In the United States Court of Federal Claims

No. 19-798
(Filed: 19 August 2022)

ACTAVIS LABORATORIES, FL, INC.,	*	
	*	
Plaintiff,	*	Summary Judgment; Hatch-Waxman Act;
	*	Tax Deduction; Capitalization; *Woodward*;
v.	*	Patent Litigation Costs; Origin of the Claim;
	*	35 U.S.C. § 271(e)(2); I.R.C. § 162(a);
THE UNITED STATES,	*	I.R.C. § 263(a); 26 C.F.R. § 1.263(a)-4;
	*	Abbreviated New Drug Application
Defendant.	*	("ANDA"); Generic Drugs; FDA.
	*	

Kevin P. Martin, with whom were *David J. Zimmer*, *Brian T. Drummond*, *Christopher J.C. Herbert*, Goodwin Proctor LLP, all of Boston, MA, for plaintiff.

Jason Bergmann, with whom were *Mary M. Abate*, Assistant Chief, *David I. Pincus*, Chief, *David A. Hubbert*, Acting Assistant Attorney General, Tax Division, U.S. Department of Justice, all of Washington, DC, for the defendant.

OPINION AND ORDER

HOLTE, **Judge.**

"[N]othing can be said to be certain, except death and taxes."[1] The exception to that exception is taxes on Hatch-Waxman patent litigation expenses.

Generic drug manufacturer Watson Pharmaceuticals, Inc. filed seven Abbreviated New Drug Applications with Paragraph IV certifications between 2008 and 2009.[2] Litigation followed the ANDA filings under the Hatch-Waxman Act. Branded drug companies—the creators of the pioneer name-brand drugs the ANDAs depended upon—sued Watson for a tortious trespass of their property rights: patent infringement. Under 35 U.S.C. § 271(e)(2), the branded drug companies alleged Watson's generic products infringe their patents and Watson should be prevented from selling the generics before expiration of the patents. The branded drug

[1] Letter from Benjamin Franklin to Jean-Baptiste Le Roy (Nov. 13, 1789), *in* 12 The Works of Benjamin Franklin 160, 161 (John Bigelow ed., Federal ed. 1904) (1888).

[2] The taxes at issue in this suit arise out of Watson's generic drug business activities. Through a complicated chain of acquisitions and business restructurings, plaintiff Actavis Laboratories, FL, Inc. became the substitute agent for the relevant tax returns. The tax returns' chain of title is undisputed and irrelevant to the pending motions for summary judgment but may be found in plaintiff's complaint. Oral Arg. Tr. ("Tr.") at 9:18–11:9, ECF No. 58; *see* Compl. at 20–23, ECF No. 1.

companies did not allege Watson's ANDAs were technically unacceptable, or the generics were ineligible for FDA approval. Rather, the branded drug companies sought to protect the property interests in their patents and Watson defended those attacks on its generic drug business practices.

Watson deducted the Hatch-Waxman patent litigation expenses on its 2008 and 2009 tax returns. At the time, patent litigation legal expenses—on either side of the "*v.*"—were generally tax deductible. Then, in 2011, the Internal Revenue Service issued a memorandum reaching the opposite conclusion: the IRS stated expenses incurred *defending* patent litigation under § 271(e)(2) must be capitalized under the origin of the claim test and Treasury Regulation § 1.263(a)-4. In 2016, the IRS issued a notice of deficiency disallowing Watson's deductions and demanding payment of the associated taxes, interest, and penalties for late payment. Plaintiff Actavis Laboratories, FL, Inc. became the substitute agent for the returns and its parent company paid the deficiency. Actavis then filed amended tax returns for 2008 and 2009 and filed suit in this Court requesting a refund of the taxes, interest, and penalties paid.

Actavis and the government filed cross-motions for summary judgment. Actavis argues the Hatch-Waxman litigation expenses were incurred defending Watson's business practices from attack and are therefore ordinary and deductible expenses. The government argues the expenses incurred defending the patent infringement suits facilitated the acquisition of FDA-approved ANDAs, intangible assets, and must be capitalized. For the reasons set forth below, the Court finds the litigation expenses originate out of the brand-name drug companies' patent assertion efforts, do not facilitate FDA approval, and do not enhance the finally approved ANDAs. Accordingly, the Court grants plaintiff's motion for summary judgment and denies the government's cross-motion for partial summary judgment.

I. Factual History[3]

A. The Hatch-Waxman Litigation

Between 2008 and 2009, Watson defended itself in Hatch-Waxman litigation involving seven different Abbreviated New Drug Applications ("ANDA") with Paragraph IV certifications. Br. of the United States in Supp. of its Cross-Mot. for Partial Summ. J. & in Resp. to Pl.'s Mot. for Summ. J. ("Def.'s MSJ") at 18, ECF No. 46-1; *see* Tr. at 12:10–15 (plaintiff's counsel stating, "we generally agree with the recitation of . . . the history of the cases that the [g]overnment set forth."). An ANDA of the "Paragraph IV" variety is a new drug application to the FDA with two important certifications: (1) the proposed "generic drug has the same active ingredients as, and is biologically equivalent to, [a] brand-name drug[,]" *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012) (citing 21 U.S.C. § 355(j)(2)(A)(ii), (iv) (2018)); and (2) the listed patents affiliated with the brand-name drug are "invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug[,]" *id.* at 407 (quoting § 355(j)(2)(A)(vii)(IV)). These certifications "allow a generic competitor to . . . piggy-back[] on

[3] All facts in this section are undisputed. *See* Rule 56(a) of the Rules of the Court of Federal Claims ("RCFC") (requiring a movant for summary judgment to show "there is no genuine dispute as to any material fact"); *see also* Oral Arg. Tr. ("Tr.") at 7:19–25 (counsel for both parties agreeing there are no disputes of material fact), 10:13–18 (government counsel agreeing the facts establishing the tax returns in the complaint are undisputed).

the" FDA-approved brand name drugs, and "speed [up] the introduction of low-cost generic drugs to market." *Id.* at 404–05 (citing *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990)). "[T]he FDA cannot authorize a generic drug that would infringe a patent," however, so the Hatch-Waxman Act "treats such a filing as itself an act of infringement, which gives the brand[ed drug company] an immediate right to sue." *Id.* at 405, 07 (citing 35 U.S.C. § 271(e)(2)(A) (2018)).[4] Generic drug companies are incentivized to file ANDAs with Paragraph IV certifications and risk litigation with the possibility of receiving 180 days of generic market exclusivity if they are among the first to file. *See infra* Section IV.C. In the order presented by the government's motion, the following cases against Watson arose from this statutory background.

Watson's first ANDA, No. 91-289, was for a generic oral extended-release form of the branded drug Sanctura XR. Def.'s MSJ at 19. Watson was among the first to file an ANDA for the drug and the patent holder sued Watson on 13 July 2009 under 35 U.S.C. § 271(e)(2) (2018). *Id.* (citing *Allergan, Inc. v. Lab'ys, Inc.*, No. 1:09-cv-511 (D. Del. filed July 13, 2009)). The district court found the asserted patent claims invalid due to obviousness, so Watson launched its generic product once it received FDA approval—it was the exclusive generic for seven months. *Id.*

The second ANDA, No. 78-834, was for a generic version of the branded drug Seasonique. *Id.* at 20. Watson was among the first to file an ANDA for a generic version of this drug. *Id.* The patent holder sued Watson on 6 March 2008 under § 271(e)(2), and the district court found the patent not obvious and ordered the effective date of Watson's ANDA approval to be the date of the patent's expiration. Def.'s MSJ at 20–21 (citing *Duramed Pharms., Inc. v. Watson Lab'ys, Inc.*, No. 3:08-cv-116 (D. Nev. filed Mar. 6, 2008)). On 25 March 2011, the Federal Circuit reversed, so Watson launched its generic product once it received FDA approval. *Id.* at 21. In response, the branded drug company launched its own authorized generic product, so Watson received no exclusivity period. *Id.*

The third ANDA, No. 79-218, was for a generic version of the branded drug Lybrel. *Id.* Watson was among the first to file an ANDA for the drug, and the patent holder sued Watson on 12 March 2008 under § 271(e)(2). *Id.* (citing *Wyeth v. Watson Lab'ys, Inc.*, No. 1:08-cv-145 (D. Del. filed Mar. 12, 2008)). The parties settled, so Watson entered the market with its generic upon FDA approval. *Id.* at 22. The FDA did not grant Watson any period of exclusivity. *Id.*

The fourth ANDA, No. 90-081, was for a generic version of the branded drug Yasmin. *Id.* The patent holder sued Watson on 17 April 2008, and the district court found "an infringement claim against an ANDA filer cannot be premised on a method-of-use patent where that use is not FDA-approved." *Bayer Schera Pharma AG v. Sandoz, Inc.*, 741 F. Supp. 2d 541, 549 (S.D.N.Y. 2010) (Watson was co-defendant with Sandoz), *aff'd sub nom. Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1326 (Fed. Cir. 2012). Watson was not one of the first to file an ANDA for the drug but was the first ANDA generic to reach the market. Def.'s MSJ at 23.

[4] For a detailed account of the Hatch-Waxman Act, see *infra* Sections IV.B–C.

The fifth ANDA, No. 78-833, was for a generic version of the branded drug Yaz. *Id.* at 24; Def.'s MSJ Ex. T at 5, ECF No. 46-22. Watson was not one of the first to file an ANDA for the drug but was still sued by the patentee for infringement in two separate venues. Def.'s MSJ at 24 (citing *Bayer Healthcare Pharms. v. Watson Pharms., Inc.*, No. 2:07-cv-1472 (D. Nev. filed Nov. 5, 2007); *Bayer Schering Pharma AG v. Sandoz, Inc.*, No. 1:08-cv-8112 (S.D.N.Y. filed Sept. 18, 2008)). The Southern District of New York dismissed Bayer's case against Watson, so Watson launched its generic product while the District of Nevada case was ongoing. Def.'s MSJ at 24–25. Watson temporarily ceased sales when the District of Nevada found the patent valid and enjoined the effectiveness of the FDA's approval until after patent expiration. *Id.* The Federal Circuit reversed the District of Nevada and found the patent invalid for obviousness, *Bayer Healthcare Pharms., Inc. v. Watson Pharms., Inc.*, 713 F.3d 1369, 1377 (Fed. Cir. 2013), so Watson relaunched its generic version of the drug. Def.'s MSJ at 25.

The sixth ANDA, No. 90-479, was for a generic version of the branded drug Ortho Tri-Cyclen Lo. *Id.* Watson was not one of the first to file an ANDA for the drug, and although it was sued by the patent holder for infringement, the parties ultimately settled. *Id.* at 25–26 (citing *Janssen Pharms., Inc. v. Watson Lab'ys, Inc.*, No. 2:08-cv-5103 (D.N.J. filed Oct. 16, 2008)). Consequently, Watson launched its generic drug but enjoyed no period of exclusivity. *Id.* at 26.

The seventh ANDA, No. 79-075, was for a generic version of the branded drug Fentora. *Id.* at 27. Watson was one of the first to file an ANDA and was sued for infringement of two patents in two separate venues. *Id.* (citing *Cephalon, Inc. v. Watson Pharms., Inc.*, No. 1:08-cv-330 (D. Del. filed June 2, 2008); *Cephalon, Inc. v. Watson Pharms., Inc.*, No. 3:08-cv-308 (D. Nev. filed June 3, 2008)); Tr. 42:5–9 (plaintiff's counsel stating they "have no reason to dispute" the government's expert report indicating ANDA 79-075 was a first to file). "After a bench trial, the [District of Delaware] found that Watson's ANDA products did not infringe and held the asserted patents invalid for lack of enablement." *Cephalon, Inc. v. Watson Pharms., Inc.*, 707 F.3d 1330, 1333 (Fed. Cir. 2013). The Federal Circuit reversed the finding of invalidity and affirmed the noninfringement finding. *Id.* Watson was sued a third time, however, for a third patent on 25 September 2009—the district court found the patent in this suit valid and infringed, and the Federal Circuit affirmed. *See Cephalon, Inc. v. Watson Pharms., Inc.*, 769 F. Supp. 2d 761 (D. Del.), *aff'd*, 446 Fed. App'x 306 (Fed. Cir. 2011) (per curiam). Accordingly, Watson could not market its Fentora generic until the patent expired in 2019. Def.'s MSJ at 27–28.

B. The Tax Returns

For 2008 and 2009, Watson filed tax returns including deductions for the legal fees incurred in defending the Hatch-Waxman litigation described above. Compl. at 20. The 2008 return included a deduction of $3,882,951 for such fees, and the 2009 return included a deduction of $8,481,237 for such fees. *Id.* The returns have a lengthy chain of title leading to plaintiff becoming their substitute agent, which the parties agree is both undisputed and irrelevant to the cross-motions for summary judgment. Tr. at 9:18–11:9; *see* Compl. at 20–23. On 7 April 2016, the IRS issued a notice of deficiency for the returns, disallowing the deduction of the Hatch-Waxman litigation legal expenses. Compl. at 21. Following payment of the deficiency and related penalties, plaintiff filed amended tax returns for 2008 and 2009 on 2 August 2018. *Id.* at 22–23. Plaintiff seeks a refund based on the IRS's refusal to allow

deductions of the Hatch-Waxman litigation expenses, the interest accrued on those taxes, and the penalties, totaling $1,964,659 for 2008 and $3,995,920 for 2009. *Id*

II. Procedural History

On 31 May 2019, plaintiff filed its complaint alleging the IRS wrongfully determined generic drug companies "must capitalize rather than deduct their [Hatch-Waxman] patent infringement defense costs . . . ." Compl. at 1. Plaintiff asserted these "costs are ordinary business expenses[,]" and requested the Court "declare that those costs are deductible and order a refund of [plaintiff]'s overpayment of taxes." *Id.* On 27 September 2019, the government filed its answer, denying that plaintiff is entitled to its claimed refunds. Answer at 1, ECF No. 8.

On 1 April 2021, plaintiff filed a motion for summary judgment. *See* Pl.'s Mem. of Law in Supp. of its Mot. for Summ. J. ("Pl.'s MSJ"), ECF No. 31-1. Plaintiff requested the Court decide the sole question of "[w]hether a generic drug company's expenses incurred in defending against patent litigation claims brought under 35 U.S.C. § 271(e)(2) are deductible under I.R.C. § 162(a) or must be capitalized under I.R.C. § 263(a)." *Id.* at 5. On 14 May 2021, plaintiff filed a supplemental brief in support of its motion for summary judgment regarding a relevant Tax Court decision ("Pl.'s Supp. Br."), ECF No. 42. Plaintiff alleged: "The United States Tax Court recently issued a thorough, precedential decision fully endorsing [p]laintiff's position in the above-captioned case before this Court." Pl.'s Supp. Br. at 2 (citing *Mylan, Inc. & Subsidiaries v. Comm'r*, 156 T.C. 137 (2021)).

