UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IVY SPORTS MEDICINE, LLC,	:		
	:		
Plaintiff,	:	Civil Action No.:	11-1006 (RC)
	:		
v.	:	Re Document No.:	82
	:		
SYLVIA M. BURWELL, *et al.*,	:		
	:		
Defendants.	:		

MEMORANDUM OPINION

DENYING PLAINTIFF'S MOTION FOR ATTORNEYS' FEES AND EXPENSES

I. INTRODUCTION

Plaintiff Ivy Sports Medicine, LLC[1] ("Ivy") successfully demonstrated in this case that the Food and Drug Administration ("FDA") had unlawfully rescinded a decision to clear Ivy's medical device for market. Ivy now seeks an award of attorneys' fees and expenses incurred in litigating its claims under the Administrative Procedure Act ("APA"), *see* 5 U.S.C. §§ 500 *et seq.* Ivy claims that it is entitled to reasonable fees and expenses pursuant to the Equal Access to Justice Act ("EAJA"), 28 U.S.C. § 2412(d)(1)(A), because it was the "prevailing party" in this litigation and because the government's position was not "substantially justified." Because the Court concludes that the government's position was substantially justified, the Court will deny Ivy's motion.

[1] This action was originally filed by ReGen Biologics, Inc. ("ReGen"). After ReGen filed for bankruptcy, Ivy acquired the right to pursue this action under a Bill of Sale dated June 30, 2011, and this Court granted ReGen's unopposed motion to substitute Ivy as plaintiff pursuant to Federal Rule of Civil Procedure 25(c). *See* Aug. 19, 2011 Order, ECF No. 12. In addition, Sylvia M. Burwell has been substituted for Kathleen Sebelius as Defendant pursuant to Federal Rule of Civil Procedure 25(d).

II. FACTUAL BACKGROUND

This Court and the D.C. Circuit have both explained the factual and regulatory background surrounding this case in detail. *See Ivy Sports Med., LLC v. Burwell*, 767 F.3d 81, 83–86 (D.C. Cir. 2014); *Ivy Sports Med., LLC v. Sebelius*, 938 F. Supp. 2d 47, 49–54 (D.D.C. 2013); *see also* ECF No. 75. The Court assumes familiarity with those prior opinions, and will confine its own discussion to the facts and regulatory provisions most relevant to the present motion.

In 1976, Congress passed the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act ("FDCA") in order to provide for the regulation of medical devices that are intended for human use. *See* Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539; *see also* 21 U.S.C. § 301 *et seq.* The amendments divided medical devices into three categories, Class I, Class II, or Class III, "according to the degree of regulation thought necessary to provide reasonable assurance of each device's 'safety and effectiveness.'" *Contact Lens Mfrs. Ass'n v. FDA*, 766 F.2d 592, 594 (D.C. Cir. 1985). As relevant here, the amendments classify a device not introduced into interstate commerce before May 28, 1976 (what the FDA refers to as a "post-amendment device"), by default, into Class III. *See* 21 U.S.C. § 360c(f)(1). A Class III device is the most heavily regulated, and cannot "be sold to the general public until, through a costly and time-consuming process, it had gained the FDA's 'premarket approval.'" *Contact Lens Mfrs.*, 766 F.2d at 594.

Alternative routes to market are available for some post-amendment devices, however. For example, a post-amendment device may be classified as a Class I or Class II device if the device is "substantially equivalent to another device" that has already been classified in those classes. *See* 21 U.S.C. § 360c(f)(1)(A). A device is considered "substantially equivalent" to a

preexisting device if the device "has the same intended use as the predicate device" and either "has the same technological characteristics as the predicate device" or has "different technological characteristics" but nevertheless has been shown to be as safe and effective as that predicate device. *Id.* § 360c(i)(1)(A). A device manufacturer may seek "substantial equivalence" status by submitting a "premarket notification," or what the agency refers to as a section 510(k) application or clearance, which triggers an FDA review. *See* 21 U.S.C. § 360(k); *see also Ivy Sports Med.*, 767 F.3d at 83. If the FDA determines that the device is substantially equivalent to an existing device, the agency issues a classification order "declaring the device to be substantially equivalent to a legally marketed predicate device," 21 C.F.R. § 807.100(a)(1), which "allow[s] the device to be marketed subject to appropriate restrictions," *Ivy Sports Med.*, 767 F.3d at 83.

