to confirming bioequivalence,²⁷ the FDA could have immediately approved Corporation X's ANDAs.

Each law suit asserted infringement pursuant to 35 U.S.C. § 271(e)(2). As explained further in Addendum A, 35 U.S.C. § 271(e)(2) creates an artificial act of infringement, making the filing of an ANDA with a paragraph IV certification an act of infringement. Each and every claim of infringement in the law suits at issue relied upon 35 U.S.C. § 271(e)(2) for the asserted acts of infringement. An infringement claim based on 35 U.S.C. § 271(e) has limited remedies, which do not include an award of lost profits. See Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676 (1990) ('The remedies prescribed by [35 U.S.C. §271(e)(4)] subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in

²² The term "NDA holders" is explained in Addendum A.

²³ The term "referenced drug" is defined and explained in Addendum A.

²⁴ The term "listed patents" is defined and explained in Addendum A.

²⁵ It is noted that Corporation X could have waited until the patents expired since, as explained in Addendum A, there are four different types of certifications to seek approval to market and sell generic drugs in the United States, with only a paragraph IV certification a direct challenge to the validity or scope of the listed patents for the referenced drugs. See 21 USC § 355 (j)(2)(A)(vii)(2010) (quoted in Addendum A).

²⁶ The term "paragraph IV certification" is further explained in Addendum A.

²⁷ The term "bioequivalence" is defined in Addendum A.

paragraph 2, except that a court may award attorney fees under [35 U.S.C.] section 285.”²⁸

Thus, other than an award of fees and costs pursuant to 35 U.S.C. § 285 for an exceptional case (e.g., frivolous paragraph IV certification or trial misconduct),²⁹ the potential statutory remedies available to the plaintiffs, given their infringement actions were based on 35 U.S.C. § 271(e)(2), were 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.³⁰

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.

²⁸ The current statute includes subparagraph (d) relative to biologics, as discussed below.

²⁹ 35 U.S.C. § 285 provides that “The court in exceptional cases may award reasonable attorney fees to the prevailing party. See Glaxo Group Limited v. Apotex, Inc., 376 F.3d 1339 (Fed. Cir. 2004) (addressing exceptional cases). See also Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc., 459 F.Supp.2d 227, 245-252 (S.D.N.Y. 2006) (“Sanctions Opinion”) and 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. 2009), cert. denied 130 S. Ct. 106 (2009) (attorneys fees awarded for bad faith filing of the Paragraph IV certification and misconduct during litigation).

³⁰ See Addendum A, footnote 66 (status of amendments enacted as part of the 2010 health care reform).

none of the complaints alleged loss of profits.³¹

Corporation X, in each law suit, in addition to denying its ANDA products would infringe the patent claims that the plaintiffs alleged would be infringed:

- denied that the patent claims that the plaintiffs alleged would be infringed were valid;
- asserted affirmative defenses that the patent claims that the plaintiffs alleged would be infringed were invalid; and
- counterclaimed that the patent claims the plaintiffs alleged would be infringed were invalid.

Corporation X's prayers for relief requested that the patent claims at issue, which plaintiffs alleged were infringed by Corporation X filing the ANDAs, be declared invalid.

Thus, the pleadings were joined on the issues of infringement and validity.

³² none of the claims included in the lawsuits filed against Corporation X, and none of Corporation X's counterclaims, arose from a cause of action other than the

³¹ Corporation X had not commercialized the products the subject of the ANDAs in the United States; it had merely filed ANDAs with paragraph IV certifications.

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filing of the ANDA pursuant to 35 U.S.C. § 271(e)(2).³³ Corporation X's ANDAs, like all ANDAs, are assets that can be transferred on a stand-alone basis from one ANDA holder to another ANDA holder.³⁴

Based on the facts and circumstances of this case it is clear that the infringement litigation originated from Corporation X's actions to obtain assets, FDA-approved ANDAs, which can be sold or used in its trade or business until such time, if ever, the FDA withdraws its approval of the ANDAs.³⁵ Approval can be withdrawn if the ANDA holder fails to comply with the requirements for keeping the ANDA effective or if, for example, there are adverse reactions to the generic product that would cause the FDA to withdraw its approval. See Addendum A, last 3 pages (addressing requirements imposed by statute and regulation on an ANDA holder). Accordingly, the character of the claims is capital since all claims are proximately related to, and have a direct nexus