On 14 June 2021, the government filed a cross-motion for partial summary judgment and response to plaintiff's motion for summary judgment. *See* Def.'s MSJ. "The government contends [Hatch-Waxman] litigation expenses may not be immediately expensed but must instead be capitalized, because they were amounts paid to 'facilitate' the 'acquisition of or creation of . . . an intangible[]' . . . ." *Id.* at 2 (citing Treas. Reg. § 1.263(a)-4(b)(1)(v)). The government also asserts the Tax Court's holding in *Mylan* is erroneous and the Court should decline to follow it. *Id.* at 3. On 16 July 2021, plaintiff filed a reply in support of its motion for summary judgment and opposition to the government's cross-motion for partial summary judgment ("Pl.'s Reply"), ECF No. 47. On 10 September 2021, the government filed a reply in support of its cross-motion for partial summary judgment ("Def.'s Reply"), ECF No. 51. The Court held a status conference with the parties on 3 November 2021 to determine the status of any potential appeal from the Tax Court's *Mylan* decision and to set a date for oral argument on the pending motions. *See* Order, ECF No. 52. The Court held oral argument on the parties' cross-motions for summary judgment on 18 February 2022.[5] *See* Order, ECF No. 56. On 11

[5] On 1 April 2021, plaintiff also filed a motion to strike portions of Brian O'Shaughnessy's expert report ("Mot. to Strike"), ECF No. 32. "This Court should strike these paragraphs," plaintiff avers, "because Mr. O'Shaughnessy lacks the expertise required to offer the testimony he proffers therein, and his opinions lack the required 'fit' to the question before this Court, such that they will not 'help the [Court] to understand the evidence or determine a fact in issue.'" Mot. to Strike at 1 (citations omitted). On 14 June 2021, the government filed a response to plaintiff's motion to strike. *See* Resp. to Mot. to Strike, ECF No. 45. On 16 July 2021, plaintiff filed a reply in support of its motion to strike, ECF No. 48. At the 18 February 2022 oral argument, the Court addressed plaintiff's motion to strike with the parties. Plaintiff's counsel stated its "motion [to strike] would become moot" if the Court does not rely on the disputed portions of the expert report in deciding summary judgment. Tr. at 234:9–11. In response,

April 2022, plaintiff filed a notice of additional authority in response to a Court inquiry at oral argument. *See* Notice, ECF No. 59.

III. Summary of the Parties' Cross-Motions for Summary Judgment

Pending before the Court are the parties' cross-motions for summary judgment. *See* Pl.'s MSJ; Def.'s MSJ. Plaintiff requests the Court find "a generic drug company's expenses incurred in defending against patent litigation claims brought under 35 U.S.C. § 271(e)(2) are deductible under I.R.C. § 162(a) . . . ."[6] Pl.'s MSJ at 5. Plaintiff contends the deductibility of "litigation costs is based on the 'origin and character of the claim.'" *Id.* at 19 (quoting *Woodward v. Comm'r*, 397 U.S. 572, 578 (1970)). Treasury Regulation § 1.263(a)-4 "provides guidance" on this matter but nevertheless "allow[s] deduction of defensive litigation expenses when the 'origin and character of the claim' is a challenge to the taxpayer's conduct of its business . . . ." *Id.* at 22, 23. According to plaintiff, "the origin and character of a claim under § 271(e)(2) relates to patent infringement, not a capital acquisition[,]" so the expenses are deductible. *Id.* at 24. Plaintiff adds, in a supplemental brief, the Tax Court recently issued a decision in *Mylan, Inc. & Subsidiaries v. Commisssioner*, 156 T.C. 137 (2021), which "endorsed all of the key arguments [plaintiff] made in its pending summary judgment motion in this case . . . ." Pl.'s Supp. Br. at 2. "The Tax Court's detailed, 49-page analysis of the question before this Court is persuasive," plaintiff argues, "so this Court should follow it . . . ." *Id.* at 2–3.

The government contends Hatch-Waxman "litigation expenses may not be immediately expensed but must instead be capitalized [under I.R.C. § 263(a)(1)], because they [a]re amounts paid to 'facilitate' the 'acquisition of or creation of . . . an intangible,' [Treas.] Reg. § 1.263(a)-4(b)(1)(v)—namely, [ANDAs] approved by the FDA prior to the expiration of all relevant patents . . . ." Def.'s MSJ at 2. The government argues the Tax Court's *Mylan* decision was erroneous so this Court should not follow it. *Id.* at 3. Plaintiff misapplies the "origin of the claim" test, the government asserts, because "the claim originates from [plaintiff's] attempt to obtain an FDA-approved Paragraph IV ANDA[,]" i.e., an intangible. *Id.* Lastly, the government argues "the origin-of-the-claim doctrine should not be applied in isolation, but rather together with" more recent legal authorities, namely: (1) the *INDOPCO, Inc. v. Commissioner*, 503 U.S. 79 (1992), significant-future-benefit test; and (2) Treasury Regulation § 1.263(a)-4. *Id.* at 4.

Plaintiff responds to the government's arguments stating: "The origin of the claim is not the generic drug company's ANDA, which itself triggers no litigation and requires no findings that might result from patent infringement litigation before approval." Pl.'s Reply at 1 (emphasis

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government counsel represented, "for purposes of taking this motion [to strike] off the table, we will withdraw the two [disputed] citations [in the government's cross-motion for partial summary judgment] and ask the Court not to rely on those portions of the report in resolving any fact issues." Tr. at 234:12–16. As the government has withdrawn its reliance on the disputed portions of Mr. O'Shaughnessy's expert report and requested the Court not to consider them in deciding summary judgment, and plaintiff agreed this renders its motion to strike moot, the Court denies as moot plaintiff's motion to strike, ECF No. 32.

[6] Plaintiff clarified at oral argument that where it refers generally to § 271(e)(2) litigation, it is only referring to patent infringement litigation related to ANDAs with a Paragraph IV certifications under 35 U.S.C. § 271(e)(2)(A). Tr. 9:5–15. This Opinion is therefore limited to that same scope, but likewise refers generally to § 271(e)(2) litigation.

removed). "[Section] 271(e)(2) litigation does not 'facilitate' acquisition of an ANDA within the meaning of Treasury Regulation § 1.263(a)-4," plaintiff argues, "because such litigation is not 'an element of acquiring effective FDA approval of an ANDA with a paragraph IV certification.'" *Id.* (citation omitted). Though plaintiff argues Treasury Regulation § 1.263(a)-4 does not apply to § 271(e)(2) litigation expenses, if it did, plaintiff states the origin of the claim test would control. *Id.* at 12–13. Plaintiff further asserts the government's reliance on *INDOPCO* is misguided "because *INDOPCO* had nothing to do with litigation[,]" and "courts have continued to apply the origin of the claim test to litigation costs[.]" *Id.* at 2. Even if the Court were to consider revenue timing, plaintiff argues § 271(e)(2) litigation is "an attack on the generic drug company's existing business, which has always been considered deductible. . . . Indeed, outside the generic drug context, patent holders still regularly sue alleged infringers prior to the commercial sale of allegedly infringing products . . . ." *Id.* at 8.

The government replies to plaintiff's arguments stating: "The defense of Hatch-Waxman litigation is one of many elements of the *transaction* in which a generic company creates a Paragraph IV ANDA." Def.'s Reply at 4. The government asserts the specific lawsuits plaintiff attempted to deduct costs from necessarily "facilitate[d] the creation of Paragraph IV ANDAs" because: (1) "[i]n all of the suits in question, an automatic thirty-month stay arose, during which the FDA was barred from granting final approval to Watson's Paragraph IV ANDAs"; (2) Watson litigated the thirty-month stay in two of the suits; and (3) the patent holders in all of the suits sought orders preventing effective FDA approval until the relevant patent expired. *Id.* at 4–5. The government further avers Treasury Regulation § 1.263(a)-4 "is fully consistent with the Internal Revenue Code[§§] 162 and 263," so "the Court must give deference . . . ." *Id.* at 8 (citing *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984)). Treasury Regulation § 1.263(a)-4 is also consistent with the origin of the claim test, the government argues, because it "announces specific standards for determining whether an expense is incurred in the 'process of acquisition' of an intangible, namely, whether it facilitates the creation of the asset." *Id.* at 9 (quoting *Woodward*, 397 U.S. at 577). The government concludes by arguing even without Treasury Regulation § 1.263(a)-4, Hatch-Waxman litigation expenses must be capitalized under both *INDOPCO*'s significant-future-benefit standard and the origin of the claim test, together or in isolation. *Id.* at 9–13.

IV. Applicable Law

Plaintiff incurred the expenses at issue under an elaborate regulatory and statutory scheme governing generic pharmaceuticals—the Hatch-Waxman Act. After establishing the standard of review, the Court describes the Hatch-Waxman Act's procedures, as the statutory framework is relevant to the Court's deductibility analysis. The Court then describes the relevant tax code, common law standards, and Treasury Regulations relevant to the deductibility of plaintiff's expenses. Finally, the Court reviews a recent non-binding Tax Court decision answering the very question before the Court.

A. Summary Judgment Standard

Summary judgment is appropriate where the evidence demonstrates there is "no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." RCFC

56(a); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). A genuine issue is one that "may reasonably be resolved in favor of either party." *Anderson*, 477 U.S. at 250.

B. The Hatch-Waxman Act

The Food and Drug Administration is charged with the approval of all pharmaceutical drugs, including new branded drugs and generic versions of such drugs. *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 404 (2012). To obtain FDA approval for a new branded drug, a drug manufacturer must submit a New Drug Application ("NDA"). *Id.* The NDA must contain information sufficient to establish that the drug is safe and effective for its intended purpose, generally by conducting clinical trials in human subjects. *Id.*; 21 U.S.C. § 355(b) (2018). Once the FDA approves the NDA, the branded drug company may begin selling and marketing the new drug to the public. *FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2013).

Before 1984, generic drug companies were required to follow the same time-consuming and expensive NDA process as branded drug companies. *See aaiPharma Inc. v. Thompson*, 296 F.3d 227, 230–31 (4th Cir. 2002). Simply making the generic drug just for FDA approval would constitute an act of infringement on any patents the branded drug companies held over the branded drugs. *Roche Prod., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984), *superseded by statute*, 35 U.S.C. § 271(e)(1), *as recognized in Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003). Generic drug companies would often be unable to develop their generic products or seek FDA approval until after patent litigation ended or the patent expired. *aaiPharma Inc.*, 296 F.3d at 231. The cost to obtain FDA approval and defend § 271(a) patent litigation severely hampered affordable generic drug availability. *Id.* at 230–31.

To address this problem, Congress enacted the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly known as the Hatch-Waxman Act ("Act"). *Actavis, Inc.*, 570 U.S. at 142. The Hatch-Waxman Act created a patent infringement safe harbor for generic drug companies' development activities for the purpose of obtaining FDA approval. 35 U.S.C. § 271(e)(1). The Act also simplified the FDA approval process for generic drugs by introducing the Abbreviated New Drug Application process. *Actavis, Inc.*, 570 U.S. at 142. A generic drug company may file an ANDA specifying "the generic has the 'same active ingredients as,' and is 'biologically equivalent' to, the already-approved brand-name drug[,]" and thereby "obtain approval while avoiding the 'costly and time-consuming studies' needed to obtain approval 'for a pioneer drug.'" *Id.* (citations omitted). The generic drug company may begin selling its product once the FDA approves the ANDA and that approval becomes effective. 21 U.S.C. § 355(a).

"To facilitate the approval of generic drugs as soon as patents allow, the Hatch[-]Waxman Amendments and FDA regulations direct brand manufacturers to file information about their patents" related to their NDAs. *Caraco*, 566 U.S. at 405. The FDA publishes the "patent numbers and expiration dates, in a fat, brightly hued volume called the Orange Book (less colorfully but more officially denominated Approved Drug Products With Therapeutic Equivalence Evaluations)." *Id.* at 405–06. Generic drug companies filing an ANDA are required to "'assure the FDA' that the generic 'will not infringe' the brand-name's patents." *Actavis, Inc.*, 570 U.S. at 143 (citations omitted). The generic drug company can

provide this assurance in one of several ways, *see* 21 U.S.C. § 355(j)(2)(A)(vii)—relevant here is Paragraph IV, in which the generic certifies that any listed patent "is invalid or will not be infringed by the manufacture, use, or sale" of the proposed ANDA generic drug. *See* § 355(j)(2)(A)(vii)(IV). "Filing a paragraph IV certification . . . [i]s itself an act of infringement, which gives the brand an immediate right to sue." *Caraco*, 566 U.S. at 407; *see* 35 U.S.C. § 271(e)(2)(A).

"If the brand-name patentee brings an infringement suit [under § 271(e)(2)] within 45 days, the FDA then must withhold approving the generic, usually for a 30[-]month period, while the parties litigate patent validity (or infringement) in court." *Actavis, Inc.*, 570 U.S. at 143. If the FDA approves the ANDA during the 30-month stay period, it will issue a "tentative approval letter." *See* 21 C.F.R. § 314.107(b)(3). The thirty-month stay terminates on a final ruling that the patent is invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iii)(I). If the courts have not yet decided the matter, the FDA approval will become effective at the conclusion of the thirty-month stay. *Id.* "The generic manufacturer then has the option to launch 'at risk,' meaning that, if the ongoing court proceeding ultimately determines that the patent was valid and infringed, the generic manufacturer will be liable for the brand-name manufacturer's lost profits despite the FDA's approval." *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 241 (3d Cir. 2017) (citing *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 396 n.8 (3d Cir. 2015)). If a court finds the patent valid and infringed, the ANDA's FDA approval will not be effective until expiration of the infringed patent. § 271(e)(4)(A).

In summary, the Hatch-Waxman Act replaced the cause of action for patent infringement available under § 271(a) for generic drug development activities before NDA filing with a cause of action for patent infringement under § 271(e)(2) brought concurrently with the FDA's assessment of an ANDA during the life of the patent. The filing of an ANDA with a Paragraph IV certification does not itself initiate litigation under § 271(e)(2), much like the development of a product does not initiate litigation under § 271(a)—each act gives a patent holder the right, but not the obligation, to sue. "Notwithstanding th[e] defined act of infringement, a district court's inquiry in a suit brought under § 271(e)(2) is the same as it is in any other infringement suit, *viz.*, whether the patent in question is 'invalid or will not be infringed by the manufacture, use, or sale of the drug for which the [ANDA] is submitted.'" *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997) (quoting 21 U.S.C. § 355(j)(2)(A)(vii)(IV)). "The only difference in actions brought under § 271(e)(2) is that the allegedly infringing drug has not yet been marketed and therefore the question of infringement must focus on what the ANDA applicant will likely market if its application is approved, an act that has not yet occurred." *Id.* Even the remedies at play, though different in name, are alike in kind: the § 271(e)(2) plaintiff may seek an order staying effective FDA approval until the relevant patent expires, *see* § 271(e)(4)(A); the § 271(a) plaintiff may seek a permanent injunction, *see, e.g.*, *Aoki v. Gilbert*, No. 211CV02797TLNCKD, 2020 WL 6741693, at *30, 33 (E.D. Cal. Nov. 17, 2020). The automatic thirty-month stay of FDA approval a § 271(e)(2) plaintiff receives is akin to the preliminary injunction a § 271(a) plaintiff may seek. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I); *see also, e.g.*, *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358 (Fed. Cir. 2017). "[T]he litigation of a Hatch-Waxman suit under 35 U.S.C. § 271(e)([2]) has much in common with a traditional infringement suit under 35 U.S.C. § 271(a) . . . ." Def.'s MSJ at 15.

C. The Policy of the Hatch-Waxman Act and Generic Exclusivity

The Hatch-Waxman Act reflects the balance Congress struck between conflicting policy objectives: incentivizing branded drug companies to invest in research and development of new drug products, while increasing the availability of cheaper, generic copies of those drugs on the market. H.R. Rep. 98-857, pt. 1, at 14–15; *see also Abbott Lab'ys v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting on other grounds) (citing *Mead Johnson Pharm. Grp. v. Bowen*, 838 F.2d 1332, 1333 (D.C. Cir. 1988)). For branded drug companies' benefit, the Act prohibits ANDA filing before the expiration of five years from the date of FDA approval of the pioneer NDA. 21 U.S.C. § 355(j)(5)(F)(ii) (2018) (but allowing ANDA filings with Paragraph IV certifications after four years); *see also* Aaron S. Kesselheim & Jonathan J. Darrow*, Hatch-Waxman Turns 30: Do We Need A Re-Designed Approach for the Modern Era?*, 15 Yale J. Health Pol'y, L. & Ethics 293, 305 (2015). When coupled with the automatic thirty-month stay of a litigated ANDA filing, most branded drug companies "expect[] to receive a minimum of seven-and-a-half years of market exclusivity" for their NDAs. Kesselheim & Darrow, *supra*, at 305 (citing § 355(j)(5)(F)(ii) (requiring extension of the thirty-month stay to guarantee "seven and one-half years")). Branded drug companies may further seek as much as a five-year patent term extension for "the patent term that was lost during the clinical testing phases and FDA review period." *Id.* at 306 (citing 35 U.S.C. § 156(c)(3), (g)(6) (2018)).