In 2005 and 2006, ReGen Biologics ("ReGen") twice submitted premarket notifications for the Collagen Scaffold ("CS"), a device which Ivy describes as intended "to reinforce damaged or weakened meniscal soft tissue in the knee and to provide a resorbable scaffold for replacement by a patient's own soft tissue." *See* Compl. ¶ 19; *see also* A.R. 559. Although the premarket notifications asserted that the CS was substantially equivalent to previously approved surgical meshes, and sought a Class II classification, *see* A.R. 559, 1279, the FDA rejected each notification, *see* A.R. 1207, 2426. In December 2007, several months after the FDA rejected the second notification, members of New Jersey's congressional delegation (where ReGen was based), wrote to the FDA concerning the agency's review of the CS. *See* A.R. 2431. Both the FDA Commissioner and the then-director of the FDA's Center of Devices and Radiological Health, Dr. Daniel Schultz, thereafter met with ReGen representatives. *See* A.R. 2627. The

officials took no further action on ReGen's previously denied applications, but ReGen was informed that it could submit a new, revised pre-market notification. *Id.*

In July 2008, ReGen did submit a third premarket notification. As with the first two notifications, the FDA reviewers recommended that the CS be found not substantially equivalent. *See* A.R. 2836. But instead of issuing a final decision, Dr. Schultz sought additional input from a special Orthopedic Advisory Panel, which concluded that the CS was "as safe and effective as the predicate devices." *See* A.R. 2976. On that basis, among others, Dr. Schultz issued a letter to ReGen informing it that the CS had been found to be substantially equivalent to the existing devices and classified the CS as a Class II device. *See* A.R. 3240–42.

After the CS was cleared for market, however, the *Wall Street Journal* published an article claiming that the CS's approval process had been colored by political pressures, several other members of Congress raised their own concerns with the FDA, and a group of FDA employees wrote to President Obama alleging that Dr. Schultz and the FDA's Commissioner had improperly influenced the agency's review of the CS. *See Ivy Sports Med.*, 767 F.3d at 85. These allegations led the FDA to conduct an internal investigation and issue a report, which found that "over the 17 year review history of the CS device, multiple departures from processes, procedures, and practices occurred," and recommended that "a focused scientific reevaluation of the decision to clear the CS device [was] warranted." A.R. 3487–88. Ultimately, Dr. Jeffrey Shuren, who had replaced Dr. Schultz as the Director of the Center for Devices and Radiological Health, notified ReGen in October 2010 that the agency's clearance of the CS had been "in error" and that the FDA was rescinding its determination that the CS was substantially equivalent to predicate devices. *See* A.R. 5458. The agency issued a formal rescission notification in March 2011. *See* A.R. 7342–43. Because the CS was designated as a Class II device solely on

the basis of its equivalency to a predicate device, the agency's rescission order "in turn, meant that the Collagen Scaffold would be in Class III and have to go through the extensive pre-market approval process to be marketed again." *Ivy Sports Med.*, 767 F.3d at 85; *see also* A.R. 7342.

As relevant to this case, the FDA did not make use of notice and comment to rescind its substantial equivalency determination. The FDCA includes a provision that allows the FDA to change the classification it has given to a device. During the time period relevant in this case, 21 U.S.C. § 360c(e) stated in relevant part that: "[b]ased on new information respecting a device, the Secretary may, upon his own initiative or upon petition of an interested person, by regulation (A) change such device's classification, and (B) revoke, because of the change in classification, any regulation or requirement in effect . . . with respect to such device." 21 U.S.C. § 360c(e). Instead of using notice and comment to change the CS's classification, the FDA simply rescinded its underlying substantial equivalency determination, which had the *de facto* effect of changing the device's classification to Class III.

Two months after the agency issued the rescission order, ReGen filed this lawsuit challenging the rescission order under the APA as contrary to the FDCA and arbitrary and capricious. *See* Compl. ¶¶ 68–69. ReGen had filed for bankruptcy, and while this lawsuit was pending Ivy was substituted as plaintiff. *See* note 1, *supra*. In its motion for summary judgment, Ivy argued that the FDA's rescission order was invalid on several grounds. Of most relevance to this motion, Ivy claimed that the FDA's rescission order was invalid because the agency could not lawfully reclassify the CS through a process other than a rulemaking under section 360c(e). *See* Pl.'s Mem. P. & A. Supp. Mot. Summ. J. at 30–36 ("Pl.'s Mem. Supp. Summ. J."), ECF No. 23-1.