³³ If the claims in the litigation pleading were not all the same, each claim would need to be considered separately, applying the origin of the claim test on a claim-by-claim basis. See Dye v. United States, 121 F.3d 1399, 1406 (10th Cir. 1997) ("Where, as here, the litigation involves more than one claim, "the origin [of the claim] test must be applied separately to each part.") The Dye Court noted that different appellate courts have different positions on how attorney fees should be allocated among claims. 121 F.3d at 1410. The Dye Court contrasted the Federal Circuit position with the 9th Circuit stating that in Baylin v. United States, 43 F.3d 1451, 1453 (Fed.Cir.1995), the Federal Circuit allocated "legal expenditures . . . according to the approximate proportion of the lawyers' efforts attributable to the pursuit of each claim." The Ninth circuit "by contrast, has rejected an approach similar to that of the Baylin court, 'because it ignores the contingent fee portion of the taxpayers' contract with their lawyers, and allocates fees only on the basis of the hourly rate portion of the contract.' Leonard v. Commissioner, 94 F.3d 523, 526 (9th Cir.1996)." Thus, if allocations of the fees were necessary, the current position of the relevant circuit courts would need to be considered in the allocation.

³⁴ "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).

³⁵ While Corporation X asserts that it did not hold title to an intangible and was not seeking title to an intangible (Facts, above, subsection titled "Corporation X's Position"), as a matter of fact, there can be no doubt that Corporation X was in the process of trying to obtain FDA approval of its ANDAs, with the ANDAs the abbreviated applications with paragraph IV certifications that Corporation X prepared and filed with the FDA. Corporation X was the holder (owner) of the ANDAs that it prepared and filed. See Addendum A (addressing the term "holder"). If Corporation X is arguing that it was not seeking title to the ANDAs since it owned the applications it had prepared *ab initio*, the argument must fail as mere sophism.

with, Corporation X's actions to obtain new assets, *i.e.*, FDA-approved ANDAs with paragraph IV certifications.

Just the recital of the facts and circumstances, including the fact that an ANDA is a transferrable commodity, provides an "adverse answer" to Corporation X's position that it can deduct the fees. See Lincoln Savings, 403 U.S. 345 at 354 (holding the expenditure at issue was not deductible as an ordinary and necessary business expense because it created or enhanced "an additional asset and that, as an inevitable consequence, the payment is capital in nature").³⁶

B. Corporation X's Reliance on the Primary Purpose Test

Corporation X argues that it can deduct the fees based on the primary purpose test. Corporation X relies on Industrial Aggregate Company v. United States, 284 F.2d 639 (8th Cir. 1960), which predates Gilmore, Woodward and Hilton Hotels. The primary purpose test used in Industrial Aggregate has been rejected by a long line of court cases, with some of said cases string cited at the beginning of Section I of the Law and Analysis, above. Corporation X may have a primary purpose of increasing its long term income, but that is a potential consequence to Corporation X's fortunes, and does not control. See United States v. Gilmore, 372 U.S. 39, 49 (1963) ("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 . . ."). See also Woodward v. Commissioner, 397 U.S. 572, 578 (1970) ("The [Gilmore] Court rejected a test that looked to the consequences of the litigation, and did not even consider the taxpayer's motives or purposes in undertaking defense of the litigation, but rather examined the origin and character of the claim against the taxpayer, and found that the claim arose out of the personal relationship of marriage.").

Corporation X also relies on Kornhauser v. United States, 276 U.S. 145 (1928), to support its position that it can deduct the expenditures because ANDA paragraph IV litigation is common in the generic pharmaceutical industry. First, it is well established that capital expenditures are not deductible merely because many members of an industry have the same capital expenditures. See Commissioner v. 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 merely be . . . paid by all similarly [situated taxpayers], or that it serves to fortify . . . purpose and operation."). See also Lychuk v Commissioner, 116 T.C. 374, 393-416 (2001)(analyzing case law establishing that expenditures are not *ipso facto* deductible because they are routine, recurring expenses

³⁶ The payment at issue in Lincoln Savings was the additional premium paid to the Federal Savings and Loan Insurance corporation (FSLIC) for a secondary reserve maintained by the FSLIC, with Lincoln Savings pro rata share transferable and refundable under certain circumstances, one of the key facts for treating the secondary reserve expenditure as paid to create or enhance an asset.

of a business).³⁷ Second, the attorney fees at issue in Kornhauser were incurred in the defense of a suit for an accounting of businesses earnings, a quintessential 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").³⁸

Corporation X also alleges that it incurred the fees at issue "to protect profits Corporation X . . . would receive from the sales of the future products." Response to IDR #12 (emphasis added). Obliquely Corporation X is, in effect, admitting that the ANDAs, once obtained, will be assets that will generate profits in the future. Thus, costs to create or enhance the ANDAs are within § 263, as addressed in Section II.

Section II. § 263(a) and the 2004 Capitalization of Intangible Regulations

There is no overall definition of "intangible" in the capitalization of intangibles regulations. As explained in the preamble to the 2004 capitalization of intangibles regulations: "The final regulations eliminate the use of, and the definition of, the term 'intangible asset' that was contained in the proposed regulations. This change was made in an effort to aid readability. The final regulations simply identify categories of 'intangibles' for which amounts are required to be capitalized." T.D. 9107, 2004-1 C.B. 447, § II.A., General Principle of Capitalization.