To "encourage generic applicants" to use Paragraph IV certifications, the Hatch-Waxman Act provides 180 days of generic market exclusivity to any Paragraph IV "first applicant." Erika King Lietzan, *A Brief History of 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act*, 59 Food & Drug L.J. 287, 288 (2004) (citing § 355(j)(5)(B)(iv)). During that period of exclusivity, only generics who have achieved first-to-file status can compete with the brand-name drug. *Actavis, Inc.*, 570 U.S. at 143–44. Being the first-to-file is not an exclusive title—"[i]f multiple applicants file substantially complete ANDAs with paragraph IV certifications on the same day as the first to do so, those applicants all are entitled to exclusivity." Lietzan, *supra*, at 290. Given the statutory time-bar on ANDA filing, multiple generic drug companies may all file on the first possible day for a particular product to acquire the 180 days of exclusivity. § 355(j)(5)(B)(iv), (F)(ii); *see also* 21 C.F.R. § 314.107(c)(1) (2016). Attaining first-to-file status alone is not enough to achieve exclusivity, however—the statute provides several ways to forfeit the period of exclusivity. *See* § 355(j)(5)(D). Additionally, assuming a generic is one of the first applicants and receives FDA approval without forfeiting exclusivity, there is only one 180-day exclusivity period per each *branded* drug product. § 355(j)(5)(B)(iv)(I). The lone 180-day exclusivity period is triggered by "the first commercial marketing of" an FDA-approved generic by "any first applicant." *Id.* An ANDA first applicant may therefore never enjoy 180 days of exclusivity if another first applicant is able to market its generic product sooner. *Id.*

Some consider "[f]iling a paragraph IV certification [to be] provoking litigation" because "such a filing [i]s itself an act of infringement . . . ." *Caraco*, 566 U.S. at 407. Some view the 180-day generic exclusivity period as a reimbursement or reward for the cost of litigation the

Paragraph IV certification provokes.[7] Scant evidence supports either proposition. There is some disagreement on the precise statistics, but it is undisputed § 271(e)(2) litigation does not arise with every ANDA containing a Paragraph IV certification.[8] Further, being a first applicant does not appear to have much statistical bearing on a generic's likelihood of being sued. FTC Study, *supra* note 8, at 18. If the 180-day generic exclusivity period was intended to be a reward for undertaking the burden of § 271(e)(2) litigation, then it does a poor job of rewarding all the generics in need. *Id.* The likelihood of receiving the exclusivity period also appears to be unrelated to whether the generic is sued or not—about half of all exclusivity periods go un-litigated, and a first applicant is not guaranteed any exclusivity even if successful in litigation and at the FDA.[9] Hemphill & Lemley, *supra* note 8, at 983; *see also* § 355(j)(5)(B)(iv). Moreover, the legislative history is effectively silent as to the relationship between the 180-day exclusivity period and the costs of defending § 271(e)(2) litigation. *See* H.R. Rep. 98-857. Congress did not contemplate the cost of litigation when determining how long to grant generic exclusivity. *See id.* Rather, the available legislative history supports a simpler conclusion—Congress wanted to promote the introduction of affordable generic drugs to the market as quickly as possible, so it provided an incentive to spur generics into action. *Id.*; *see* Tr. at 42:15–44:18 (counsel for both parties agreeing this is the case). Congress often incentivizes behavior it wants to promote and there's no evidence to suggest the generic exclusivity period was intended to subsidize § 271(e)(2) litigation. Those drawing this conclusion, *supra* note 7, do not cite any authority for support. Neither party to this case believes the generic exclusivity period was intended to be compensatory.[10]

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[7] *See* Kesselheim & Darrow, *supra*, at 326 ("Indeed, the 180-day generic exclusivity period was originally inserted into the Hatch-Waxman Act because of the concern that the patent challenge and litigation process may be too time-consuming and costly for many generic manufacturers without some sort of bonus."); *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1361–62 (Fed. Cir. 2008) ("The 180[-]day exclusivity period is important to generic pharmaceutical companies as it promotes patent challenges by enabling a generic company a period to recover its investment in these challenges."); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1605 (2006) (noting the 180-day exclusivity period incentivizes patent challenges); *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 879 (D.C. Cir. 2004) ("In order to encourage paragraph IV challenges, thereby increasing the availability of low-cost generic drugs . . . [the first-filer] has the right to sell its drug without competition [from other generics] for 180 days.").

[8] *Compare* Pl.'s MSJ at 11–12 ("[B]randed drug companies decide not to file patent infringement lawsuits under § 271(e)(2) in response to approximately 30% to 50% of ANDAs with a Paragraph IV certification."), 12 n.22 (citing Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* ("FTC Study"), 14 ("The data revealed 75 drug products, out of a total of 104 NDAs (72 percent), in which the brand-name company sued the first generic applicant." (emphasis removed)), 18 ("If the brand-name company sued the first generic applicant, it also sued the second generic applicant, if there was one, in nearly 85 percent of the cases.") (July 2002), https://www.ftc.gov/sites/default/files/ documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf; C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 Antitrust L.J. 947, 983 (2011) ("47 percent . . . of 180-day exclusivity [periods] occurred because the patentee chose not to file a suit against the ANDA at all.")); *with* Def.'s MSJ at 14 n.8 ("[A]ccording to Paragraph Four[.com], only '[a]bout 15% of the time, a brand company will not file a suit against the generic.'").

[9] Indeed, in this case alone, Watson was sued under § 271(e)(2) over seven ANDAs with Paragraph IV certifications but was the first to file in only four of those seven and received an exclusivity period for only one of those four. *See supra* Section I.A.

[10] Tr. 44:12–18 ("THE COURT: . . . [D]oes the [g]overnment argue at all that the purpose of the 180 days was to reward first filers for having to cover the cost of litigation? [GOVERNMENT]: Not from a compensatory

D. The Tax Code, Origin of the Claim Test, & Treasury Regulations

The Internal Revenue Code ("I.R.C." or "26 U.S.C.") allows a deduction for "all the ordinary and necessary expenses paid or incurred during the taxable year in carrying on any trade or business."[11] I.R.C. § 162(a). By contrast, I.R.C. § 263(a) provides that "[n]o deduction shall be allowed for" a capital expenditure.[12] "[D]eductions are exceptions to the norm of capitalization . . . ." *INDOPCO, Inc. v. Comm'r*, 503 U.S. 79, 84 (1992). Where an expenditure fits within both Section 162 and Section 263, the capitalization requirement controls and bars the deduction. I.R.C. § 161; *Comm'r v. Idaho Power Co.*, 418 U.S. 1, 17–18 (1974). "The primary effect of characterizing a payment as either a [deductible] business expense or a [nondeductible] capital expenditure concerns the timing of the taxpayer's cost recovery . . . ." *INDOPCO*, 503 U.S. at 83. A deduction for an ordinary and necessary business expenditure taken in the current year yields an immediate corresponding reduction in taxable income. *Id.* A capital expenditure, on the other hand, "is amortized and depreciated over the life of the relevant asset . . . ." *Id.* at 83–84. Section 263 "serves to prevent a taxpayer from utilizing currently a deduction properly attributable, through amortization, to later tax years when the capital asset becomes income producing." *Idaho Power Co.*, 418 U.S. at 16.

In its 1963 decision in *United States v. Gilmore*, on appeal from the United States Court of Claims, the United States Supreme Court set forth what is commonly known as the "origin of the claim" test. *Woodward v. Comm'r*, 397 U.S. 572, 578 (1970) (citing *United States v. Gilmore*, 372 U.S. 39 (1963)). In *Gilmore*, the Court held the deductibility of "litigation costs of resisting a claim depends on whether or not the claim arises in connection with the taxpayer's profit-seeking activities." *Gilmore*, 372 U.S. at 48. The Court continued: "It does not depend on the consequences that might result to a taxpayer's income-producing property from a failure to defeat the claim for . . . that 'would carry us too far[,]' would not be compatible with the basic lines of expense deductibility drawn by Congress[, and] would lead to capricious results." *Id.* (footnotes omitted). In so holding, the Court found the expense of defending a divorce suit was a

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standpoint but, rather, to provide them with an incentive to launch the Paragraph IV ANDA . . . ."); 45:9–23 ("THE COURT: But no specific incentive of 180-day reward balanced to the cost of litigation. It's just . . . one of the general benefits a generic receives. . . . [GOVERNMENT]: No, I think—you're right. The [g]overnment is not arguing" the exclusivity period is a compensatory reward.); 45:25–46:6 (government counsel stating, "the litigation costs of a generic in a Hatch-Waxman suit are relatively modest, but the reward for becoming the first to file and getting a 180-day exclusivity period is so great that generics are incentive[z]ed to bring suit even when they may have less than 10 percent chance of ultimately prevailing in the litigation against the patent."); 46:17–47:5 (plaintiff's counsel stating, undisputed, the exclusivity period "can't be designed to cover the litigation costs because you've got 180 days exclusivity if you're a first file[r] . . . whether you're sued or not . . . [and] you might get sued even if you weren't a first filer . . . ."); 47:6–18 (both parties stating they are unaware of any evidence that "Congress . . . analyzed what the average litigation cost was, [and] there was no teetering balance to equate the" benefit of exclusivity with the cost of litigation.).

[11] An expense is "ordinary" if it is customary or usual within a particular trade, business, or industry or relates to a common or frequent transaction in the type of business involved. *See Deputy v. du Pont*, 308 U.S. 488, 495 (1940). An expense is "necessary" if it is appropriate and helpful to the operation of the taxpayer's business. *See Comm'r v. Tellier*, 383 U.S. 687, 689 (1966).

[12] An expense is capital if it is incurred in the acquisition of an asset. *Comm'r v. Idaho Power Co.*, 418 U.S. 1, 12–13 (1974); *see also* I.R.C. § 263(a) ("Any amount paid out for new buildings or for permanent improvements or betterments made to increase the value of any property or estate [is a capital expenditure].").

nondeductible personal expense, even though the litigation was over ownership of controlling stock interests in three corporations. *Id.* at 41, 51–52.

In 1970, the Supreme Court addressed the origin of the claim test once more in *Woodward v. Commissioner*. In *Woodward*, the Court explained the deductibility of litigation expenses hinges not on the taxpayer's "primary purpose" in incurring the costs, but "involves the simpler inquiry whether the origin of the claim litigated is in the process of acquisition [of a capital asset] itself." *Woodward*, 397 U.S. at 577. "A test based upon the taxpayer's 'purpose' in undertaking or defending a particular piece of litigation would encourage resort to formalisms and artificial distinctions." *Id.* The Court stated the taxpayer's motives or purposes in undertaking defense of the litigation, as well as the consequences of the litigation, are irrelevant to the costs' deductibility. *Id.* at 578 (citing *Gilmore*, 372 U.S. 39). "The standard here pronounced . . . [is] whether the origin of particular litigation lies in the process of acquisition." *Id.* Under state law, the litigation in *Woodward* was "required to fix the price" of the taxpayers' acquired stock, so "the expenses incurred in that litigation were properly treated as part of the cost of the stock that the taxpayers acquired." *Id.* at 579.

Separate from the origin of the claim test, "[e]xpenses must generally be capitalized when they either: (1) [c]reate or enhance a separate and distinct asset, or (2) otherwise generate significant benefits for the taxpayer extending beyond the end of the taxable year." *Santa Fe Pac. Gold Co. & Subsidiaries v. Comm'r*, 132 T.C. 240, 262 (2009) (citing *Metrocorp, Inc. v. Comm'r,* 116 T.C. 211, 222 (2001)); *INDOPCO*, 503 U.S. at 87; *Comm'r v. Lincoln Sav. & Loan Ass'n*, 403 U.S. 345, 354 (1971)). Due to challenges applying this significant-future benefits standard to intangible assets, the IRS and the Department of the Treasury enacted regulations that "defined the exclusive scope of the significant future benefit test through the specific categories of intangible assets for which capitalization is required." Guidance Regarding Deduction and Capitalization of Expenditures, 67 Fed. Reg. 77,701, 77,702 (Dec. 19, 2002). "[A]n amount paid to acquire or create an intangible not otherwise required to be capitalized by the regulations is not required to be capitalized on the ground that it produces significant future benefits for the taxpayer, unless the IRS publishes guidance requiring capitalization of the expenditure." Guidance Regarding Deduction and Capitalization of Expenditures, 69 Fed. Reg. 436, 436 (Jan. 5, 2004); Tr. at 195:23–24 ("[GOVERNMENT]: No such guidance has been published [for Hatch-Waxman litigation expenses]."); *see also* Def.'s Reply at 11 n.4 ("[T]he Treasury Department published the regulation to supplant the prior, categorical '"significant future benefit" standard' with 'the specific categories of intangible assets for which capitalization is required' in the regulations, categories that '[t]he future benefit standard underlies.'" (quoting Guidance Regarding Deduction and Capitalization of Expenditures, 67 Fed. Reg. 77,701 (Dec. 19, 2002))).

E. A Review of *Mylan, Inc. v. Commissioner*

On 27 April 2021, the United States Tax Court issued an opinion deciding the same issue before this Court. *See Mylan, Inc. & Subsidiaries v. Comm'r*, 156 T.C. 137 (2021) (pending appeal to the United States Court of Appeals for the Third Circuit). "While decisions of the Tax Court are not binding, the Court of Federal Claims 'will follow these decisions if the underlying rationale is persuasive.'" *Buser v. United States*, 85 Fed. Cl. 248, 264 n.16 (2009)

(quoting *Southland Royalty Co. v. United States,* 22 Cl. Ct. 525, 530 n.15 (1991); citing *Travelers Ins. Co. v. United States,* 25 Cl. Ct. 141, 145 (1992) (deeming decisions of the Tax Court persuasive authority)).

In *Mylan*, the petitioner was a generic drug manufacturer that deducted legal expenses incurred while defending § 271(e)(2) patent infringement litigation. *Mylan*, 156 T.C. at 138. The Tax Court found the legal expenses deductible because "[a]lthough the filing of an ANDA with a paragraph IV certification triggers the opportunity for patent litigation as well as the FDA review process, this statutory design does not transform patent litigation into a step in the ANDA approval process." *Id.* at 156–57. "The outcome of a Section 271(e)(2) suit[,]" the Tax Court noted, "has no bearing on the FDA's safety and bioequivalence review." *Id.* at 157. "[T]he Hatch-Waxman Act moved up the timing of patent litigation," but the Tax Court observed "its character remained unchanged." *Id.* at 158. "Congress' decision to coordinate effective FDA approval with the outcome of a Section 271(e)(2) suit does not convert such litigation into a link in the ANDA approval chain." *Id.* at 159. "[A] patent on a brand name drug presents no impediment to FDA approval of a generic version unless the patent holder decides to take advantage of the mechanism Congress provided for an early adjudication of the patent holder's rights." *Mylan*, 156 T.C. at 160. The Tax Court explained: "Even absent the transaction, the patent holder would doubtless seek to defend its intellectual property against a potential infringer, and the generic manufacturer would incur the same litigation costs in defending such suit." *Id.* at 161. "Accordingly, expenses [petitioner] incurred in defending Section 271(e)(2) suits were not 'paid to facilitate' the transaction and are not required to be capitalized [under Treasury Regulation § 1.263(a)-4]." *Id.* at 161–62.