Generally, "administrative agencies are assumed to possess at least some inherent authority to revisit their prior decisions, at least if done in a timely fashion." *Ivy Sports Med.*, 767 F.3d at 86. In *American Methyl Corp. v. EPA*, however, the D.C. Circuit held that "when Congress has provided a mechanism capable of rectifying mistaken actions," it is "not reasonable" for a court to infer that the agency retains inherent authority to reconsider its actions. 749 F.2d 826, 835 (D.C. Cir. 1984). In that case, the EPA had issued a waiver under the Clean Air Act to allow the American Methyl Corporation to introduce a new methanol/gasoline fuel blend into commerce for the first time, but later proposed to revoke that waiver based on a new study that had come to the agency's attention. *See id.* at 828–31. Despite the fact that a particular section of the Clean Air Act, section 211(c), imposed "a number of substantive and procedural requirements the agency must satisfy before controlling or prohibiting a fuel or fuel additive," *id.* at 830 (citing 42 U.S.C. § 7545(c)), the EPA simply proposed to rescind the waiver it had granted. The Circuit concluded that, while the Clean Air Act's waiver provision "does not state whether waivers granted . . . may be reconsidered and revoked," the legislative history made clear that "Congress contemplated regulation of fuels and fuel additives so waived into commerce only through proceedings under section 211(c)." *Id.* at 834. The Court determined that Congress "provided a mechanism sufficient to this task," and "further understood this mechanism as the exclusive means by which [the EPA Administrator] was to correct waivers mistakenly granted." *Id.* at 836. In a footnote, however, the Circuit also stated that it "intimate[d] no view as to EPA's power to revoke a waiver obtained through fraud, ex parte contacts, or other misconduct tainting the original record and thereby affecting the integrity of the agency's proceedings." *Id.* at 834 n.51.

Invoking *American Methyl*, Ivy's motion argued that because the FDCA provided an explicit statutory mechanism to change a device's classification in section 513(e), the FDA was foreclosed from using any inherent authority to rescind the substantial equivalency determination (which had served as the conduit for classifying the CS in Class II and the rescission of which would functionally reclassify the CS into Class III). *See* Pl.'s Mem. Supp. Summ. J. at 30–36. In its own cross-motion for summary judgment, the government argued that the FDA had inherent authority to rescind what it described as an erroneous clearance of the CS, and further sought to distinguish *American Methyl* on several grounds. *See* Defs.' Mem. Supp. Cross-Mot. Summ. J. & Opp'n to Pl.'s Mot. at 18–23, 23–28, ECF No. 33. Two of those grounds are relevant here. First, the government invoked the footnote in *American Methyl* in which the Circuit had expressly stated that it would "intimate no view as to EPA's power to revoke a waiver obtained through fraud, ex parte contacts, or other misconduct tainting the original record thereby affecting the integrity of an agency's proceedings.'" *Id.* at 24–25 (emphasis omitted) (quoting *American Methyl*, 749 F.2d at 834 n.51). On this basis, the government argued that *American Methyl* could be distinguished because the FDA had found numerous departures from agency processes, procedures, and practices during ReGen's review that had affected the review process's integrity. *Id.* at 25. Second, the FDA pointed out that, in *American Methyl*, the Circuit had emphasized that the legislative history there demonstrated Congress had intended § 211(c) to provide the exclusive, and only, means for revoking or correcting a waiver that the EPA had mistakenly granted. *See id.* at 25–26. The government contended that no comparable legislative history existed to demonstrate that Congress intended to deprive the FDA of its inherent rescission authority, or that it intended section 360c(e) to be the exclusive remedy for addressing

an erroneously issued 510(k) clearance, even if the agency *could* make use of that method. *See id.* at 26.

This Court[2] granted summary judgment for the government, and concluded that the FDA had properly invoked its inherent authority to revisit a substantial equivalency determination. *See Ivy Sports Med.*, 938 F. Supp. 2d at 55–59; *see also* ECF No. 75. This Court agreed with the government that *American Methyl* was distinguishable because the FDA had sought to remedy defects in its original approval process, rather than on the basis of "new information" that had since come to light, and because "*American Methyl* carves out the situation, present in this case, where misconduct impacted the agency's initial decision," so that "the fact that the FDA concedes it could have used 21 U.S.C. § 360c(e) does not change the determination that the agency properly invoked its inherent authority." *Id.* at 58.[3]

A divided panel of the D.C. Circuit reversed. On appeal, the government had reiterated, albeit more clearly, its argument that section 360c(e) did not bar the agency's reconsideration of substantial equivalency determinations. *See* Brief for Appellees at 36–43, *Ivy Sports Med., Inc. v. Burwell*, No. 13-5139 (D.C. Cir. Dec. 11, 2013). The government emphasized that section 360c(e) involves "a different question from substantial equivalence" and that section 360c(e) "is

[2] A different judge in this district decided the merits of Ivy's claims. This case was randomly reassigned to the undersigned after it was reversed and remanded by the D.C. Circuit. *See* ECF No. 81.