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)³⁹;

³⁷ 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 minimis transaction costs, expenditures not addressed in this advice. The current position of the Commissioner on capitalization is set for the capitalization of intangible regulations as in effect for the years at issue, regulations that were originally promulgated in 2004, T.D. 9107, 2004-1 C.B. 447.

³⁸ Urquhart v. Commissioner, 215 F.2d 17 (3rd Cir. 1954) and Corporation X's arguments relative Treas. Reg. § 1.263(a)-4(d)(9) are addressed in footnote 60, below.

³⁹ 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

- (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; [⁴⁰] and
- (v) An amount paid to facilitate (within the meaning of paragraph (e)(1) of this section) an acquisition or creation of an intangible described in paragraph (b)(1)(i), (ii), (iii) or (iv) of this section.

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

Thus, rather than providing an overall definition of intangibles, 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 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, taking into account the facts and circumstances of each case. T.D. 9107, 2004-1 C.B. 447, § II. D.

Considering the facts and circumstances of this case, and the intangible regulations as a whole, the professional fees at issue are clearly within one or more of the identified categories of expenditures that must be capitalized. At a minimum, the amounts were

pharmaceutical company for consideration. In Media Space Inc. v. Commissioner, 135 T.C. 424, 440-441 (2010), after finding that the intangibles at issue were not, in substance, exchanged (as argued by the government), the Court found that Treas. Reg. § 1.263(a)-4(c)(1) did not apply because there was no exchange. There was no purchase based on the facts; however, the Court did not define “purchase or similar transaction.”

⁴⁰ To date, no guidance has been published requiring the capitalization of expenditures with respect to intangibles not within the capitalization of intangible regulations that must be capitalized based solely on future benefit.

paid to facilitate the creation of intangible assets and/or paid to create, facilitate or enhance separate and distinct intangibles,⁴¹ as addressed in the below subsections.

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 below, amounts paid to obtain ANDAs are paid to create intangibles within the meaning of the -4(d) regulations on created intangibles, with the professional fees at issue paid to facilitate the creation of said ANDAs.

The -4(d) regulations (created intangibles), in subsection (5)(i), require the capitalization of amounts paid to obtain rights from a government, treating such payments as paid to create an intangible. Specifically, the -4(d) regulations provide, 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.

Treas. Reg. § 1.263(a)-4(d)(5)(i)(emphasis added).

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).

⁴¹ To the extent Corporation X contends that Treas. Reg. §1.263(a)-4(d)(9) is not applicable because the FDA-approved ANDAs being created by Corporation X did not yet exist so Corporation X could not be defending or perfecting title to FDA-approved ANDAs, that is a moot issue since the fees at issue are clearly capitalizable as paid to facilitate, directly or indirectly, the creation of the ANDAs. 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* outside the scope of Treas. Reg. §1.263(a)-4(d)(9), Corporation X errs. In Urquhart, at the appellate level, it was “conceded that no question of title was involved.” 215 F.2d at 19 (emphasis added). Thus, Urquhart is the quintessential example of a case that did not involve title since it was conceded that the case did not involve title. Moreover, the joint venture that deducted the fees in Urquhart was merely protecting its earnings 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 was from collecting the royalties generated by patents it did not own. See Urquhart v. Commissioner, 20 T.C. 944, 945 (1953), rev'd, 215 F.2d 17 (3rd Cir. 1954)(“From 1942 through 1946 [the years at issue] the sole business conducted by the joint venture was the licensing of the two patents.”). Accordingly, Urquhart does not establish precedent for cases where the litigation is, in whole or part, to protect or perfect title to patents.

Specifically, 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.” For example, an ANDA is within the definition of a franchise as used in the 2004 capitalization of intangible regulations.⁴²

While none of the amounts at issue were paid to the government, the regulations specifically require costs that facilitate the creation of an intangible, such as governmental rights, to be capitalized. Treas. Reg. § 1.263(a)-4(b)(1) (iv). The regulations provide clear guidance on what type of costs are treated as facilitating the creation of intangibles as follows:

(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

⁴² While the -4(d) regulations addressing created intangibles do not define the term “franchise,” the term is defined within the capitalization of intangible regulations addressing acquired intangibles. “Franchise” for purpose of acquired intangibles has the same meaning the term is given in Treas. Reg. § 1.197-2(b)(10). Treas. Reg. § 1.263(a)-4(c)(1)(viii). Treas. Reg. § 1.197-2(b)(10) states that a “franchise has the meaning given in I.R.C. § 1253(b)(1) and “includes any agreement that provides one of the parties to the agreement with the right to distribute, sell, or provide goods, services, or facilities, within a specified area.” Treas. Reg. § 1.197-2(b)(10). Section 1253(b)(1) defines a franchise to “include an agreement which gives one of the parties to the agreement the right to distribute, sell, or provide goods, services, or facilities, within a specified area.”