The *Mylan* decision then assessed petitioner's § 271(e)(2) litigation expenses under the origin of the claim test. *Id.* at 162 ("Under this test, we inquire 'whether the origin of the claim litigated is in the process of acquisition,' enhancement, or other disposition of a capital asset." (quoting *Woodward*, 397 U.S. at 577; citing *Santa Fe Pac. Gold*, 132 T.C. at 264–65)). The Tax Court found petitioner's § 271(e)(2) litigation expenses "arose out of actions initiated by patent holders to protect their intellectual property from infringement and exploitation." *Id.* (citing *Glaxo*, 110 F.3d at 1569). "Patent infringement suits are creatures of tort with an aim of preventing and recovering damages to the patent holder's business of exploiting its patent." *Mylan*, 156 T.C. at 162 (citing *Urquhart v. Comm'r*, 215 F.2d 17, 20 (3d Cir. 1954); *Schillinger v. United States*, 155 U.S. 163, 169 (1894); *Giesecke+Devrient GmbH v. United States*, 150 Fed. Cl. 330, 344 (2020)). The Tax Court then illustrated the Third Circuit decision in *Urquhart* where the circuit court held "patent infringement 'litigation is a far cry from removing a cloud of title, or defending ownership of property.'" *Mylan*, 156 T.C. at 162 (quoting *Urquhart*, 215 F.2d at 20). "[T]he litigation expenses were incurred not to defend or protect title but rather, 'to prevent (and recover) damage to their business, that is, to protect, conserve and maintain their business profits.'" *Id.* at 162–63 (quoting *Urquhart*, 215 F.2d at 20). The Tax Court compared petitioner's § 271(e)(2) litigation expenses and found they, like *Urquhart*, "arose out of patent infringement claims." *Id.* (citing *Santa Fe Pac. Gold*, 132 T.C. at 264–65 ("[T]he substance of the underlying claim or transaction out of which the expenditure in controversy arose governs whether the item is a deductible expense or a capital expenditure[.]")). The *Mylan* decision concluded § 271(e)(2) litigation expenses "seem clearly deductible" under *Urquhart*. *Id.* (citing *Appeal of F. Meyer & Bro. Co.*, 4 B.T.A. 481, 482 (1926); *Addressograph-Multigraph Corp. v*

Comm'r, 4 T.C.M. (CCH) 147, 166 (1945)) ("Expenses incurred in defending patent infringement claims have been found deductible in the past."). "[T]he litigation expenses that [petitioner] incurred in defending Section 271(e)(2) suits arose out of the ordinary and necessary activities of its generic drug business and accordingly are deductible." *Id.* at 163–64 (citing *Am. Stores Co. v. Comm'r*, 114 T.C. 458, 468 (2000)).

V. The Appropriate Tests for Determining § 271(e)(2) Litigation Expense Deductibility

As a threshold matter, the parties present competing analytical frameworks for determining whether Hatch-Waxman litigation defense expenses are deductible under I.R.C. § 162(a) or must be capitalized under I.R.C. § 263(a). The Court must therefore determine the applicable legal standards and their order of application before reaching the merits of the parties' cross-motions for summary judgment.

Plaintiff argues the expenses at issue are litigation expenses and not transaction costs, so the Supreme Court's origin of the claim test is the controlling standard. Pl.'s MSJ at 19. "Plaintiff agree[s] that an approved Paragraph IV ANDA is a created intangible[,]" Tr. at 161:24–25, so to the extent Treasury Regulation § 1.263(a)-4 is relevant to this inquiry, plaintiff argues the origin of the claim test should inform the regulation analysis. Tr. at 158:13–15. The government counters Treasury Regulation § 1.263(a)-4 is the lone standard for the Court to apply. Tr. at 142:3–6; Def.'s MSJ at 31. Should the Court find § 1.263(a)-4 inapplicable to § 271(e)(2) litigation expenses, the government argues the Court must then harmonize the origin of the claim test with "*INDOPCO*'s significant-future-benefit standard." Def.'s Reply at 10–11; Tr. at 142:11–13. The government further posits, like plaintiff, the origin of the claim test should inform the § 1.263(a)-4 analysis. Tr. 152:8–11. Both parties agree there is no conflict between Treasury Regulation § 1.263(a)-4 and the origin of the claim test; the standards, though different from one another, should reach the same conclusion. Def.'s Reply at 9; Pl.'s Reply at 12–13.

The origin of the claim test, originating in 1963, *United States v. Gilmore*, 372 U.S. 39, 48 (1963), is the Supreme Court's direct guidance on whether litigation expenses must be capitalized under I.R.C. § 263(a). *Woodward v. Comm'r*, 397 U.S. 572, 574 (1970) (citing I.R.C. § 263). When presented with the question of litigation expense deductibility, courts regularly apply the origin of the claim test. *See, e.g.*, *Nw. Indiana Tel. Co. v. Comm'r*, 127 F.3d 643, 646 (7th Cir. 1997) ("*Gilmore*, the undisputed leading case on this issue . . . ."); *Mylan, Inc. & Subsidiaries v. Comm'r*, 156 T.C. 137 (2021); *Baylin v. United States*, 30 Fed. Cl. 248, 254 (1993) (citing *Woodward*), *aff'd,* 43 F.3d 1451 (Fed. Cir. 1995); *McKeague v. United States*, 12 Cl. Ct. 671, 675 (1987), *aff'd,* 852 F.2d 1294 (Fed. Cir. 1988); *Keller St. Dev. Co. v. Comm'r*, 688 F.2d 675, 681 (9th Cir. 1982).

Treasury Regulation § 1.263(a)-4, enacted in 2004, is the IRS's attempt to "explain how [I.R.C. § 263(a)] applies to amounts paid to acquire or create intangibles." Guidance Regarding Deduction and Capitalization of Expenditures, 69 Fed. Reg. 436, 436 (Jan. 5, 2004). Treasury Regulation § 1.263(a)-4 is not as narrowly focused as the origin of the claim test. The regulation enumerates broad categories of expenses for which capitalization is required, specifically: amounts paid to acquire, create, enhance, or facilitate the acquisition of an intangible. Treas. Reg. § 1.263(a)-4(b). An expense may fall under the regulation through a determination "based

on all of the facts and circumstances." Treas. Reg. § 1.263(a)-4(b)(3)(i), (e)(1)(i). The regulation provides no bright-line test and sets forth no specific standard for the deductibility of litigation costs. *See* Treas. Reg. § 1.263(a)-4. The regulation addresses litigation costs only once—in the examples, it illustrates the facts of *Woodward* and concludes those litigation costs must be capitalized under the regulation, just as the origin of the claim test required. Treas. Reg. § 1.263(a)-4(e)(5) (example four). The regulation was not intended to replace, modify, or limit the origin of the claim test. *See id.*; Guidance Regarding Deduction and Capitalization of Expenditures, 67 Fed. Reg. 77,701, 77,705 (Dec. 19, 2002). Notably, the preamble from the notice of proposed rulemaking states the regulation was not intended to displace existing caselaw holding the cost of patent infringement litigation is "generally deductible." Guidance Regarding Deduction and Capitalization of Expenditures, 67 Fed. Reg. at 77,705 (citing *Urquhart v. Comm'r*, 215 F.2d 17 (3d Cir. 1954)). Further, the regulatory history is replete with IRS statements of intent to supplant the *INDOPCO* significant-future-benefit standard.[13]

The question of what legal standards determine the deductibility of Hatch-Waxman litigation expenses has been addressed before. The Tax Court and the Office of Chief Counsel of the IRS both follow a two-part analysis when presented this question. *Mylan*, 156 T.C. 137 (first applying the regulation and then the origin of the claim test, but not *INDOPCO*'s significant-future-benefit standard); Pl.'s Appx. ("Pl.'s MSJ Appx.") at A0948, A0953–54 (14 September 2011 memorandum from the Office of Chief Counsel of the IRS first applying the origin of the claim test and then the regulation, but not *INDOPCO*'s significant-future-benefit standard), ECF 31-2.[14] By way of example, the IRS explains this process as follows:

> When legal fees are incurred in litigation, there is a two-step process for determining whether the fees must be capitalized. First, the origin of the claim doctrine must be applied to ascertain the character and nature of the expenditures. Second, the capitalization of intangibles regulations must be applied to determine,

[13] *See, e.g.*, Guidance Regarding Deduction and Capitalization of Expenditures, 69 Fed. Reg. at 436 ("[A]n amount paid to acquire or create an intangible not otherwise required to be capitalized by the regulations is not required to be capitalized on the ground that it produces significant future benefits for the taxpayer, unless the IRS publishes guidance requiring capitalization of the expenditure."), 438 ("The reference to 'benefits to be received in the future' has been deleted to avoid any implication of a 'significant future benefits' test."); Guidance Regarding Deduction and Capitalization of Expenditures, 67 Fed. Reg. at 77,702 ("A 'significant future benefit' standard, however, does not provide the certainty and clarity necessary for compliance with, and sound administration of, the law. Consequently, the IRS and Treasury Department believe that simply restating the significant future benefit test, without more, would lead to continued uncertainty on the part of taxpayers and continued controversy between taxpayers and the IRS. Accordingly, the IRS and Treasury Department have initially defined the exclusive scope of the significant future benefit test through the specific categories of intangible assets for which capitalization is required in the proposed regulations. The future benefit standard underlies many of these categories."), 77,703 ("If an expenditure is not described in one of the categories in the proposed regulations or in subsequent future guidance, taxpayers and IRS field personnel need not determine whether that expenditure produces a significant future benefit.").

[14] "Determining whether the expenditures at issue must be capitalized as within I.R.C. § 263 (rather than deducted under § 162 or excluded from capitalization under I.R.C. § 174) requires a two step analysis. In the first step, . . . the origin of the claim test must be applied, considering the relevant facts and circumstances. . . . In the second step, . . . whether the fees are within § 263 must be analyzed, specifically considering the 2004 capitalization of intangibles regulations." Pl.'s MSJ Appx. at A0953–54 (14 September 2011 memorandum from the Office of Chief Counsel of the IRS) (footnotes omitted).

> *based on the ascertained character and nature*, whether the expenditures are within any of the categories of expenditures that must be capitalized under the regulations.

Pl.'s MSJ Appx. at A0921–22 (6 November 2015 memorandum from the Office of Chief Counsel of the IRS) (footnote omitted) (emphasis added).[15] Further, the Department of Treasury, the Tax Court, and the Office of Chief Counsel of the IRS all agree an expense not otherwise required to be capitalized under the regulation should not then be capitalized on the ground that it produces significant future benefits under *INDOPCO*. *See id.*; *Mylan*, 156 T.C. 137; *supra* note 13. While none of the above are binding precedent, the uniform interpretation of applicable law is instructive.

The Court finds the two-step process as explained by the IRS persuasive. The expenses at issue are § 271(e)(2) patent infringement litigation expenses. *See supra* Section III. The origin of the claim test is directly applicable to litigation expenses, *Woodward*, 397 U.S. at 577–79, whereas Treasury Regulation § 1.263(a)-4 only may require the capitalization of litigation expenses under some "facts and circumstances." Treas. Reg. § 1.263(a)-4(b)(3)(i), (e)(1)(i), (e)(5) (example four). It is undisputed, however, "that an approved Paragraph IV ANDA is a created intangible[,]" Tr. at 161:24–25, so Treasury Regulation § 1.263(a)-4 must apply to *some* of plaintiff's ANDA-related expenses. *See* Treas. Reg. § 1.263(a)-4(b). Further, Treasury Regulation § 1.263(a)-4 was intended to replace the prior, categorical *INDOPCO* significant-future-benefit standard with specific categories of intangible assets which "[t]he future benefit standard underlies."[16] Guidance Regarding Deduction and Capitalization of Expenditures, 67 Fed. Reg. at 77,702; *see supra* note 13. Based on this background, the Court analyzes the deductibility of plaintiff's § 271(e)(2) patent litigation expenses in the following order: (1) as the most directly applicable standard, the Court will apply the origin of the claim test first, ascertaining the nature and character of the expenditures; (2) then, the Court will apply Treasury Regulation § 1.263(a)-4 to assess whether the expenses, based on their nature and character, fall within the category of ANDA-related expenses the regulation requires plaintiff to capitalize. As the parties agreed, the Court's origin of the claim analysis will inform the Court's application of the regulation due to its full consideration of the facts and circumstances, an exercise relevant to both standards. Tr. 152:8–11, 158:13–15; *see also* Pl.'s MSJ Appx. at A0921–22. Further, the Court will not attempt to harmonize the origin of the claim test with *INDOPCO*'s significant-future-benefit standard because the history of the regulation reveals an application of the regulation is effectively an application of the significant-future-benefit standard. *See supra* note 13. Allowing the origin of the claim test to inform the application of the regulation therefore provides the government's requested harmonization of the origin of the

[15] *See Hanover Bank v. Comm'r*, 369 U.S. 672, 686 (1962) (holding these unpublished private rulings are not precedential); I.R.C. § 6110(k)(3) ("Unless the Secretary otherwise establishes by regulations, a written determination may not be used or cited as precedent.").

[16] The question of whether the IRS may overwrite the Supreme Court's interpretations of the tax code is not before the Court. *But see Nat'l Cable & Telecommunications Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 983 (2005) ("Neither *Chevron* nor the doctrine of *stare decisis*" "preclude[es] agencies from revising unwise judicial constructions of ambiguous statutes.").

claim test with "*INDOPCO*'s significant-future-benefit standard."[17] Def.'s Reply at 10–11; Tr. at 142:11–13.

VI. Whether the Origin of a § 271(e)(2) Claim is in the Process of a Capital Acquisition

The first step in determining the deductibility of Hatch-Waxman litigation expenses is applying the origin of the claim test. *See supra* Section V. This analysis begins with first determining the substance of a § 271(e)(2) patent infringement claim. *See infra* Section VI.A. The Court then assesses the nature and character of Hatch-Waxman litigation. *See infra* Section VI.B. The second step in determining deductibility of Hatch-Waxman litigation expenses is applying Treasury Regulation § 1.263(a)-4. *See supra* Section V. The Court does so in view of the nature and character of the expenses incurred, as determined by the origin of the claim test from step one. *See infra* Section VII. Finally, once the Court has determined the origin of the § 271(e)(2) patent infringement claims against plaintiff and whether Treasury Regulation § 1.263(a)-4 requires capitalization of the expenses incurred defending those claims, the Court applies I.R.C. §§ 162(a), 263(a) to decide whether plaintiff's Hatch-Waxman litigation expenses are deductible. *See infra* Section VIII.

A. The Substance of a § 271(e)(2) Patent Infringement Claim

Plaintiff argues the origin of a § 271(e)(2) patent infringement claim "is the decision by a branded drug company to enforce its patent rights against potential competitors[.]" Pl.'s MSJ at 25. Plaintiff contends these claims stem from the branded drug company's incentive "to protect its own business, revenues and profits, against allegedly infringing sales by a competitor[.]" *Id.* The government responds by arguing the Court must evaluate the origin of the claim test "from the perspective of the party whose taxes are at issue"—the generic drug company. Def.'s MSJ at 38. "For the generic company defendant in a Hatch-Waxman suit," the government argues "the origin of the claim is the ANDA approval process itself, a process by which the generic company seeks to obtain a capital asset." Def.'s Reply at 12.