[3] In its motion for summary judgment, Ivy had also argued in the alternative that the FDA's rescission was untimely, because the FDA only had authority to rescind the substantial equivalency determination during the time period in which an appeal of that decision may be taken, *see* Pl.'s Mem. Supp. Summ. J. at 37–40, or that the agency acted arbitrarily and capriciously in failing to base its rescission decision on an intended use that was not identified in the premarket notification report, *see id.* at 40–43. This Court rejected both of these arguments, *see Ivy Sports Med.*, 938 F. Supp. 2d at 59–67, and they were not reached by the D.C. Circuit in light of its determination that the FDA lacked inherent authority to rescind its substantial equivalency determination in the first place, *see Ivy Sports Med.*, 767 F.3d at 89.

aimed not at correcting decisions that were invalid *ab initio* but rather at updating device classifications in light of available information." *Id.* at 37, 39. Ultimately, the government claimed that "[a]lthough FDA could have used its authority under [s]ection 360c(e) to evaluate whether the CS device fits the statutory criteria for Class II or Class III, that is *a different question than whether the device is substantially equivalent to a predicate*." *Id.* at 39 (emphasis added) (internal citation omitted). In the alternative, the government again claimed that *American Methyl* was distinguishable because that case did not involve an infirmity in the EPA's original determination, and that the circuit had made clear it was not addressing the agency's "inherent authority to rescind a waiver in which there was 'misconduct tainting the original record.'" *Id.* at 42 (quoting *American Methyl*, 749 F.2d at 834 n.51).

The majority rejected these arguments. Although acknowledging that "administrative agencies are assumed to possess at least some inherent authority to revisit their prior decisions, at least if done in a timely fashion," the majority reiterated that the circuit had "also recognized that any inherent reconsideration authority does not apply in cases where Congress has spoken." *Ivy Sports Med.*, 767 F.3d at 86. In this case, the majority concluded that, "as a practical matter, the decision to revoke a substantial equivalence determination . . . is a de facto reclassification of the device into Class III, at least absent other FDA action," and therefore, "to revoke a substantial equivalence determination is to 'change the classification' of that device." *Id.* at 87 (internal citation omitted) (quoting 21 U.S.C. § 360c(e)(2)). Because Congress had provided a mechanism to rectify the agency's mistaken clearance, the majority concluded that it would "be unreasonable under this statutory scheme to infer that FDA retains inherent authority to short-circuit or end-run the carefully prescribed statutory reclassification process in order to correct the same mistake." *Id.* The majority also rejected the government's alternative argument that any

misconduct exception applied, finding that "the record indicates that the review process for the Collagen Scaffold was perhaps imperfect, but the supposed mistakes do not rise to the level of misconduct contemplated by *American Methyl*." *Id.* at 88.

In dissent, Judge Pillard read the mechanism created by 21 U.S.C. § 360c(e) as "narrower than Ivy supposes," and concluded that the provision "does not relate to the type of *de facto* reclassification to Class III that occurs upon revocation of an erroneous clearance into a lower class under the substantial equivalence determination." *Id.* at 90 (Pillard, J., dissenting). Emphasizing *American Methyl*'s determination that the EPA's statutory authority in that case was intended to be "the *exclusive means* by which [the agency] was to correct" mistakenly granted waivers, *id.* at 93 (emphasis in original) (quoting *American Methyl*, 749 F.2d at 836), Judge Pillard concluded that an analysis of the statute's text, structure, purpose, and agency practice all indicated that "Congress never intended to require the FDA to use subsection (e) to rescind an erroneous substantial equivalence determination," *id.* at 94. On that basis, Judge Pillard would have held that the FDA retained its inherent authority to reconsider its substantial equivalency determinations. *Id.* at 102.

Consistent with the D.C. Circuit's decision, this Court vacated the FDA's decision and remanded to the agency for further proceedings. *See* Minute Order, Apr. 8, 2015. Having prevailed, Ivy has now filed a motion seeking an award of attorneys' fees and costs under the EAJA (ECF No. 82).

III. ANALYSIS

The Equal Access to Justice Act ("EAJA") permits a plaintiff "to obtain expenses in litigation against the federal government" under certain circumstances. *Select Milk Producers, Inc. v. Johanns*, 400 F.3d 939, 941 (D.C. Cir. 2005). The EAJA provides in pertinent part that:

> [A] court shall award to a prevailing party other than the United States fees and other expenses . . . incurred by that party in any civil action (other than cases sounding in tort), including proceedings for judicial review of agency action, brought by or against the United States in any court having jurisdiction of that action, unless the court finds that the position of the United States was substantially justified or that special circumstances make an award unjust.