Corporation X’s ANDAs fit neatly into the I.R.C. § 1253(b)(1) definition since the ANDAs give Corporation X the right to market and sell its ANDA products within the United States, a territory that encompasses the entire country. Courts have noted that Congress provided an “expansive definition” of franchise to “include” agreements to sell or distribute goods within a specified area, which does not exclude other things otherwise within the meaning of a franchise. See, e.g., Jefferson-Pilot Corp. v. Commissioner, 98 T.C. 435, 443 (1992), aff’d 995 F.2d 530 (4th Cir. 1993) (FCC licenses are agreements “between the Federal Government and the licensee, under which the licensee agrees to provide the service of radio broadcasting within a specified area in exchange for the right to broadcast”). See also, Jefferson-Pilot Corp. v. Commissioner, 995 F. 2d 530 at 531 (4th Cir. 1993)(“The definition of term ‘franchise’ is sufficiently broad to include licenses issued by the FCC.”).

That the right to market and sell came from the FDA, not the Federal Communications Commission (FCC), is a distinction without a difference – both the FDA and FCC are granting, for a territory, commercialization rights. See also Addendum A, last 3 pages (enumerating the quality controls and other restrictions imposed on the ANDA holder to retain the rights to market and sell, with the controls similar in nature to the “strings” a franchiser would retain over its franchise, e.g., quality controls). In addition, the identified categories of expenditures that must be capitalized are construed broadly, and not limited by narrow technical arguments. T.D. 9107, 2004-1 C.B. 447 § II. D. Accordingly, FDA-approved ANDAs that allow the marketing and selling of new drugs in the United States are franchises within the meaning of Treas. Reg. § 1.263(a)-4(d)(5)(i).

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.

Treas. Reg. § 1.263(a)-4(e)(1)(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).

The transactions at issue in this case, which generated the fees at issue, arose from Corporation X's filing of ANDAs with paragraph IV certifications to obtain FDA-approved ANDAs allowing Corporation X to market and sell generic pharmaceuticals in the territory of the United States prior to the expiration of the United States patents for the referenced NDA-approved drugs. Corporation X was pursuing obtaining each ANDA as part of one overall transaction for FDA approval of each ANDA to be able to market and sell the new drugs the subject of each ANDA in the United States (e.g., license, permit, franchise or similar right to market and sell its generic drugs in the United States). On an ANDA-by-ANDA basis Corporation X was seeking to obtain FDA-approved ANDAs by carrying out the series of steps required by the statutory and regulatory regime to obtain approval of its ANDAs. The steps included notifying the NDA holders and patentees of the filing of an ANDA with a paragraph IV certification, with that certification necessitating outside counsels to research the patents. Once the NDA holders and patentees filed suit, Corporation X had to defend itself to obtain FDA approval of an ANDA effective before the expiration of the patents. Accordingly, the professional fees incurred in researching the paragraph IV certifications and infringement litigation defense fees were incurred to facilitate obtaining governmental-granted rights and thus must be capitalized.

Alternatively, even if one could argue the fees did not directly facilitate obtaining the FDA-approved ANDAs, the fees would be an indirect payment relative to obtaining the ANDAs that also must be capitalized, as were the attorney fees in the following examples set forth in Treas. Reg. §1.263(a)-4(l):

(l) Examples. The rules of this section are illustrated by the following examples in which it is assumed that the Internal Revenue Service has not published guidance that requires capitalization under paragraph (b)(1)(iv) of this section (relating to amounts paid to create or enhance a future benefit that is identified in published guidance as an intangible for which capitalization is required):

Example 1. License granted by a governmental unit. (i) X corporation pays \$25,000 to state R to obtain a license to sell alcoholic beverages in its restaurant. The license is valid indefinitely, provided X complies with all applicable laws regarding the sale of alcoholic beverages in state R. X pays its outside counsel \$4,000 for legal services rendered in preparing the license application and otherwise representing X during the licensing process. In addition, X determines that \$2,000 of salaries paid to its employees is allocable to services rendered by the employees in obtaining the license.

(ii) X's payment of \$25,000 is an amount paid to a governmental unit to obtain a license granted by that agency, as described in paragraph (d)(5)(i) of this section. The right has an indefinite duration and constitutes an amortizable section 197 intangible. Accordingly, as provided in paragraph (f)(3) of this section, the provisions of paragraph (f) of this section (relating to the 12-month rule) do not apply to X's payment. X must capitalize its \$25,000 payment to obtain the license from state R.