The deductibility of litigation expenses generally depends on the origin and character of the claim which caused the expenses. *See Woodward v. Comm'r*, 397 U.S. 572, 577–78 (1970); *United States v. Hilton Hotels Corp.*, 397 U.S. 580, 583 (1970); *United States v. Gilmore*, 372 U.S. 39, 48–49 (1963); *Wellpoint, Inc. v. Comm'r*, 599 F.3d 641, 647 (7th Cir. 2010); *Newark Morning Ledger Co. v. United States*, 539 F.2d 929, 934–35 (3d Cir. 1976). The Court determines the origin and character of a claim by looking to "the substance of the underlying claim or transaction out of which the expenditure in controversy arose . . . ." *Santa Fe Pac. Gold Co. & Subsidiaries v. Comm'r*, 132 T.C. 240, 264–65 (2009); *see also Woodward*, 397 U.S. at 578. The Court makes "an objective inquiry into the nature and circumstances of the lawsuit." *Putnam-Greene Fin. Corp. v. United States*, 308 F. Supp. 2d 1374, 1379 (M.D. Ga. 2004) (citations omitted) (considering "the issues involved, the nature and objectives of the suit in which the expenditures were made, the defenses asserted, the purpose for which the claimed

[17] Even if *INDOPCO*'s significant-future-benefit standard remained in effect beyond the regulation, *INDOPCO* is likely inapplicable—*INDOPCO* did not involve litigation expenses and did not address the origin of the claim test. *See INDOPCO, Inc. v. Comm'r*, 503 U.S. 79, 81 (1992); *A.E. Staley Mfg. Co. & Subsidiaries v. Comm'r*, 119 F.3d 482, 488 (7th Cir. 1997).

deductions were expended, the background of the litigation, and all facts pertaining to the entire controversy out of which the disputed expenses arose[.]"). It is "the 'substance' of an action, more so than the 'form' of the action, [that] is critical in determining the origin of the action." *Id.* Under the origin of the claim doctrine framework, it is a "well-worn notion that expenses incurred in defending a business and its policies from attack are necessary and ordinary—and deductible—business expenses." *A.E. Staley Mfg. Co. & Subsidiaries v. Comm'r*, 119 F.3d 482, 487 (7th Cir. 1997) (citing *Comm'r v. Heininger*, 320 U.S. 467 (1943)); *see also Santa Fe Pac. Gold*, 132 T.C. at 261 ("[D]eduction is generally allowed for expenses incurred in defending a business and its policies from attack."). If the "origin of particular litigation lies in the process of acquisition[,]" however, the expenses incurred from that litigation must be capitalized. *Woodward*, 397 U.S. at 578.

It is further helpful to know what the origin of the claim test is not. The Court does not determine the origin and character of a claim by looking to "the motives of the payor or the consequences that may result from the failure to defeat the claim." *Santa Fe Pac. Gold*, 132 T.C. at 264–65. The test "does not involve a mechanical search for the first in the chain of events[.]" *Id.* at 265. Proximity to a capital expense is not determinative, as "[a]n ordinary expense does not become a capital expenditure simply because of some relation in time or circumstance to an admittedly capital expenditure." *McKeague v. United States*, 12 Cl. Ct. 671, 675 (1987) (citing *Connecticut Light & Power Co. v. United States*, 299 F.2d 259, 264 (Ct. Cl. 1962)), *aff'd,* 852 F.2d 1294 (Fed. Cir. 1988) ("[I]t is . . . irrelevant that [plaintiff] brought the counts in the complaint in order to achieve the relief granted in Count XIII, i.e., the [capital acquisition]."). It does not matter whether a litigation's "result indirectly enhances capital values" under the origin of the claim test; rather, "the nature and origin of the expense" controls. *Id.* (citation omitted). It is irrelevant whether the litigation is the taxpayer's "means used to attain a" capital acquisition—the expense "must be directly related to the acquisition or disposition of a capital asset." *Id.* (citing *Gilmore*, 372 U.S. at 48; I.R.C. § 263(a) (1982); *Hilton Hotels*, 397 U.S. at 583; *Kutz v. United States*, 392 F. Supp. 539, 541 (M.D. Pa. 1975); *Reed v. Comm'r*, 55 T.C. 32, 42 (1970)). The origin of the claim test is narrowly focused on the substance of the claim litigated. *Woodward*, 397 U.S. at 577–78.

In this case, the claims which caused plaintiff's expenses were § 271(e)(2) patent infringement claims. A claim brought under § 271(e)(2) involves "a highly artificial act of [patent] infringement that consists of submitting an ANDA . . . containing the fourth type of certification . . . ." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). While Hatch-Waxman litigation may be relatively new, patent infringement claims have longstanding origins in the law. A granted patent is "the property of the patentee, and as such is entitled to the same legal protection as other property."[18] *McCormick Harvesting Mach. Co. v. C. Aultman & Co.*,

[18] Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J. L. & Econ. 265, 266 (1977) ("The patent system achieves these ends by awarding exclusive and publicly recorded ownership of a prospect shortly after its discovery. The patent system so viewed is closely analogous to the American mineral claim system for public lands. . . . [T]his view of the patent system [is] called the prospect theory."); F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 Minn. L. Rev. 697, 703 (2001) ("[T]the treatment of patents as property rights is necessary to facilitate investment in the complex, costly, and risky commercialization activities required to turn nascent inventions into new goods and services. Furthermore, property treatment is equally necessary to help society decide which inventive activities are worth protecting in the first instance.").

169 U.S. 606, 609 (1898) (citing *Seymour v. Osborne*, 78 U.S. 516 (1870); *Cammeyer v. Newton*, 94 U.S. 225 (1876); *United States v. Palmer*, 128 U.S. 262 (1888); *James v. Campbell*, 104 U.S. 356 (1881)). "[T]he 'right to exclude,' [is] universally held to be a fundamental element of the property right . . . ." *Kaiser Aetna v. United States*, 444 U.S. 164, 179–80, 180 n.11 (1979) ("As stated by Mr. Justice Brandeis, '[a]n essential element of individual property is the legal right to exclude others from enjoying it.'" (quoting *Int'l News Serv. v. Associated Press*, 248 U.S. 215, 250 (1918) (Brandeis, J., dissenting))). A patent provides its owner "a limited right to exclude others from making, using, or selling a claimed invention for a limited period of time . . . ." *Leatherman Tool Grp., Inc. v. Cooper Indus., Inc.*, 131 F.3d 1011, 1015 (Fed. Cir. 1997). To "trespass upon the rights" of a patentee—a property owner—is to commit an act of patent "infringement" in violation of the patentee's right to exclude.[19] *Schillinger v. United States*, 155 U.S. 163, 169–70 (1894); *Leatherman Tool Grp., Inc.*, 131 F.3d at 1015. Put simply, the § 271(e)(2) patent infringement claims plaintiff defended were akin to claims for trespass of the patentee's property. *Schillinger*, 155 U.S. at 169–70.

The government attempts to obscure the differences between infringement litigation and suits involving asset ownership. The government contends plaintiff's "litigation objective" in defending the § 271(e)(2) claims was to prevent the delay of acquisition of an "intangible capital asset[,]" the approved ANDA, so the origin of the expenses was a capital acquisition. Def.'s Reply at 12. The origin of the claim test and tax law, however, have long distinguished between patent infringement litigation and suits involving acquisition of a capital asset. *Compare Urquhart v. Comm'r*, 215 F.2d 17, 20 (3d Cir. 1954) (finding patent litigation legal expenses deductible because "[i]nfringement litigation is a far cry from removing a cloud of title, or defending ownership of property"), *and Mylan*, 156 T.C. at 152 (same), with *Baier's Est. v. Comm'r*, 533 F.2d 117, 120 (3d Cir. 1976) (holding the origin of litigation expenses incurred incident to a dispute over the terms of a patent assignment agreement were capital), *and Safety Tube Corp. v. Comm'r*, 168 F.2d 787, 789 (6th Cir. 1948) ("Legal expenses incurred in [litigation over property ownership] constitute capital expenditures and are not deductible . . . ."). The former seeks to enforce existing property rights against another, and the latter involves ownership of an asset itself. *Schillinger*, 155 U.S. at 169–70; *Urquhart*, 215 F.2d at 20. Unlike an action for "removing a cloud of title, or defending ownership of property[,]" *Urquhart*, 215 F.2d at 20, a claim for patent infringement, like a claim for trespass, "is one sounding in tort . . . ." *Schillinger*, 155 U.S. at 169. "[W]hat a patent owner loses from infringement is the acquisition of 'a just and deserved gain' from the exploitation of the invention embodied in his patent." *Mathey v. Comm'r*, 177 F.2d 259, 263 (1st Cir. 1949). Hatch-Waxman litigation involves only questions of patent validity and infringement and therefore receives different treatment than suits over asset title under the origin of the claim test and tax law. *Urquhart*, 215 F.2d at 20; *see supra* Section IV.B.

[19] Ryan T. Holte, *The Misinterpretation of* eBay v. MercExchange *and Why: An Analysis of the Case History, Precedent, and Parties*, 18 Chap. L. Rev. 677, 682 (2015) ("As stated recently by a district court . . . emphasizing the importance of equitable remedy options for patent holders: ' . . . [W]hether for Thomas Edison and his light bulb patents or [a patent holder today] and its off-the-shelf purchase, the exclusive rights under 35 U.S.C. § 271 are the same; that period of exclusivity never comes back.'" (quoting *Sealant Sys. Int'l, Inc. v. TEK Glob., S.R.L.*, No. 5:11-CV-00774-PSG, 2014 WL 5141819, at *5 (N.D. Cal. Oct. 13, 2014))).

The government also argues the origin of a Hatch-Waxman suit is the ANDA filing because it "is the first of many steps in a lengthy process intended to create an intangible that will generate future income." Def.'s MSJ at 39–40. The government's proffered origin of the claim test analysis has been repeatedly rejected for at least three reasons. First, even if the ANDA filing is the "artificial act of infringement," *Eli Lilly & Co.*, 496 U.S. at 678, the test "does not involve a mechanical search for the first in the chain of events[.]" *Santa Fe Pac. Gold*, 132 T.C. at 265. If the government believes the origin of the claim is "the pebble that starts the avalanche of the Paragraph IV litigation[,]" Tr. at 44:18–19, it is the "Orange Book listing of a patent . . . [that] is the trigger for [Hatch-Waxman Act] protection."[20] *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 232 (4th Cir. 2002). Second, even if an FDA-approved ANDA is an income-generating intangible, "[a]n ordinary [and deductible] expense does not become a capital expenditure simply because of some relation in time or circumstance to an admittedly capital expenditure." *McKeague*, 12 Cl. Ct. at 675 (citing *Connecticut Light & Power Co.*, 299 F.2d at 264), *aff'd,* 852 F.2d 1294 (Fed. Cir. 1988) ("[I]t is . . . irrelevant that [plaintiff] brought the counts in the complaint in order to achieve the relief granted in Count XIII, i.e., the [capital acquisition]."). Third, even if the successful defense of a § 271(e)(2) claim prevents a patentee from staying effective FDA approval, § 271(e)(4)(A), whether a litigation's "result indirectly enhances capital values is not a factor [under the origin of the claim test]; the only consideration that controls is the nature and origin of the expense." *McKeague*, 12 Cl. Ct. at 675 (citation omitted). It is irrelevant whether defending a Hatch-Waxman suit is the taxpayer's "means used to attain a certain end"—the litigation expenses "must be *directly* related to the acquisition or disposition of [the ANDA]." *Id.* (emphasis added) (citing *Gilmore*, 372 U.S. at 48; I.R.C. § 263(a) (1982); *Hilton Hotels*, 397 U.S. at 583; *Kutz*, 392 F. Supp. at 541; *Reed*, 55 T.C. at 42); *Wells Fargo & Co. & Subsidiaries v. Comm'r*, 224 F.3d 874, 886 (8th Cir. 2000). The government's proposed origin of the claim test is accordingly unsupported by caselaw.

[20] Of note, the FDA's Orange Book management practices reinforce that Hatch-Waxman litigation is controlled by the patent holders. The FDA does not "police the [Orange Book] listing process by analyzing whether the patents listed by NDA applicants actually claim the subject drugs or applicable methods of using those drugs." *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1349 (Fed. Cir. 2003); *Caraco Pharm. Lab'ys, Ltd. V. Novo Nordisk A/S*, 566 U.S. 399, 406–07 (2012) ("[The FDA] does not independently assess the patent's scope or otherwise look behind the description authored by the brand. According to the agency, it lacks 'both [the] expertise and [the] authority' to review patent claims; . . . its . . . 'role with respect to patent listing is ministerial.'"); Tr. at 47:19–48:2 (government counsel stating he does not "know that the FDA necessarily is making any assumptions" regarding patent validity or infringement). "[A]ccepting at face value the accuracy of NDA holders' patent declarations[,]" the FDA "follow[s branded drug company] listing instructions" blindly. *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1080 (D.C. Cir. 2001). "In the late 1990's, evidence mounted that some brands were exploiting this statutory scheme to prevent or delay the marketing of generic drugs[.]" *Caraco*, 566 U.S. at 408 (citing FTC Study, *supra* note 8); *see, e.g.*, *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001) (holding an ANDA filer did not have a cause of action to delist an Orange Book patent, even where the patent does not cover the relevant drug or its method of use, and the patent was listed just eleven hours prior to the original patent's expiration). Though generic drug companies may have a counterclaim to seek correction of exploitative Orange Book listings, they cannot prospectively correct such listings and avoid filing a Paragraph IV certification—i.e., the "artificial act of infringement," *Eli Lilly & Co.*, 496 U.S. at 678. 21 U.S.C. § 355(j)(5)(C)(ii)(I)–(II) ("No independent cause of action[.]"). Recognizing this problem, on 16 June 2022, Senator Richard Durbin introduced a bill that would create an interagency task force on patents required "to assist the [FDA] in its ministerial role of listing appropriate and accurate descriptions of patents." Interagency Patent Coordination and Improvement Act of 2022, S. 4430, 117th Cong. § 15(d)(3)(B) (2022).

In sum, the substance of a patent infringement claim under § 271(e)(2) is no different than a traditional patent infringement claim: both are property trespass claims originating in tort. *Schillinger*, 155 U.S. at 169. A branded drug company owns intangible property—a patent—analogous to real property in an action for physical trespass. *McCormick Harvesting Mach. Co.*, 169 U.S. at 609. Filing an ANDA with a Paragraph IV certification is a statutorily created act of trespass onto that intangible property. *Eli Lilly & Co.*, 496 U.S. at 678. Once a generic drug company files an ANDA with a Paragraph IV certification and commits the statutorily defined act of trespass onto a branded drug company's property, the branded drug company's claim accrues. *See* § 271(e)(2); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). By statute, the branded drug company (the patentee) may enforce its right to exclude the generic drug company from the manufacture, use, or sale of a drug that infringes upon its patent when the generic drug company files an ANDA with a Paragraph IV certification. § 271(e)(2); *see also Kaiser Aetna*, 444 U.S. at 179–80; *Schillinger*, 155 U.S. at 169. The ANDA filing itself does not affect the property rights of either the branded or generic drug companies—a branded company's title to a patent is not called into question, and a generic company does not acquire the right to infringe. *See supra* Section IV.B. Rather, the ANDA merely begins an administrative process, itself spurring no litigation. *Id.* Litigation does not begin until a patentee determines its intellectual property is infringed and sues to prevent that infringement; even then, the litigation is not concerned with whether the FDA will eventually approve the ANDA. *See* § 271(e)(2); *Glaxo, Inc.*, 110 F.3d at 1569. All the legal expenses plaintiff seeks to deduct stem from litigation originating in precisely this way. Given this posture, the § 271(e)(2) claims against plaintiff arose out of patentee efforts to protect their intellectual property from infringement, not generic drug company efforts to acquire an approved ANDA. *See Woodward*, 397 U.S. at 577–78; *Hilton Hotels*, 397 U.S. at 583; *Gilmore*, 372 U.S. at 48–49. As such, the substance of Hatch-Waxman litigation is the same as any other patent infringement litigation—a property trespass action originating in tort. *Schillinger*, 155 U.S. at 169; *Urquhart*, 215 F.2d at 20; *Santa Fe Pac. Gold*, 132 T.C. at 264–65.