28 U.S.C. § 2412(d)(1)(A). Accordingly, eligibility for a fee award requires: "(1) that the claimant be a 'prevailing party'; (2) that the Government's position was not 'substantially justified'; (3) that no 'special circumstances make an award unjust'; and, (4) pursuant to 28 U.S.C. § 2412(d)(1)(B), that any fee application be submitted to the court within 30 days of final judgment in the action and be supported by an itemized statement." *Comm'r, INS v. Jean*, 496 U.S. 154, 158 (1990). The plaintiff has an initial burden to demonstrate that she is a prevailing party; after she does so, the burden shifts to the government, which must show that its legal position was substantially justified or that special circumstances exist making an award unjust. *Taucher v. Brown-Hruska*, 396 F.3d 1168, 1173 (D.C. Cir. 2005); *Carey v. Fed. Election Comm'n*, 864 F. Supp. 2d 57, 62 (D.D.C. 2012).

Here, the government challenges both Ivy's status as a "party" as defined in the EAJA, and contends that its position throughout this litigation was substantially justified.

A. Prevailing Party Status

There is no dispute that Ivy prevailed before the Court of Appeals, but the government claims that Ivy has not adequately demonstrated that ReGen, the plaintiff that initiated this lawsuit and for which Ivy was substituted as a plaintiff in interest, is a "party" as defined in the EAJA. As relevant here, the EAJA defines a "party" to include "any partnership, corporation, association, unit of local government, or organization, the net worth of which did not exceed $7,000,000 at the time the civil action was filed, and which had no more than 500 employees at the time the civil action was filed." 28 U.S.C. § 2412(d)(2)(B). The EAJA's legislative history

directs that "net worth be calculated by subtracting total liabilities from total assets." *Nat'l Ass'n of Mfrs. v. Dep't of Labor*, 159 F.3d 597, 600 n.1 (D.C. Cir. 1998) (quoting H.R. Rep. No. 96-1418, at 15 (1980)); *accord City of Brunswick, Ga. v. United States*, 849 F.2d 501, 503 (11th Cir. 1988).

Initially, Ivy vaguely asserted in a declaration from its CEO, Robert Pangia, that at the time this lawsuit was filed "ReGen's net worth did not exceed $7,000,000" (referencing ReGen's bankruptcy filing), and that the company employed "substantially fewer than 500 employees." Pangia Decl. ¶ 4, ECF No. 82-2. In its opposition, the government challenged Mr. Pangia's declaration as conclusory and insufficient to satisfy Ivy's burden to show it is a party under the EAJA definition. *See* Defs.' Opp'n to Pl.'s Mot. for Att'ys Fees & Expenses at 11–12 ("Defs.' Mem. Opp'n"), ECF No. 84; *see also Al Ghanim Combined Grp. Co. Gen. Trad. & Cont. W.L.L. v. United States*, 67 Fed. Cl. 494, 496–97 (Fed. Cl. 2005) (denying an application for fees under the EAJA where "plaintiff in the instant case submitted only a self-serving, non-probative affidavit, providing nothing resembling a balance sheet); *cf. Kuhns v. Bd. of Governors of Fed. Reserve Sys.*, 930 F.2d 39, 40–42 (D.C. Cir. 1991) (sustaining the Federal Reserve Board's refusal to award fees under the EAJA where the petitioner's statement "did not reveal the basis on which [petitioner] had valued his assets and liabilities").

In its Reply, Ivy has provided a more robust affidavit from Mr. Pangia, attaching documents filed in the bankruptcy court around the time this lawsuit was filed.[4] *See generally*

[4] Mr. Pangia's initial declaration also represented in conclusory terms that, at the time Ivy substituted as plaintiff in this case, its "net worth did not exceed $7 million." Pangia Decl. ¶ 5. While the government similarly claimed in its opposition that the information regarding Ivy's net worth or employment figures also had not been supported by evidence, *see* Defs.' Mem. Opp'n at 11–12 (expressly citing ¶ 5 of Mr. Pangia's Declaration), Ivy oddly does not provide additional factual support in its Reply regarding Ivy's net worth or its employee numbers as of the date it was substituted as plaintiff in this case, *see generally* Pl.'s Reply at 3–6, ECF No. 89.

Supp. Pangia Decl., ECF No. 89-5. Those documents demonstrate that ReGen had liabilities that exceeded its assets around the time this lawsuit was filed, *see* Compl., ECF No. 1, and at which point ReGen was in bankruptcy proceedings. For example, in a May 24, 2011 filing to the bankruptcy court, ReGen's balance sheet reports that the company and its subsidiary, RBio, Inc., had combined assets of approximately $7.3 million and total liabilities of approximately $17.2 million.[5] *See* Supp. Pangia Decl. ¶ 6 & Ex. 4. Thus, ReGen's net worth was well into the negative, and below the $7 million threshold. In addition, Mr. Pangia provided ReGen's W-2 forms for 2011, which establish that the company paid wages to only seven employees that year. *See* Supp. Pangia Decl. ¶ 10 & Ex. 8. Accordingly, ReGen was a "party" within EAJA's definition at the time it filed this lawsuit and Ivy therefore has established "prevailing party" status.