* * *

(iv) X's payment of \$4,000 to its outside counsel is an amount paid to facilitate the creation of an intangible, as described in paragraph (e)(1)(i) of this section. Because X's transaction costs do not exceed \$5,000, X's transaction costs are de minimis within the meaning of paragraph (e)(4)(iii)(A) of this section. Accordingly, X is not required to capitalize the \$4,000 payment to its outside counsel under this section.

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

In the example quoted above, the \$4,000 paid to outside counsel was below the de minimus safe harbor so was not capitalizable. In this case, the attorney fees for each ANDA far exceed \$5,000, and must be aggregated by ANDA because the investigations and litigation fees for each ANDA were part of a series of steps in a plan to obtain an FDA-approved ANDA. Treas. Reg. § 1.263(a)-4(e)(3). Just as the license addressed in the example, Corporation X's ANDAs are effective indefinitely provided Corporation X complies with all applicable laws and regulations, and the drugs do not have adverse side effects that cause the FDA to withdraw its approval. Accordingly, the attorney fees Corporation X incurred that are the subject of this advice must be capitalized because they were incurred to facilitate, directly or indirectly, obtaining the FDA-approved ANDAs that granted Corporation X 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 the ANDAs.⁴³ While it would take an expert, the expected stream of income from each ANDA could be projected and then valued at its net present value. Accordingly, each ANDA is a separate and distinct asset with the professional fees paid to enhance or facilitate the creation of these separate and distinct assets capitalized. Treas. Reg. §§ 1.263(a)-4(b)(1)(v) and -4(b)(3)(i).

Treas. Reg. § 1.263(a)-4(e)(3) provides that a “transaction” for purposes of the -4 regulations “includes a series of steps carried out as part of a single plan.” Specifically stating that

(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).

⁴³ See generally Generic Pharmaceutical Association Providing Extraordinary Savings for Americans. <http://www.gphaonline.org/> (last visited on June 14, 2011)

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CASE DEVELOPMENT, HAZARDS AND OTHER CONSIDERATIONS

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

This writing may contain privileged information. Any unauthorized disclosure of this writing may undermine our ability to protect the privileged information. If disclosure is determined to be necessary, please contact this office for our views.

By: _____

Marjory A. Gilbert
Industry Counsel (Pharmaceuticals and Biotech)
Retailers, Food, Pharmaceuticals & Healthcare
Large Business & International
Office of Chief Counsel, IRS

Attachments: Addendum -A

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)(2010) (“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.”).⁴⁶ 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.”).

A. New Drug Application (NDA)

The 2007 Coordinated Issue Paper on taxation of drug development agreements⁴⁷ summarizes the process for developing a new (non-generic) drug for FDA approval as follows:

The pharmaceutical/biotech drug development process is generally composed of four stages: Preclinical or discovery research, clinical

⁴⁶ The Westlaw electronic research service has a red flag on 21 U.S.C. § 355 asserting that § 355 was held unconstitutional and not severable by Florida v. United States Department of Health and Human Services, 2011 WL 285683 (N.D. Fla. Jan. 31, 2011), clarified and order provisionally stayed in Florida v. United States Department of Health and Human Services, 2011 WL 723117 (N.D. Fla. March 3, 2011), aff'd in part and rev'd in part, 2011 WL 3519178 (11th Cir.) (hereinafter collectively Florida vs. HHS). Florida v HHS does not address § 355, *per se*, and does not address § 355 as in force for the years at issue. Rather, Florida v HHS addressed the 2010 health reform legislation. Specifically Florida v HHS holds unconstitutional the requirement that individuals purchase health insurance in the Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, 124 Stat. 119 (2010), as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010 (HCERA), Pub. L. No. 111-152, 124 Stat. 1029 (2010) (hereinafter collectively referred to as the ACA), with the District Court in Florida v HHS also holding the insurance requirement cannot be severed so the entire ACA is unconstitutional. However, the Eleventh Circuit reversed the District Court's severability holding and other cases have upheld the constitutionality of the minimum essential coverage requirements, including Mead v. Holder, 766 F. Supp 2d. 16, 2011 WL 611139 (D.D.C. 2011); Liberty University, Inc. v. Geithner, 753 F.Supp.2d 611, 2010 WL 4860299 (W.D.Va. 2010); and Thomas More Law Center v. Obama, 720 F.Supp.2d 882 (E.D.Mich.2010), aff'd, 2011 WL 2556039, (6th Cir. Mich.) Jun 29, 2011, Petition for Writ of Certiorari, 2011 WL 3860758 (No. 11-117) (July 26, 2011). See Congressional Research Service, Requiring Individuals to Obtain Health Insurance: A Constitutional Analysis, August 26, 2011, at 25-32 (analysis of legal challenges to the minimum essential coverage requirement). The provisions of the ACA that impact 21 U.S.C. § 355 are §§ 7002 and 10609, which amended 21 U.S.C. § 355 to add language relative to biologics and labeling, respectively. See Pub. L. No. 111-148, 124 stat. 119 at 816-817, 820, 860, and 1014-15 (2010). Neither amendment impacts the constitutionality of 21 U.S.C. § 355 as in force and effect in the years here at issue.