B. The Nature and Character of Hatch-Waxman Litigation

Continuing the origin of the claim test analysis the Court next makes "an objective inquiry into the nature and circumstances of [a § 271(e)(2) patent infringement] lawsuit." *Putnam-Greene Fin. Corp.*, 308 F. Supp. 2d at 1379; *Woodward*, 397 U.S. at 577–78. If the nature and character of Hatch-Waxman "litigation lies in the process of [ANDA] acquisition[,]" that would support the capitalization of plaintiff's legal expenses. *Woodward*, 397 U.S. at 578. Plaintiff argues the character of § 271(e)(2) litigation confirms it "does not concern 'the process of [ANDA] acquisition itself,' but the generic drug company's business." Pl.'s MSJ at 25 (quoting *Woodward*, 397 U.S. at 577). Plaintiff claims "the allegations in [a § 271(e)(2)] complaint, the legal issues involved, the defenses asserted, and the purposes for which the amounts claimed as deductible were expended," all show Hatch-Waxman litigation is indistinguishable from traditional patent infringement litigation. *Id.* at 25–26. The government does not disagree with plaintiff—it states "the litigation of a Hatch-Waxman suit under 35 U.S.C. § 271(e)([2]) has much in common with a traditional infringement suit under 35 U.S.C. § 271(a)[.]" Def.'s MSJ at 15. Although the government acknowledges the commonalities between Hatch-Waxman litigation and traditional patent infringement litigation, the government argues the "unique remedies in Hatch-Waxman litigation . . . show that the origin of the claim is

the generic company's Paragraph IV ANDA application." Def.'s MSJ at 40. The Court assesses these arguments in turn below.

1. The Facts and Circumstances of a § 271(e)(2) Action

Hatch-Waxman litigation amounts to nothing more than ordinary patent litigation. As emphasized by the Federal Circuit: "Notwithstanding th[e] defined act of infringement, a district court's inquiry in a suit brought under § 271(e)(2) is the same as it is in any other infringement suit, *viz.*, whether the patent in question is 'invalid or will not be infringed by the manufacture, use, or sale of the drug for which the [ANDA] is submitted.'" *Glaxo, Inc.*, 110 F.3d at 1569 (quoting 21 U.S.C. § 355(j)(2)(A)(vii)(IV))). So, although "[s]ection 271(e)(2)(A) defines the filing of an ANDA as an act of infringement, . . . it does not alter the underlying patent infringement analysis . . . ." *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1325 (Fed. Cir. 2012); *see also, e.g.*, *Abbott Lab'ys v. TorPharm, Inc.*, 503 F.3d 1372, 1379 (Fed. Cir. 2007) (noting the lack of "any authority, be it statute, case law, or legislative history of the Hatch-Waxman Act, suggesting that suits commenced under the provisions of the Act are to be treated any differently than patent infringement suits under 35 U.S.C. § 27l(a)."); *Allergan, Inc. v. Alcon Lab'ys*, *Inc.*, 324 F.3d 1322, 1331 (Fed. Cir. 2003) (finding timing is the only difference between § 271(a) and § 271(e)(2) claims). In Hatch-Waxman litigation, the Court looks to whether a generic company's prospective "commercial manufacture, use, or sale of a drug," § 271(e)(2), infringes upon a branded drug company's valid and enforceable patent, and, if so, grants an appropriate remedy—like a conventional patent infringement claim. *Glaxo, Inc.*, 110 F.3d at 1569–70. The issues involved, the nature of the suit, and the defenses asserted in a § 271(e)(2) action are substantively indistinguishable from a traditional § 271(a) patent infringement case. *Putnam-Greene Fin. Corp.*, 308 F. Supp. 2d at 1379; *Glaxo, Inc.*, 110 F.3d at 1569; *Bayer Schering Pharma AG*, 676 F.3d at 1325; *Abbott Lab'ys*, 503 F.3d at 1379; *Allergan, Inc.*, 324 F.3d at 1331. Thus, while the "form" of plaintiff's defense against § 271(e)(2) claims arose in the context of plaintiff's attempt to attain FDA approved ANDAs, the "substance" of the defense was resisting claims of tortious trespass to intellectual property—patent infringement. *Clark Oil & Ref. Corp. v. United States*, 473 F.2d 1217, 1220 (7th Cir. 1973); *see also Glaxo, Inc.*, 110 F.3d at 1569; *Bayer Schering Pharma AG*, 676 F.3d at 1325; *Abbott Lab'ys*, 503 F.3d at 1379; *Allergan, Inc.*, 324 F.3d at 1331. The facts and circumstances of Hatch-Waxman litigation therefore support treating related legal expenses the same as traditional patent infringement legal expenses under the origin of the claim test.

2. Comparison of Hatch-Waxman Litigation Remedies to Traditional Patent Infringement Litigation Remedies

The government argues "[t]he unique remedies in Hatch-Waxman litigation . . . show that the origin of the claim is the generic company's Paragraph IV ANDA application." Def.'s MSJ at 40. Although the government agrees Hatch-Waxman litigation "has much in common" with traditional patent litigation, *id.* at 15, the government alleges the automatic thirty-month stay of FDA approval, the stay of approval effectiveness until expiration of an infringed patent, and the limited availability of monetary damages are "[u]nlike traditional patent infringement cases[.]" *Id.* at 40. According to the government, under the origin of the claim test, these "unique remedies" overcome all that Hatch-Waxman litigation has in common with traditional patent

litigation. *Id.*; Def.'s Reply at 13. Under the origin of the claim test framework, the Court must assess these remedies for their "substance" rather than their "form." *Clark Oil & Ref. Corp.*, 473 F.2d at 1220.

i. The Automatic Thirty-Month Stay

The government first argues the automatic thirty-month stay of ANDA approval effectiveness shows the origin of a § 271(e)(2) claim is the ANDA. Def.'s MSJ at 40 ("The mere filing of the action within forty-five days triggers a thirty-month stay of approval of the Paragraph IV ANDA . . . ."). The government, however, fails to show how the Hatch-Waxman automatic thirty-month stay is substantively different from a traditional preliminary injunction. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I); *see also, e.g.*, *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358 (Fed. Cir. 2017). Both remedies prevent the commercial manufacture, use, or sale of a drug while patent infringement litigation is ongoing. Indeed, that was the purpose of the automatic thirty-month stay of effective ANDA approval.[21] Although the thirty-month stay is automatic in Hatch-Waxman litigation, generic drug companies can and do litigate the stay, just as a § 271(a) defendant would litigate a motion for preliminary injunction. *Compare Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1361 (Fed. Cir. 2012) (litigating a preliminary injunction through a motion to dissolve the injunction and a Federal Circuit appeal), *and Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 977–78 (Fed. Cir. 1996), *with* Def.'s Reply at 5 (describing two instances where plaintiff in this case litigated the automatic thirty-month stay). A preliminary injunction benefits a patent holder by allowing litigation over patent rights prior to diminished market share. *See, e.g.*, *Abbott Lab'ys v. Sandoz, Inc.*, 544 F.3d 1341, 1361–62 (Fed. Cir. 2008). The automatic thirty-month stay likewise benefits patent holders as it

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[21] In a recent statutory interpretation case, the Court stated it "considers the text paramount and does not find legislative history persuasive[.]" *ITServe Alliance, Inc. v. United States*, No. 1:21-cv-01190-RTH, Op. & Order at 8 n.5 (Fed. Cl. Aug. 12, 2022), ECF No. 53. The Court reasoned, "[w]hile legislative history is one of the traditional tools of statutory construction the Court can use to determine the plainness or ambiguity of statutory language, . . . legislative history cannot overcome the statutory text to provide a wider application of the statute than the plain meaning can bear." *Id.* (citing *Ariz. Pub. Serv. Co. v. EPA*, 211 F.3d 1280, 1287 (D.C. Cir. 2000), *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 457 (2002)). While the legislative history is not a starting place to understand statutory purpose, here the legislative floor statements do support the conclusion there is no material difference between an automatic thirty-month stay and a preliminary injunction. *See* Notice at 1–2, ECF No. 59. As stated by Senator Orin Hatch in 130 Cong. Rec. S10503-13 (daily ed. August 10, 1984) at page S10504:

> The period of time during which an abbreviated new drug application is not to be made effective, during the pendency of a patent challenge under the statute, is extended from 18 to 30 months from the date of submission of an ANDA application containing bioequivalency data. This increases the likelihood that the litigation will be concluded within the time period during which ANDA's are not allowed.

As stated by Representative Henry Waxman in 130 Cong. Rec. H9105-51 (daily ed. Sept. 6, 1984) at page H9114:

> [T]he period during which a generic drugmaker may not market pending the judicial resolution of a challenge to patent validity is expanded from the 18 months currently in the bill to 30 months. Some of the brand name drug companies felt this change increases the likelihood that such patent, litigation will be concluded before the generic drugmaker begins marketing.

Here, the bill's co-sponsors' floor statements accord with each other and do not contradict the plain meaning of the text.

"giv[es] the patent holder a chance to vindicate its intellectual property rights before the FDA approves a generic version of the drug." *aaiPharma Inc.*, 296 F.3d at 232 (citing *Bristol-Myers Squibb Co. v. Royce Lab'ys, Inc.*, 69 F.3d 1130, 1135 (Fed. Cir. 1995)). Also like a preliminary injunction, the automatic stay is initiated by the patent holder—"[i]f a patent is not listed in the Orange Book, ANDA applicants do not have to file a Paragraph IV certification, and the patent holder is unable to take advantage of the thirty-month stay." *Id.* In sum, the differences between the automatic stay and a preliminary injunction are a matter of form and serve only to benefit the patent holder. *Clark Oil & Ref. Corp.*, 473 F.2d at 1220. The automatic stay therefore does not show the origin of a Hatch-Waxman claim is the generic drug company's ANDA. *Id.*; *Woodward*, 397 U.S. at 577–78.

ii. The Stay of Effective FDA Approval

The government next contends the stay of effective FDA approval until an infringed patent expires also shows the ANDA is the origin of Hatch-Waxman litigation. Def.'s MSJ at 40. The government again fails to show how the stay of approval effectiveness upon a finding of infringement is substantively different from a permanent injunction in traditional patent litigation. Both prevent the commercial manufacture, use, or sale of a drug until expiration of the infringed property right. *Compare* § 271(e)(4)(A) *with W. Plastics, Inc. v. DuBose Strapping, Inc.*, No. 5:15-CV-294-D, 2020 WL 5709250, at *4 (E.D.N.C. Sept. 24, 2020) (enjoining the manufacture, use, sale, or importation of infringing products until patent expiration), *aff'd,* No. 2021-1371, 2021 WL 5985361 (Fed. Cir. Dec. 17, 2021). Though the stay of approval effectiveness is automatic under the statute—not requiring a showing of the permanent injunction factors required in *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006)—this is a matter of form, not substance. *Clark Oil & Ref. Corp.*, 473 F.2d at 1220; *Santa Fe Pac. Gold*, 132 T.C. at 264–65; *see also Woodward*, 397 U.S. at 578. By enacting this de facto permanent injunction provision, Congress implicitly determined the public interest is best served by an equitable remedy upon a finding of § 271(e)(2) infringement. *eBay Inc.*, 547 U.S. at 391. Moreover, the stay entered under § 271(e)(4)(A) applies strictly to "the effective date of any approval"—in other words, the FDA reaches its approval decision regardless of any infringement finding, and that approval is effective once trespass to intellectual property is eliminated. § 271(e)(4)(A). This further supports the origin of the claim in § 271(e)(2) litigation being the patentee's decision to protect its patent rights, because even if it were proper to consider the consequences of litigation, the consequences here are strictly tied to enforceability of a property right, not FDA approval. *Woodward*, 397 U.S. at 578 (citing *Gilmore*, 372 U.S. 39); *see also McKeague*, 12 Cl. Ct. at 675; *Santa Fe Pac. Gold*, 132 T.C. at 264–65. This remedy therefore does not show the origin of a Hatch-Waxman claim is the ANDA filing. *Clark Oil & Ref. Corp.*, 473 F.2d at 1220; *Woodward*, 397 U.S. at 577–78.

iii. The Exclusion of Damages

Lastly, the government argues the exclusion of damages absent a commercial manufacture, use, or sale in Hatch-Waxman litigation shows the origin of the claim is the ANDA. Def.'s MSJ at 40; *see* 35 U.S.C. § 271(e)(4)(C) (". . . [D]amages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale . . . ."). "Unlike traditional patent infringement cases, which often seek

reasonable royalties or lost profits designed to compensate the patent holder for losses suffered to its present income," the government avers, "the focus of the Hatch-Waxman suit is an effort to defeat or delay FDA approval of the Paragraph IV ANDA." Def.'s MSJ at 40–41 (emphasis removed).

The government emphasizes that monetary damages in traditional § 271(a) patent infringement cases are limited to "damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention . . . ." 35 U.S.C. § 284 (2018). The government, however, does not explain how this difference creates a meaningful distinction. Though the Hatch-Waxman plaintiff's claim for damages is barred absent "commercial manufacture, use, offer to sell, or sale," § 271(e)(4)(C), a traditional plaintiff may not receive damages without similar conduct because the traditional plaintiff cannot bring a claim in the first place. § 271(a) (barring traditional patent infringement claims themselves absent someone who "makes, uses, offers to sell, or sells any patented invention"). Even if the traditional plaintiff had a cause of action without this conduct, it is difficult to imagine a circumstance where a traditional plaintiff could recover significant damages without identifying some infringing "commercial manufacture, use, offer to sell, or sale." *See, e.g.*, *Whitserve, LLC v. Computer Packages, Inc.*, 694 F.3d 10, 26 (Fed. Cir. 2012) (citing *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1324 (Fed. Cir. 2009)). Without any commercial manufacture, use, offer to sell, or sale of an infringing product, even the most sophisticated expert witness may have difficulty finding a theory upon which to base a claim for lost profits or a reasonable royalty. *Id.* Monetary relief in Hatch-Waxman litigation may therefore differ in form from traditional litigation, but the government fails to show how it differs in substance. *Clark Oil & Ref. Corp.*, 473 F.2d at 1220; *see* §§ 271(e)(4)(C), 284; *cf.* § 271(a) (barring patent infringement claims themselves absent someone who "makes, uses, offers to sell, or sells any patented invention").