Nevertheless, the government has not expressly advanced an argument that Ivy's net worth should be independently considered, or that the Court should consider Ivy's net worth at the time that it became successor in interest and substituted as plaintiff for purposes of determining whether Ivy is a "party" entitled to fees. *See* Defs.' Mem. Opp'n at 11–12. As Ivy notes, "the statute focuses solely on the status of the plaintiff at the time of filing." Pl.'s Mem. Supp. Fees at 9. Accordingly, the Court assumes without deciding that the only relevant net worth for determining whether the plaintiff is a "party" is the net worth of the party who served as the plaintiff "at the time the civil action was filed," 28 U.S.C. § 2412(d)(2)(B)—which, in this case, is ReGen. In any event, because the Court finds that Ivy is not entitled to attorneys' fees and expenses on the ground that the government's position was substantially justified, the resolution of this issue would not alter the outcome of this motion.

[5] On ReGen's own, individual balance sheet submitted for the same month, the agency listed as an asset over $62 million in intercompany receivables from RBio. *See* Supp. Pangia Decl. Ex. 6. Mr. Pangia asserts that those intercompany receivables "would not have been collectable." Supp. Pangia Decl. ¶ 7. The record supports this claim. During that same time period, RBio listed over $500,000 in intercompany receivables from ReGen and a related entity on its own, individual balance sheet, *see* Supp. Pangia Decl. Ex. 5, but, like the intercompany receivables ReGen listed on its individual balance sheet, RBio's intercompany receivables were similarly omitted from the combined balance sheet submitted covering the same month, *see* Supp. Pangia Decl. Ex. 4.

B. Substantial Justification

The burden now shifts to the government to show that its legal position was substantially justified. *Taucher*, 396 F.3d at 1173. The government's "position" is defined by statute to include both its litigating position in court, as well as "the action or failure to act by the agency upon which the civil action is based." 28 U.S.C. § 2412(d)(2)(D); *see also Role Models Am., Inc. v. Brownlee*, 353 F.3d 962, 967 (D.C. Cir. 2004) ("The government . . . must demonstrate the reasonableness not only of its litigating position, but also of the *agency's* actions." (emphasis in original)). Despite focusing on both of the agency's actions and the government's subsequent litigating position, the Court "is not to review the different elements of the government's position separately." *Ctr. for Food Safety v. Burwell*, --- F. Supp. 3d ----, No. 14-0267, 2015 WL 5185692, at *6 (D.D.C. Sept. 4, 2015). Instead, the Court must consider the agency's conduct and the government's subsequent defense of that conduct "as an inclusive whole," *id.*, and make "only one threshold determination for the entire civil action," *Comm'r, INS*, 496 U.S. at 159.

To establish that its position was substantially justified, "the government need not establish that it was correct—indeed, since the movant is established as a prevailing party it could never do so." *Air Transp. Ass'n of Can. v. FAA*, 156 F.3d 1329, 1332 (D.C. Cir. 1998). Instead, the government must only shoulder the burden to show that its position was "one that 'a reasonable person could think . . . correct, that is, [that the position] has a reasonable basis in law and fact.'" *Id.* (quoting *Pierce v. Underwood*, 487 U.S. 552, 566 n.2 (1988)). The "hallmark of the substantial justification test is reasonableness." *Role Models Am.*, 353 F.3d at 967. Accordingly, "the district court must analyze the merits panel's reasoning to determine whether the [agency's] position, though rejected, was substantially justified." *Halverson v. Slater*, 206 F.3d 1205, 1209 (D.C. Cir. 2000). The court must "do more than explain, repeat, characterize,

and describe the merits . . . decision." *Taucher*, 396 F.3d at 1174 (internal quotation mark omitted) (quoting *Halverson*, 206 F.3d at 1209). Instead, a court must "analyze *why* the government's position failed in court." *Id.*