⁴⁷ 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.

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 non clinical 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.

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.⁴⁸ The entity that holds the rights to the NDA is sometimes referred to as the holder of the NDA. See aiPharma, 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 in the FDA-published document "Approved Drug Products With Therapeutic Equivalence Evaluations," also known as the Orange Book).

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 (2009). The FDA posts the patent information provided by the NDA holder to its publication called "Approved Drug Products With Therapeutic Equivalence Evaluations," also known as the "Orange Book," available in hard copy or electronically on the FDA website.⁴⁹

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.⁵⁰ The term "pioneer drug" was used in early case law to refer to a 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 FDA, 625 F. 3d 760, 761-62, 764 (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."). Current literature uses the term "innovator

⁴⁸ 21 C.F.R. § 314.72(a)(2009) ("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 . . .").

⁴⁹ 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).

⁵⁰ Pharmaceutical companies generally do not submit NDAs on drugs that are not, at least initially, covered by patents due to the time and expense of developing a new drug.

drug” without specifying if the term “innovator drug” means the same as “pioneer drug” or refers only to innovator drugs that have extended exclusivity.⁵¹

B. Abbreviated new drug application (ANDA)

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)).⁵² 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 bioequivalent⁵³ of the

⁵¹ Pursuant to 21 U.S.C. §355(c)(3)(E)(i)-(v)(2010) (See also § 355(j)(5)(F)(i)-(v)), certain innovative drugs with an FDA-approved NDA can be granted additional years of exclusivity (3 years for a new use or dosage based on additional clinical trials and 5 years for a new chemical entity). See Abbott Laboratories v. Young, 920 F.2d 984, 986 (D.C. Cir. 1990) (“Congress thereby sought to encourage innovation in the drug industry, by rewarding a pioneer drug with . . . exclusivity, while protecting consumers from unduly high prices by refusing to give a long period of market exclusivity to drugs which required no new research effort.”); Actavis Elizabeth LLC v. FDA, 625 F. 3d 760 (D.C. Cir. 2010)(addressing a generic drug makers challenge to the award of five years exclusivity to a branded drug). Separate statutory provisions provide for patent extensions in certain circumstances (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, Practising Law Institute, 878 PLI/Pat 939, §§ I.C.6, 7 and 8 (2006) (patent extensions and exclusivity).

⁵² 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 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.”). See footnote 66, above (constitutionality of the Patient Protection and Affordable Care Act).

⁵³ “‘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, Practising 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).⁵⁴ 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, 272 (4th Cir. 2007) (“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.

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.

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

⁵⁴ 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).

to lengthy regulatory delays and could not be marketed prior to regulatory approval.

* * *

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.

469 U.S. at 669-71 (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,⁵⁵ 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.⁵⁶ 35 U.S.C. § 271(e)(2010).

However, the “safe harbor” from infringement terminates when the ANDA is submitted to 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 (35 U.S.C. § 271(e)(2)(2010)), which has limited remedies (35 U.S.C. § 271(e)(4)).⁵⁷ 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).⁵⁸

⁵⁵ Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858 (Fed.Cir.1984), cert. denied, 469 U.S. 856 (1984).

⁵⁶ See 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).

⁵⁷ In exceptional cases, pursuant to 35 U.S.C. § 271(e)(4) attorney fees can be awarded to the NDA holder if it prevails in an infringement actions against the sponsor of an ANDA. Yamanouchi Pharmaceutical Co., Ltd. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1345-47 (Fed. Cir. 2000).

⁵⁸ The Court in Eli Lilly quoted 35 U.S.C. § 271(e)(2) and (e)(4), 496 U.S. at 675, as follows: “ (2) It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug claimed in a patent or the use of which is claimed in a patent before the expiration of such patent. * * *

* * * *

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).

The Supreme Court went on to explain, with respect to the Hatch-Waxman Act regime of exempting the use of patented inventions to develop generic drugs from infringement suits then creating an artificial act of infringement, 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,

‘(4) For an act of infringement described in paragraph (2)-

‘(A) the court shall order the effective date of any approval of the drug involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been in-fringed,

‘(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, or sale of an approved drug,

and

‘(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, or sale of an approved drug.

‘The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph, except that a court may award attorney fees under section 285.’ 35 U.S.C. §§ 271(e)(2), (4).