Hatch-Waxman litigation begins with an "artificial act of infringement[,]" *Eli Lilly & Co.*, 496 U.S. at 678—an ANDA filing—but this does not affect the above damages analysis. Generic drug companies make and use patented drugs before filing ANDAs. *Supra* Section IV.B.[22] Under the Hatch-Waxman Act, generic drug companies enjoy an infringement safe harbor for that use if it is "reasonably related to the development and submission of" an ANDA. § 271(e)(1). In other industries, such use of an invention is actionable patent infringement under § 271(a). *C.f. Roche Prod., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984) (holding experimental use of an invention in furtherance of the infringer's business is § 271(a) patent infringement), *superseded by statute*, 35 U.S.C. § 271(e)(1), *as recognized in Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003). Hatch-Waxman litigation and traditional patent infringement litigation therefore are both preceded by the same "mak[ing]" and "us[ing]" of a "patented invention." § 271(a); *supra* Section IV.B. The two differ in that the Hatch-Waxman Act: exempts from infringement the use of an invention for developing an ANDA, § 271(e)(1); and excludes damages claims when there are no commercial sales, §§ 355(j)(5)(B)(iii), 271(e)(4)(C). Hatch-Waxman litigation necessarily occurs after use of an invention, but before FDA approval and monetary damages accrual. *See* § 271(e)(2). If

[22] "The purpose of sections 271(e)(1) and (2) is to establish that experimentation with a patented drug product, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement." H.R. Rep. No. 98-857, pt. 1, at 45 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2678.

traditional patent infringement litigation occurred under the same facts—after use, but before marketing or sales—the patentee is unlikely to recover significant damages. *See, e.g.*, *Whitserve, LLC*, 694 F.3d at 28 (basing reasonable royalty calculations on the number of "infringing transactions"). Congress implicitly recognized branded drug companies incur miniscule damages *before* the generic drug receives FDA approval and reaches market. *See generally* § 271(e) (creating a safe harbor for infringing activities relating to ANDA applications and barring damages in ANDA litigation where there is no commercial activity). Congress coordinated Hatch-Waxman litigation with the FDA approval process and streamlined it by preventing litigation over little to no damages. *See id.*; *FTC v. Actavis, Inc.*, 570 U.S. 136, 142–43 (2013); *Caraco*, 566 U.S. at 406–07. These differences do not make damages in Hatch-Waxman litigation materially different from traditional patent infringement litigation; in either scenario, as stated *supra*, there is use of a patented drug but little monetary damages before commercial marketing. Accordingly, the bar on damages does not show the origin of a Hatch-Waxman claim is the ANDA filing—it is merely the effect of litigating patent issues before any "commercial manufacture, use, offer to sell, or sale." § 271(e)(4)(C); *Clark Oil & Ref. Corp.*, 473 F.2d at 1220; *Woodward*, 397 U.S. at 577–78.

iv. Hatch-Waxman Litigation Remedies Summary

The above Hatch-Waxman litigation remedies differ from those in traditional patent infringement litigation only in form, not substance. *Clark Oil & Ref. Corp.*, 473 F.2d at 1220. Even if they differed in substance, the Supreme Court in *Woodward* stated "the origin of the claim litigated" is not based on "the consequences of the litigation, [or] . . . the taxpayer's motives or purposes in undertaking defense of the litigation . . . ." *Woodward*, 397 U.S. at 578 (citing *Gilmore*, 372 U.S. 39); *see also McKeague*, 12 Cl. Ct. at 675; *Santa Fe Pac. Gold*, 132 T.C. at 264–65. Nor is "the origin and character of the claim with respect to which an expense was incurred" affected by the "potential consequences upon the fortunes of the taxpayer[.]" *Gilmore*, 372 U.S. at 49. Whether the result of litigation "indirectly enhances capital values is not a factor"; the Court may not look to whether a § 271(e)(2) claim is a "means used to attain a certain end[.]" *McKeague*, 12 Cl. Ct. at 674–75 (citing *Gilmore*, 372 U.S. at 48) (a taxpayer's "purpose or motive" is "irrelevant in determining the origin of the claim"); *see also Woodward*, 397 U.S. at 577 (rejecting the notion that a taxpayer's "primary purpose" in incurring an expense should inform the origin of the claim test). Even if the Court were to assume branded drug companies suing generics under § 271(e)(2) are solely focused on "delay[ing] FDA approval of the Paragraph IV ANDA" with no anticipation of compensation or concern for their property rights, as the government posits, it would have no bearing on the origin of the claim test. Def.'s MSJ at 41; *Woodward*, 397 U.S. at 578. The availability of an exclusivity period for a first ANDA-filer and the possible motivations for defending against a § 271(e)(2) claim also do not alter this conclusion.[23] *Gilmore*, 372 U.S. at 49; *Woodward*, 397 U.S. at 578. The government

[23] Plaintiff states the IRS has taken the position in three memoranda that the possibility of a 180-day generic exclusivity period is a factor differentiating § 271(e)(2) litigation from § 271(a) litigation, therefore justifying different tax treatment. Pl.'s MSJ at 38 (citing Pl.'s MSJ Appx. at A0925–32, A0913, A0980–84). The government's brief describes the 180-day exclusivity period in the background section, Def.'s MSJ at 16–18, but otherwise the government does not embrace the IRS's position with respect to generic exclusivity in this case. *See* Def.'s MSJ; Def.'s Reply. There is accordingly no reason for the Court to engage with this proposition beyond noting: the receipt of an exclusivity period is uncorrelated with whether a first-filer is sued; there is no guarantee a

appeals "to formalisms and artificial distinctions" in its effort to assert the origin of a § 271(e)(2) claim is the acquisition of an approved ANDA. *Woodward*, 397 U.S. at 577; *Gilmore*, 372 U.S. at 47–49; *McKeague*, 12 Cl. Ct. at 675; *Santa Fe Pac. Gold*, 132 T.C. at 264–65. The Court concludes the nature and character of § 271(e)(2) patent infringement litigation is that of traditional patent infringement—a property trespass tort—and the government's remedy arguments fail to overcome that. *See supra* Section VI.A.; *Woodward*, 397 U.S. at 577–78; *Hilton Hotels Corp.*, 397 U.S. at 583; *Gilmore*, 372 U.S. at 48–49.

C. Origin of the Claim Test Conclusion

The substance of a § 271(e)(2) claim is that of traditional patent infringement—a property trespass action sounding in tort. *See supra* Section VI.A. The nature and character of Hatch-Waxman litigation are indistinguishable from traditional patent infringement litigation, with any differences being a matter of form. *See supra* Section VI.B. The Court therefore concludes "the origin of the" § 271(e)(2) claims plaintiff litigated is not "in the process of acquisition" of the ANDAs themselves. *Woodward*, 397 U.S. at 577. Rather, the origin of the § 271(e)(2) claims is the branded drug companies' patent enforcement efforts to maintain their business profits and cease plaintiff's generic drug business activities. *See Woodward*, 397 U.S. at 577–78; *Gilmore*, 372 U.S. at 48–49.

VII. Whether Treasury Regulation § 1.263(a)-4 Requires Capitalization (Preventing Deduction) of § 271(e)(2) Litigation Expenses

The second step in determining deductibility of Hatch-Waxman litigation expenses is applying Treasury Regulation § 1.263(a)-4. *See supra* Section V. Treasury Regulation § 1.263(a)-4 sets forth standards for determining whether "[a]mounts paid to acquire or create intangibles" must be capitalized, preventing their deduction. The parties agree an FDA-approved ANDA is a qualifying intangible under the regulation.[24] Accordingly, the Court must only determine whether Hatch-Waxman litigation defense expenses—which, as the Court concluded *supra* Section VI, originate from the branded drug companies' patent enforcement efforts—are: (1) a part of the ANDA transaction; (2) "facilitate the acquisition or creation of" the approved ANDA; or (3) otherwise "enhance" the approved ANDA. Treas. Reg. § 1.263(a)-4(b).

The regulation enumerates specific categories of expenses that must be capitalized. Treas. Reg. § 1.263(a)-4(b). Relevant here, the regulation requires capitalization of amounts: (1) paid to acquire an intangible asset ("the transaction"); (2) "paid to facilitate . . . an acquisition

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first-filer enjoys any period of exclusivity; there is no evidence to suggest the exclusivity period is intended to reimburse generics specifically for the costs of § 271(e)(2) litigation, as opposed to acting as a simple incentive for early ANDA filing; and whether the result of litigation "indirectly enhances capital values is not a factor" in determining the tax treatment of plaintiff's § 271(e)(2) litigation expenses, *McKeague*, 12 Cl. Ct. at 675. *See supra* Section IV.C.; *see also Woodward*, 397 U.S. at 577; *Gilmore*, 372 U.S. at 47–49.

[24] Def.'s MSJ at 31 ("An FDA-approved Paragraph IV ANDA is a 'created intangible,' because it is a 'license, permit, franchise, or other similar right granted by [a] governmental agency.'" (quoting Treas. Reg. § 1.263(a)-4(d)(5)(i))); Tr. at 161:24–162:6 ("THE COURT: . . . Does Plaintiff agree that an approved Paragraph IV ANDA is a created intangible? . . . [PLAINTIFF]: Yes, Your Honor. . . . THE COURT: Okay. And the Government? [GOVERNMENT]: Yes.").

or creation of an intangible [asset]"; and (3) "paid to create or enhance a separate and distinct intangible asset." *Id.* "For purposes of [the first inquiry], 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." Treas. Reg. § 1.263(a)-4(e)(3). For the second inquiry, "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." Treas. Reg. § 1.263(a)-4(e)(1)(i). "Whether an amount is paid in the process of investigating or otherwise pursuing the transaction is determined based on all of the facts and circumstances." *Id.* "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." *Id.* For the third inquiry, the regulation does not provide any explanation or example of when an amount "enhance[s] a separate and distinct intangible asset." Treas. Reg. § 1.263(a)-4(b)(iii).

The "transaction" at issue here is the acquisition of an FDA-approved ANDA with a Paragraph IV certification. Treas. Reg. § 1.263(a)-4(e)(3); *see supra* Section I. The primary step in that transaction is FDA review of the ANDA to ensure the "generic drug and the relevant listed drug share the same active ingredients and are bioequivalent." *Caraco Pharm. Lab'ys, Ltd. v. Forest Lab'ys, Inc.*, 527 F.3d 1278, 1282 (Fed. Cir. 2008) (citing § 355(j)(2)(A)(ii), (iv)). The FDA "shall approve" an ANDA unless it fails to satisfy certain technical requirements enumerated in the statute and accompanying regulations. 21 U.S.C. § 355(j)(4). Such technical requirements include: "the active ingredient is the same as that of the [branded] drug"; the drugs are bioequivalent; the production methods would preserve the generic's identity, strength, quality, and purity; and proper labeling. § 355(j)(4); 21 C.F.R. § 314.105(d), .127. If the FDA finds the ANDA application satisfies the technical requirements, the FDA "shall approve" the application and that is the end of the "transaction." § 355(j)(4); Treas. Reg. § 1.263(a)-4(e)(3).

The FDA's review of an ANDA does not include patent related questions. When a generic drug company files an ANDA with a Paragraph IV certification, it certifies the patents associated with the relevant NDA in the Orange Book are either invalid or will not be infringed by the proposed generic drug. § 355(j)(2)(A)(vii)(IV); *see supra* Section IV.B. The FDA performs no assessment of that certification as a part of its ANDA review process—"[a]ccording to the agency, it lacks 'both [the] expertise and [the] authority' to review patent claims[.]" *Caraco Pharm. Lab'ys, Ltd. V. Novo Nordisk A/S*, 566 U.S. 399, 406–07 (2012); *Mylan, Inc. & Subsidiaries v. Comm'r*, 156 T.C. 137, 157 (2021) ("The FDA does not analyze patent issues as part of its review . . . ."); *cf. Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1080 (D.C. Cir. 2001); *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1349 (Fed. Cir. 2003); Tr. at 47:19–48:2 (government counsel stating he does not "know that the FDA necessarily is making any assumptions" regarding patent validity or infringement). "If the brand-name patentee brings an infringement suit [under § 271(e)(2)] within 45 days," *FTC v. Actavis, Inc.*, 570 U.S. 136, 143 (2013), the FDA continues the ANDA review during the pendency of the suit and may issue a tentative or final approval before the suit is resolved. *See* 21 C.F.R. § 314.107(b)(3); 21 U.S.C. § 355(j)(5)(B)(iii)(I). FDA approval of an ANDA does not hinge on any patent issues in the Hatch-Waxman suit—at most, if a court finds the patent valid and infringed, the generic's FDA approval will not become effective until expiration of the infringed patent. § 271(e)(4)(A); *see Mylan*, 156 T.C. at 157. Further, prevailing in the Hatch-Waxman suit does not aid ANDA

approval, as the FDA may disapprove an ANDA for not meeting safety and bioequivalence standards. 21 U.S.C. § 355(j)(4)(F)); *see supra* Section IV.B. Thus, defending a claim of patent infringement under § 271(e)(2) is not in the "series of steps carried out as part of a single plan" to acquire an approved ANDA. Treas. Reg. § 1.263(a)-4(e)(3).

Hatch-Waxman litigation is not a part of the ANDA "transaction." Treas. Reg. § 1.263(a)-4(e)(3). Although the ANDA filing may be the "artificial act of infringement[,]" *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990), this is, among other reasons, to enable the use of branded drug products for generic drug research and development during the life of the patent.[25] *See* § 271(e)(1). This artificial act of infringement permits drug manufacturers to preemptively litigate patent infringement and validity, so if a patent is either invalid or not infringed, an affordable generic becomes available to the public sooner. *See AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1377 (Fed. Cir. 2012) ("[Section] 271(e)(2) provided a new cause of action so that courts could promptly resolve infringement and validity disputes before the ANDA applicant had engaged in the traditional statutorily defined acts of infringement."); *Bristol-Myers Squibb Co. v. Royce Lab'ys, Inc.*, 69 F.3d 1130, 1135 (Fed. Cir. 1995) (holding that a Section 271(e)(2) suit makes "it possible for a patent owner to have the court determine whether, if a particular drug were put on the market, it would infringe the relevant patent"). If a patent is valid and infringed, then the affordable generic will still receive FDA approval and will be ready to launch into the marketplace on the day the patent expires. *See* § 271(e)(4)(A). If the branded drug company chooses not to bring a § 271(e)(2) claim—and it is under no obligation to do so[26]—then the affordable generic becomes available to the public as soon as the FDA processes the ANDA. *See* § 355(j)(4). In any case, the FDA's review of the ANDA is the same—the FDA "shall approve" a technically acceptable ANDA. *Id.* Accordingly, Hatch-Waxman litigation is not a part of the ANDA "transaction" under Treasury Regulation § 1.263(a)-4.

For the same reasons Hatch-Waxman litigation is not a part of the ANDA transaction, Hatch-Waxman litigation expenses also do not "facilitate" the "acquisition or creation" of an approved ANDA. As illustrated *supra*, the expenses are not "paid in the process of investigating or otherwise pursuing [an ANDA]." Treas. Reg. § 1.263(a)-4(b), (e)(1)(i). The FDA does not concern itself with patent issues when determining an ANDA's technical acceptability. *See* § 355(j)(4); *Caraco*, 566 U.S. at 406–07. Further, as described *supra* Section VI.B., considering "all of the facts and circumstances" as required under Treasury Regulation § 1.263(a)-4(e)(1)(i), a claim under the Hatch-Waxman Act may alter the suit's timing, "but it does not alter the underlying patent infringement analysis . . . ." *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1325 (Fed. Cir. 2012); *Abbott Lab'ys v. TorPharm, Inc.*, 503 F.3d 1372, 1379 (Fed. Cir. 2007) (noting the lack of "any authority, be it statute, case law, or legislative history of the Hatch-Waxman Act, suggesting that suits commenced under . . . the Act are to be treated any differently than patent infringement suits under 35 U.S.C. § 271(a)."); *Allergan, Inc. v. Alcon Lab'ys, Inc.*, 324 F.3d 1322, 1331 (Fed. Cir. 2003) (finding timing is the only difference between

[25] "The purpose of sections 271(e)(1) and (2) is to establish that experimentation with a patented drug product, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement." H.R. Rep. No. 98-857, pt. 1, at 45 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2678.

[26] *See supra* note 8.

§ 271(a) and § 271(e)(2) claims). An expense incurred defending a § 271(e)(2) patent infringement claim does nothing to "facilitate" or advance FDA approval of a pending ANDA. Treas. Reg. § 1.263(a)-4(b).

To illustrate how Hatch-Waxman litigation expenses do not facilitate ANDA approval, what the Hatch-Waxman Act and the Federal Food, Drug, and Cosmetic Act provide are two coordinated, but distinct processes. *See Actavis, Inc.*, 570 U.S. at 142–43. On one track, the FDA considers whether the ANDA satisfies all technical requirements for a generic drug safe for the American public. *See* § 355(j)(4). On another track, the district courts perform an entirely different analysis, initiated by the patent holder,[27] to determine whether a branded drug company's patent rights are valid and infringed. *Glaxo, Inc. v. Novopharm Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). These two tracks remain in parallel regarding whether the ANDA should be approved or whether the patent is valid and infringed. The tracks cross only when *both* the FDA approves the ANDA and the district court finds a valid patent infringed—at which point, the Hatch-Waxman Act requires delay of ANDA approval effectiveness until expiration of the infringed patent. *See* § 271(e)(4)(A); *Caraco*, 566 U.S. at 405 ("[T]he FDA cannot authorize a generic drug that would infringe a patent[.]"). The generic drug company is not obligated to demonstrate patent invalidity or noninfringement to the FDA to obtain ANDA approval, nor is it obligated to show the technical acceptability of its ANDA application to the court during Hatch-Waxman litigation. *See supra* Section IV.B. As such, amounts paid during Hatch-Waxman litigation to secure a judgment of patent invalidity or noninfringement can never be amounts "paid in the process of investigating or otherwise pursuing" an approved ANDA; they do nothing to advance ANDA approval. Treas. Reg. § 1.263(a)-4(b), (e)(1)(i). "[A]n amount . . . paid to facilitate the acquisition or creation of an" approved ANDA is an amount that goes to whether the FDA approves the ANDA—not whether a patent is valid and infringed. Treas. Reg. § 1.263(a)-4(e)(1)(i); *Mylan*, 156 T.C. at 159 ("Congress' decision to coordinate effective FDA approval with the outcome of a Section 271(e)(2) suit does not convert such litigation into a link in the ANDA approval chain.").[28] Accordingly, Hatch-Waxman litigation expenses do not "facilitate the acquisition or creation" of an ANDA. Treas. Reg. § 1.263(a)-4(b).