Here, the Court concludes that both the agency's conduct and the government's defense of that conduct in litigation before this Court and the D.C. Circuit was substantially justified. The issue in this case—whether the FDA had inherent authority to rescind its substantial equivalency determination—rested on the resolution of two competing principles of statutory construction that arise in the administrative law field. On the one hand is the long-standing principle that "administrative agencies are assumed to possess at least some inherent authority to revisit their prior decisions, at least if done in a timely fashion." *Ivy Sports Med.*, 767 F.3d at 86. On the other is the principle established in *American Methyl*, that "when Congress has provided a mechanism capable of rectifying mistaken actions . . . it is not reasonable to infer authority to reconsider agency action." 749 F.2d at 835. The central question in this case was whether the FDA's ability to reclassify a device through 21 U.S.C. § 360c(e) displaced the FDA's inherent authority to revisit a substantial equivalency determination it considered to have been made in error. Of course, the D.C. Circuit determined that section 360c(e) did displace that inherent authority. But, for several reasons, the FDA's contrary position was "one that 'a reasonable person could think . . . correct," and had "a reasonable basis in law and fact.'" *Air Transp. Ass'n of Can.*, 156 F.3d at 1332 (quoting *Pierce*, 487 U.S. at 566 n.2).

Starting with the agency's conduct, Ivy argues that it was "incumbent upon the agency" to explain the legal basis for its authority to rescind its substantial equivalency determination, and that because the FDA failed to do so in its rescission order (or otherwise), the FDA's position at the agency level was not substantially justified. *See* Pl.'s Mem. Supp. Mot. for Att'ys

Fees & Expenses at 12 ("Pl.'s Mem. Supp. Fees"); *see also* Pl.'s Reply at 7, ECF No. 89 ("The question is whether the legal justification that FDA actually articulated at the agency level holds water."). Yet, Ivy misconceives the correct inquiry, and cites no authority for this contention. When considering "the action or failure to act by the agency upon which the civil action is based," 28 U.S.C. § 2412(d)(2)(D), a court must focus on the reasonableness of the agency's *conduct*, not necessarily the agency's own articulated explanation or justification for its actions. The Supreme Court and the Circuit's decisions consistently describe the question as whether the agency's *conduct* or *actions* were substantially justified. *See, e.g.*, *Comm'r, INS*, 496 U.S. at 158 (noting that the inquiry "encompass[es] both the agency's prelitigation *conduct* and the Department of Justice's subsequent litigation positions" (emphasis added)); *see also Role Models Am.*, 353 F.3d at 967 ("The government . . . must demonstrate the reasonableness not only of its litigating position, but also of the *agency's actions*." (emphasis added)).

If there were any doubt, the D.C. Circuit's EAJA cases considering situations in which an agency's action was found arbitrary and capricious for failing to provide an adequate explanation provide instructive guidance. For example, the Circuit has explained that "the 'adequacy of an agency's explanation' is in some cases 'logically unrelated to whether *the underlying agency action* is justified under the organic statute.'" *Hill v. Gould*, 555 F.3d 1003, 1008 (D.C. Cir. 2009) (emphasis added) (quoting *FEC v. Rose*, 806 F.2d 1081, 1088 (D.C. Cir. 1986)); *see also Wilkett v. Interstate Commerce Comm'n*, 844 F.2d 867, 871 (D.C. Cir. 1988) (noting that "[s]ome types of arbitrary and capricious behavior, such as an agency's failure to provide an adequate explanation for its actions . . . may not warrant a finding that *an agency's action* lacked substantial justification under applicable statutes or regulations" (emphasis added)). If an agency's action can remain substantially justified even after a court has concluded that its action

was arbitrary and capricious for *lack of an adequate explanation*, it would be perverse to conclude that the FDA's action here was not substantially justified on the sole basis that it failed to explain the legal grounds for its power to rescind—particularly where Ivy never even challenged the agency's rescission order on that ground.[6] *See* Defs.' Mem. Opp'n at 16 (noting that Ivy never made that argument). Indeed, Ivy's own memorandum at summary judgment suggests that it understood the agency's rescission order to have relied on inherent authority. *See* Pl.'s Mem. Supp. Mot. Summ. J. at 30 ("Because FDA failed to identify any statutory or other legal basis for the Rescission Order in the order itself, Ivy can only guess that the agency asserts that it has the inherent authority to revoke a section 510(k) determination, and thereby to reclassify a device into Class III.").