496 U.S. at 675-676 (emphasis added).

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).

By this exemption/infringement scheme/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.”).

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 USC § 355 (j)(2)(A)(vii).

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 filing⁵⁹ to the NDA holder for the referenced drug⁶⁰ and all patentees of record for the listed patents⁶¹ that the

⁵⁹ 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.

⁶⁰ 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),

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 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):

(6) 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 patents 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, 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)

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.

⁶¹ The patents in the Orange Book for the referenced drugs are referred to herein as “listed.”

However, 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 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 and 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 and Shaw W. Scott, A New History and Discussion of 180-Day Exclusivity, 64 Food & Drug L.J. 335 at 335 (2009)(emphasis added).

The first to file⁶² a substantially complete ANDA with a paragraph IV certification (subject to other requirements, including the applicable exclusivity periods granted to the FDA-approved NDA⁶³) obtains 180 days of exclusivity over other generic drug

⁶² 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).

⁶³ 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

ANDA filings.⁶⁴ 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,⁶⁵ with one view stated as follows:⁶⁶

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 pediatric drug exclusivity or new innovative drug for rare condition 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.

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”).

⁶⁴ The exclusivity does not extend to the drugs known as authorized generics (AG), “generics” that are marketed and sold pursuant to a license from an NDA holder. The Federal Trade Commission Study, “Authorized Generics; An Interim Report, 2009 WL 1847678 (F.T.C.), June 2009 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 41, 42 (Fall, 2009) (addressing two reports issued by FTC). See also “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,” by J. Thomas Rosch, Federal Trade Commission, 2009 WL 4047975, November 19, 2009 (presented at the World Generic Medicine Congress by an F.T.C. Commissioner).

⁶⁵ 64 Food & Drug L.J. at 383-385.

⁶⁶ Id. at 384 (footnotes omitted) (emphasis added).

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.

The 180-day exclusivity is transferable in certain circumstances. See Mary W. Bourke and Edward Danberg, Current Trends in Hatch-Waxman Patent Litigation: A System Still in Flux, Practising 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 [e]xclusivity periods are a transferable commodity which can be waived in favor of another generic manufacturer for a substantial price.”)(emphasis added).⁶⁷ 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 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 and Shaw W. Scott, A New History and Discussion of 180-Day Exclusivity, 64 Food & Drug L.J. 335 at 362

⁶⁷ See also David E. Korn, Erika Lietzan and 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.”).

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,⁶⁸ provided the requirements of 21 C.F.R. § 314.72 are met. The transferee is called the “holder” of the ANDA.

Many cases describe one or more aspects of the regulatory regime summarized above. See Schering-Plough Corporation v. FTC, 402 F. 3d 1056 (11th Cir. 2005);⁶⁹ Mylan Pharmaceuticals, Inc. vs. United States Food and Drug Administration, 454 F. 3d 270 (4th Cir. 2006);⁷⁰ Teva Pharmaceuticals v. Leavitt, HHS, 548 F. 3d 103 (D. C. Cir.

⁶⁸ “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).

⁶⁹ “Previously, applications for FDA approval proceeded under a new drug application (“NDA”). 21 U.S.C. § 355(b). This cumbersome and involved process required each applicant to submit safety and efficacy studies, even if it duplicated previous studies done on identical drugs with the same ingredients. In 1984, Congress passed [the] Drug Price Competition and Patent Term Restoration Act (the “Hatch-Waxman Act”), Pub. L. No. 98-417, 98 Stat. 1585 (1984). The purpose of the Hatch-Waxman Act was threefold: (1) to reduce the average price paid by consumers; (2) preserve the technologies pioneered by the brand-name pharmaceutical companies; and (3) create an abbreviated new drug application (“ANDA”) to bring generic drugs to the market.” 402 F.3d at 1059, n.2.

“The ANDA process allows the manufacturers of generic drugs to gain early entry into the market. Hatch-Waxman’s truncated procedure avoids the duplication of expensive safety and efficacy studies, so long as the generic manufacturer proves that its drug is bioequivalent to the already-approved brand-name/pioneer drug. As part of the application process, the generic applicant must certify that the relevant patent(s) on the brand-name drug are either invalid or will not be infringed. This is commonly known as a ‘Paragraph IV certification.’ The patent holder is then notified of the ANDA, and if the patent holder sues for infringement within forty-five days of receiving the notice, the FDA automatically institutes a thirty-month delay on the generic manufacturer’s ANDA approval. See 21 U.S.C. 355(j)(5)(B)(iii).” *Id.*

⁷⁰ “The Hatch-Waxman scheme distinguishes between New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs). To seek FDA approval for a pioneer drug, the manufacturer must file a complete NDA. Such a filing must ‘provide the FDA with a listing of all patents that claim the approved drug or a method of using the drug.’ aaiPharma Inc., 296 F.3d at 230. The NDA must also set forth data establishing that the drug is safe and effective. See 21 U.S.C. § 355(b). Later, a company that makes a generic drug that is biologically equivalent to the pioneer drug may seek FDA approval for the drug by filing an ANDA. The ANDA relies on the pioneer drug’s safety and effectiveness studies. See 21 U.S.C. § 355(j); aaiPharma Inc., 296 F.3d at 231.” 454 F.3d at 272.