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[27] The government argues the generic drug company may initiate Hatch-Waxman litigation because, if the branded drug company does not bring a § 271(e)(2) claim against the generic within forty-five days, "the generic company may itself file suit 'for a declaratory judgment that such patent is invalid or not infringed.'" Def.'s MSJ at 35 (quoting 35 U.S.C. § 271(e)(5)). The litigation expenses at issue in this case arose only out of branded drug companies' § 271(e)(2) claims, as plaintiff does not argue it is entitled to a refund for any § 271(e)(5) declaratory judgment litigation expenses. Accordingly, the Court does not reach this question and does not consider the argument relevant.

[28] Although branded drug companies cannot file § 271(e)(2) claims absent an ANDA with a Paragraph IV certification, that does not necessarily mean plaintiff would not have incurred patent infringement legal expenses. Branded drug companies previously brought suit under § 271(a) before the Hatch-Waxman Act coordinated such litigation timing with the FDA's generic drug review process. *See Roche Prod., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984); 35 U.S.C. § 271(e)(1); Treas. Reg. § 1.263(a)-4(e)(1)(i) ("[T]he fact that the amount would (or would not) have been paid but for the transaction is relevant, but is not determinative."); *cf. Mylan*, 156 T.C. at 161 ("Even absent the [ANDA] transaction, the patent holder would doubtless seek to defend its intellectual property against a potential infringer, and the generic manufacturer would incur the same litigation costs in defending such suit."). Even if a branded drug company chooses not to pursue Hatch-Waxman litigation against an ANDA-filer, the branded drug company may still sue later for traditional patent infringement. § 271(a). As such, plaintiff's litigation expenses are not unique to its ANDA filings.

In arguing Hatch-Waxman litigation facilitates ANDA approval, the government provides its own definition of "facilitate." The government proposes: "To 'facilitate' means 'to make the occurrence of (something) easier; to render less difficult.'" Def.'s Reply at 6 (citing *Facilitate*, Black's Law Dictionary (10th ed. 2014)); *but see* Treas. Reg. § 1.263(a)-4(e)(1)(i) ("[A]n amount is paid to facilitate . . . if the amount is paid in the process of investigating or otherwise pursuing the transaction."). The government's definition, however, further shows why Hatch-Waxman litigation does not "facilitate" ANDA acquisition. If Hatch-Waxman litigation made receiving an approved ANDA easier, the Court would expect that to mean the litigation removes some ANDA technical requirement under § 355(j)(4), or otherwise expedites the FDA approval process. *See* Def.'s Reply at 6. Hatch-Waxman litigation does no such thing. Saliently, Hatch-Waxman litigation can only *delay*, never accelerate, final ANDA approval, and no district court decision during litigation can affect that final approval decision. *See* 21 C.F.R. § 314.107(b)(3); 21 U.S.C. § 355(j)(5)(B)(iii)(I); *Mylan*, 156 T.C. at 157. If a technically acceptable ANDA is on track for FDA approval but is then stalled by § 271(e)(2) patent infringement litigation, it would not follow that legal expenses incurred to prevent the delay "facilitates" or "renders less difficult" FDA approval. Treas. Reg. § 1.263(a)-4(e)(1)(i); Def.'s Reply at 6. The best result a generic drug company can secure from successfully defending a § 271(e)(2) claim is FDA approval on the same date it otherwise would have been approved if no litigation had occurred. The government's argument assumes Hatch-Waxman litigation is integral to the ANDA transaction, so litigation expenses always ensure easier ANDA approval. Def.'s Reply at 6–7. As discussed *supra*, however, Hatch-Waxman litigation is not part of the ANDA transaction and does not arise with every filed ANDA, *see supra* note 8. Accordingly, even under the government's extrinsic definition, Hatch-Waxman litigation does not "facilitate" ANDA approval. Def.'s Reply at 6 (citing *Facilitate*, Black's Law Dictionary (10th ed. 2014)).

Finally, Hatch-Waxman litigation defense expenses do not "enhance" an ANDA with a Paragraph IV certification under Treasury Regulation § 1.263(a)-4. As noted *supra*, Hatch-Waxman litigation can only delay the effective date of FDA approval; it cannot accelerate approval, render approval less difficult to obtain, or improve the ANDA. *See* 21 C.F.R. § 314.107(b)(3); 21 U.S.C. § 355(j)(5)(B)(iii); *Mylan*, 156 T.C. at 157. The government argues successful defense of a § 271(e)(2) claim removes a barrier to obtaining effective FDA approval and therefore necessarily "enhances" the ANDA, "both by advancing the date of final FDA approval and ensuring that such approval is not later revoked." Def.'s MSJ at 36 n.13; Def.'s Reply at 8 n.3. This argument mischaracterizes the nature of an approved ANDA. When a generic drug company submits a technically acceptable ANDA, it is on track to its earliest possible effective approval date. *See* 21 C.F.R. § 314.107(b)(3); 21 U.S.C. § 355(j)(5)(B)(iii)(I); *Mylan*, 156 T.C. at 157. Then, when a branded drug company files a § 271(e)(2) claim, the branded drug company places an obstacle in the way of effective FDA approval. § 355(j)(5)(B)(iii). That obstacle may stay approval effectiveness for a period of up to thirty months while litigation is ongoing, it may stay approval effectiveness for the life of the patent, or it may not delay approval effectiveness at all. *Id.* The successful defense of a § 271(e)(2) claim, however, may under no circumstances advance the ANDA approval to a date sooner than it otherwise would have been approved. *See* 21 C.F.R. § 314.107(b)(3); 21 U.S.C. § 355(j)(5)(B)(iii); *Mylan*, 156 T.C. at 157. Failure to defend a § 271(e)(2) claim also cannot result in revocation of FDA approval; it can only stay approval effectiveness for the life of the

patent. § 355(j)(5)(B)(iii)(II); § 271(e)(4)(A). Accordingly, costs paid to remove a litigation barrier blocking FDA approval do not "enhance" the ANDA; they merely prevent its further diminishment through extended delays to its effectiveness.[29] Treas. Reg. § 1.263(a)-4(b).

In conclusion, no provision of Treasury Regulation § 1.263(a)-4 requires capitalization of Hatch-Waxman litigation expenses. Although the parties agree an FDA-approved ANDA with a Paragraph IV certification is a qualifying intangible under § 1.263(a)-4, defending Hatch-Waxman litigation is not a part of that transaction. Treas. Reg. § 1.263(a)-4(e)(3). The legal expenses incurred—which originate from the branded drug companies' patent enforcement—do not "facilitate the acquisition or creation of" the approved ANDA, as they are not "paid in the process of investigating or otherwise pursuing the transaction." Treas. Reg. § 1.263(a)-4(b), (e)(1)(i). The expenses do not make acquiring ANDA approval "easier" or "render [it] less difficult." Def.'s Reply at 6. Lastly, the expenses do not "enhance" the approved ANDA; they only prevent its further diminishment. Treas. Reg. § 1.263(a)-4(b). Accordingly, Treasury Regulation § 1.263(a)-4 does not require the capitalization of § 271(e)(2) litigation expenses. *See Mylan*, 156 T.C. at 161.

VIII. Tax Treatment of § 271(e)(2) Patent Litigation Expenses

The Court holds *supra* Section VI under the origin of the claim test that a generic drug company's expenses incurred defending § 271(e)(2) patent litigation claims originate in branded drug companies' patent enforcement efforts—property trespass claims sounding in tort. *Schillinger v. United States*, 155 U.S. 163, 169 (1894). The Court further holds *supra* Section VII Treasury Regulation § 1.263(a)-4 does not require the capitalization of these expenses. Having established the origin of these expenses and their treatment under the regulation, the Court next considers whether the expenses are deductible under the tax code. I.R.C. §§ 162(a), 263(a).

Patent litigation expenses are generally tax deductible. The Internal Revenue Code allows a deduction for "all the ordinary and necessary expenses paid or incurred during the taxable year in carrying on any trade or business[.]" I.R.C. § 162(a); *see supra* note 11. Litigation expenses for taxpayers "engaged in the business of exploiting and licensing patents . . . are peculiarly normal" to their business. *Urquhart v. Comm'r*, 215 F.2d 17, 19 (3d Cir. 1954).

[29] Though the government does not take this position, the Court notes the availability of a 180-day exclusivity period for first-applicants also does not support the proposition Hatch-Waxman litigation enhances an approved ANDA with a Paragraph IV certification. *See supra* note 23; Section IV.C. Notwithstanding the receipt of an exclusivity period is uncorrelated with whether litigation happens at all, *supra* Section IV.C., notes 7–8, 20, the exclusivity period is not an intangible right of the generic drug company that enjoys it, but merely a limitation on the FDA's authority to approve other ANDAs—it is a disability impeding those other companies for failure to file sooner. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (subsequent filers' "application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant"). Though a first-applicant may enjoy and benefit from this disability, an ANDA holder that believes it is entitled to exclusivity cannot sue another generic drug company to stop it from launching. *Id.* Further, as discussed *supra* Section IV.C., "[i]f multiple applicants file substantially complete ANDAs with paragraph IV certifications on the same day as the first to do so, those applicants all are entitled to exclusivity." Lietzan, *supra*, at 290. A first-applicant may therefore be one of many to enjoy this period of exclusivity, or it may never enjoy the exclusivity if another first-applicant begins marketing first. § 355(j)(5)(B)(iv), (F)(ii); *see also* 21 C.F.R. § 314.107(c)(1) (2016).

Such "litigation expenses [a]re incurred to prevent (and recover) damage to their business, that is, to protect, conserve and maintain their business profits." *Id.* at 20. Patent litigation "expenditures which yield benefits over a period of years" does not mean the expenditures are "not current operating expenses . . . ." *Id.* at 20–21. Accordingly, under I.R.C. § 162(a), legal expenses incurred during patent litigation are tax deductible regardless of future benefits derived from such litigation.

Like expenses incurred pursuing patent infringement claims, expenses incurred defending patent infringement claims have also historically been deductible under I.R.C. § 162(a). *Mylan, Inc. & Subsidiaries v. Comm'r*, 156 T.C. 137, 163 (2021) (citing *Appeal of F. Meyer & Bro. Co.*, 4 B.T.A. 481, 482 (1926) (holding that amount paid by defendant in a patent infringement suit for an accounting was an ordinary and necessary expense); *Addressograph-Multigraph Corp. v Comm'r*, 4 T.C.M. (CCH) 147, 166 (1945) (upholding treatment of amounts incurred in defending patent infringement suits as ordinary and necessary business expenses)); *cf. Mathey v. Comm'r*, 177 F.2d 259, 263 (1st Cir. 1949); *Urquhart*, 215 F.2d at 20. The government does not "know of any [published] case in which a patent infringement defendant, outside of ANDA, was not allowed to deduct litigation expenses[.]" Tr. at 101:2–25. The IRS Office of Chief Counsel stated in an 11 August 2014 memo: "In general, costs to defend against a claim of patent infringement are deductible on the theory that the taxpayer is protecting or maintaining its income-generating business." Pl.'s MSJ Appx. at A0912; *see also* Guidance Regarding Deduction and Capitalization of Expenditures, 67 Fed. Reg. 77,701, 77,705 (Dec. 19, 2002) ("[A]mounts paid to protect . . . property against infringement and to recover profits and damages as a result of an infringement . . . under current law, . . . are generally deductible." (citing *Urquhart*, 215 F.2d 17)). Accordingly, absent any precedent to the contrary, a patent infringement defendant's legal expenses are, like the patent owner's, tax deductible.

As established *supra* Section VI, patent infringement claims are property trespass claims sounding in tort. *Schillinger*, 155 U.S. at 169. Consistent with the tax treatment of patent infringement litigation expenses, expenses incurred defending against tort claims are also deductible business expenses. *Kornhauser v. United States*, 276 U.S. 145, 153 (1928); *Mylan*, 156 T.C. at 153–54. It is a "well-worn notion that expenses incurred in defending a business and its policies from attack are necessary and ordinary—and deductible—business expenses." *A.E. Staley Mfg. Co. & Subsidiaries v. Comm'r*, 119 F.3d 482, 487 (7th Cir. 1997) (citing *Comm'r v. Heininger*, 320 U.S. 467 (1943)); *see also Santa Fe Pac. Gold Co. & Subsidiaries v. Comm'r*, 132 T.C. 240, 261 (2009) ("[D]eduction is generally allowed for expenses incurred in defending a business and its policies from attack."). The deductibility of patent infringement litigation expenses is further "consistent with the treatment of damages paid in the wake of such litigation." *Mylan*, 156 T.C. at 154 (citing *Schnadig Corp. v. Gaines Mfg. Co.*, 620 F.2d 1166, 1169 (6th Cir. 1980) ("When an infringer is required to pay damages to a design patentee, the amount so paid is deductible from his income tax.")); *Mathey*, 177 F.2d at 263 (noting "an award of damages in patent li[tig]ation is ordinarily . . . taxable . . . as income in the year received"). Accordingly, further supporting the deductibility of patent infringement legal expenses, tort litigation expenses and patent infringement damages are likewise deductible under I.R.C. § 162(a).

In summary, the origin of the Hatch-Waxman patent infringement litigation defense expenses plaintiff incurred lies in the branded drug companies' patent enforcement efforts—a claim sounding in tort. *Schillinger*, 155 U.S. at 169; *Giesecke+Devrient GmbH v. United States*, 150 Fed. Cl. 330, 344 (2020); *see supra* Section VI. Treasury Regulation § 1.263(a)-4 does not require the capitalization of these litigation expenses. *See supra* Section VII; *Mylan*, 156 T.C. at 161; Guidance Regarding Deduction and Capitalization of Expenditures, 67 Fed. Reg. at 77705 (noting that the proposed regulation was consistent with "existing regulations" and "current law" and "is not intended to require capitalization of amounts paid to protect the property against infringement"). The government fails to convince the Court the litigation expenses arise out of the acquisition, ownership, or improvement of property as might support their capitalization under the tax code. I.R.C. § 263(a); *Mylan*, 156 T.C. at 164. Accordingly, as expenses incurred defending both patent infringement claims and tort claims have historically been treated as tax deductible under I.R.C. § 162(a), the Court concludes plaintiff's § 271(e)(2) litigation expenses are tax deductible and plaintiff is entitled to summary judgment on its claims. I.R.C. § 162(a); *Woodward v. Comm'r*, 397 U.S. 572, 577–78 (1970); *United States v. Gilmore*, 372 U.S. 39, 48–49 (1963); *Kornhauser*, 276 U.S. at 153; *Mylan*, 156 T.C. at 163; *Urquhart*, 215 F.2d at 19–21; *see supra* Section VI.

IX. Conclusion

For the reasons discussed *supra*, the Court **GRANTS** plaintiff's motion for summary judgment, **DENIES** the government's cross-motion for partial summary judgment, and **DENIES as MOOT** plaintiff's motion to strike, *see supra* note 5. As agreed by the parties, this decision results in "a judgment for . . . plaintiff." Tr. 228:7; Pl.'s MSJ at 40. As the specific monetary figures remain undecided, the parties **SHALL FILE** a joint status report proposing a timeline for further proceedings consistent with this opinion, if any, on or before **20 September 2022**.

IT IS SO ORDERED.

s/ Ryan T. Holte
RYAN T. HOLTE
Judge