“The ANDA must contain a certification as to whether the proposed generic drug would infringe the patent protecting the pioneer drug, and if not, why not. Pertinent here is the fourth of the statute’s four certification options (the paragraph IV option), allowing the ANDA applicant to certify that the pioneer drug’s 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)(IV). Thus, ‘an ANDA applicant making a paragraph IV certification intends to market its product before the relevant patents have expired.’ aaiPharma Inc., 296 F.3d at 232. The patent holder and the NDA holder (which usually are the same company, the pioneer drug maker) are entitled to notice that a paragraph IV ANDA has been filed. If, upon receiving such notice, the patent holder sues the applicant for patent infringement within 45 days, the FDA must stay a decision on whether to approve the ANDA for 30 months (unless the patent expires or a court holds that it is invalid or not infringed during that time). 21 U.S.C. § 355(j)(5)(B)(iii).” *Id.*

2008).⁷¹ See also In the Matter of 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, Docket No. 85N-0214, Comment of the Staff of the Bureau of Competition and of Policy Planning of the Federal Trade Commissioner, November 4, 1999.⁷²

Once an ANDA is approved, the holder of the ANDA is still subject to numerous FDA requirements in order to retain the right to market and sell the approved generic drug. If the requirements are not met, the ANDA will no longer be effective.⁷³

Some of the FDA-imposed requirements to maintain the ANDA are in 21 C.F.R. § 314.80 (2009), Postmarketing Reporting of Adverse Drug Experiences,⁷⁴ which requires that the ANDA applicant/holder⁷⁵ shall, *inter alia*:

⁷¹ “To start the process, the ANDA applicant must certify-for each patent claiming a drug for which the applicant is seeking approval-under one of four paragraphs that (I) patent information has not been filed; (II) the patent has expired; (III) the patent will expire on a specified date; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted. Id. § 355(j)(2)(A)(vii). The first drug manufacturer to file an approved ANDA, containing a paragraph IV certification, is rewarded with a 180-day period of marketing exclusivity for the manufacturer's generic version of the drug. Id. § 355(j)(5)(B)(iv). Marketing exclusivity is valuable, designed to compensate manufacturers for research and development costs as well as the risk of litigation from patent holders. See 35 U.S.C. § 271(e)(2)(A) (stating a generic drug company certifying under paragraph IV commits an act of infringement for which the brand-name drug's patent holder can sue).” 548 F.3d at 104.

⁷² “In 1984, Congress enacted the Hatch-Waxman Act to establish a streamlined approval process for the FDA to use in approving generic versions of previously approved branded drugs. The Hatch-Waxman Act specifies in detail the required contents of an ANDA. * * *

* * * [I]f an ANDA applicant files a paragraph IV certification, the Hatch-Waxman Act requires the applicant to provide the patent holder with notice of that certification and provides the patent holder with a 45-day window, during which it may bring suit against the applicant. If patent litigation is initiated during this period, the FDA may not approve the ANDA until the earlier of (1) 30 months from the patent holder's receipt of the notice (the 30-month stay) or (2) the issuance of a non-appealable court decision finding the patent invalid or not infringed. This allows the patent holder time to enforce its patent in court before the generic competitor is allowed to enter the market.” (footnotes omitted).

⁷³ 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) (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 of 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).

⁷⁴ “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.

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

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)(2011)(emphasis added);
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

* * * “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).

⁷⁵ 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 ANDA applicant also has continuing responsibilities after it has sold or otherwise transferred its ANDA to another unrelated party.

- to meet the specification established for it in the application.” 21 C.F.R. § 314.81(b)(1)(ii)(2010)(emphasis added);
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)(2010)(emphasis added).
 - b. “Information about the quantity of the drug product distributed under the approved application . . . ” 21 C.F.R. § 314.81(b)(2)(ii)(a)(2010)(emphasis added);
 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)(2010)(emphasis added).
 - 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)(2010)(emphasis added);
 5. Numerous reporting requirements on clinical and other studies; and
 6. 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)(2010)(emphasis added).

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.⁷⁶

⁷⁶ See <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm> (search by ANDA number to find approval letters that are online) (last visited on June 2, 2011).

In addition, the ANDA holder must follow the FDA's rules on good 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).