[6] For this reason, the Court does not find particularly informative Ivy's reliance on the FDA's Principal Deputy Commissioner's passing suggestion, during a media briefing and before agency experts had reevaluated the merits of the underlying substantial equivalency determination, that the agency would "move to reclassify the device." A.R. 7651; *see also* Pl.'s Mem. Supp. Fees at 11. At most, the Principal Deputy Commissioner's statement perhaps revealed a "lack of consensus" regarding the route the agency would take, but it does not bind the agency or necessarily indicate that the agency viewed that route as the *only* one it could take to rescind its order. *See Defs. of Wildlife & Ctr. for Biological Diversity v. Jewell*, -- F.3d ----, No. 14-5284, 2016 WL 790900, at *9 (D.C. Cir. Mar. 1, 2016); *Comcast Corp. v. FCC*, 526 F.3d 763, 769 (D.C. Cir. 2008). Moreover, by the time it decided to rescind the substantial equivalency determination, the agency cited a regulation, 21 C.F.R. § 10.33, and stated that its decision was consistent with "FDA regulations that provide for the reconsideration of a matter on the agency's own initiative." *See* A.R. 5458. Ivy quibbles with whether Dr. Shuren, who signed that letter, could exercise that regulatory authority because the regulation states only that the "Commissioner" may reconsider a matter. *See* 21 C.F.R. § 10.33 (a), (h). Yet, at summary judgment then-Commissioner of the FDA Margaret Hamburg supplied a declaration indicating that Dr. Shuren reconsidered the CS with her "agreement and authorization," Hamburg Decl. ¶ 5, ECF No. 67-1, and "there is nothing improper in receiving declarations that merely illuminate[ ] reasons obscured but implicit in the administrative record," *Clifford v. Pena*, 77 F.3d 1414, 1418 (D.C. Cir. 1996) (alteration in original) (internal quotation marks omitted). In any event, and for the reasons stated above, the particular statutory provision or regulation the agency invoked to justify its authority to rescind the CS substantial equivalency determination is not determinative of whether the agency's exercise of its purported authority was substantially justified.

Thus, the Court concludes that whether or not the FDA supplied a defense or legal basis for the invocation of its inherent authority at the agency level is "logically unrelated" to whether the FDA's *action* in doing so was justified under the provisions of the FDCA. *Hill*, 555 F.3d at 1008. In this case, the relevant question is whether the agency's effort to exercise inherent authority that it turned out not to have was substantially *justified*, not whether the agency itself articulated a substantial *justification* for its authority to take that action. The resolution of that question in this case is inherently bound up with the legal determination of whether section 360c(e) displaced the agency's inherent authority. Accordingly, the Court will focus on the overall reasonableness of the government's litigation position that the agency could rescind, and therefore acted justifiably in rescinding, a substantial equivalency determination without using notice and comment. *See Comm'r, I.N.S.*, 496 U.S. at 159 (explaining that a court should make "only one threshold determination for the entire civil action").

Several considerations indicate that the government's litigation position—that section 360c(e)'s classification scheme did not eliminate the agency's inherent authority to reconsider underlying substantial equivalency determinations—was reasonable and therefore substantially justified.

First, the governing presumption is that an agency does have the inherent authority to reconsider its decisions, and the exact reach of *American Methyl*'s exception to that presumption was not entirely apparent. Although the opinion had held that "when Congress has provided a mechanism capable of rectifying mistaken actions . . . it is not reasonable to infer authority to reconsider agency action," the D.C. Circuit had also emphasized that Congress "further understood this mechanism as *the exclusive means* by which" the EPA Administrator was to correct mistakes. 749 F.2d at 835, 836 (emphasis added). Since that case was decided, the D.C.

Circuit only directly discussed this holding once, and only fleetingly. The Circuit invoked *American Methyl*'s language that "'when Congress has provided a mechanism capable of rectifying mistaken actions . . . it is not reasonable to infer authority to reconsider agency action,'" in the course of holding that another section of the Clean Air Act unambiguously required the EPA to make particular findings before it could remove electric utility steam generating units from a list of sources of emissions subject to regulation. *New Jersey v. EPA*, 517 F.3d 574, 583 (D.C. Cir. 2008) (quoting *American Methyl*, 749 F.2d at 835). But that panel did not further explain—nor had any other case of which the Court is aware—whether a mechanism must be the *exclusive* one envisioned by Congress in order to displace an agency's authority.

The FDA did acknowledge in this case that it could have used section 360c(e) to change the CS's classification from Class II to Class III. *See, e.g.*, Brief for Appellees at 39, *Ivy Sports Med., Inc. v. Burwell*, No. 13-5139 (D.C. Cir. Dec. 11, 2013). On this basis, Ivy claims that the FDA's position was "'flatly at odds with controlling case law,'" because section 360c(e) provided a mechanism for the agency to make the *de facto* classification change that resulted from the agency's revocation of its substantial equivalence determination. Pl.'s Mem. Supp. Fees at 13–14. But, as the government points out, Ivy's argument "rests on reading one sentence in [*American Methyl*] in isolation." Defs.' Mem. Opp'n at 17. The government claims that it had reasonably read *American Methyl* to have held EPA's rescission of a waiver unlawful because Congress had intended the provision at issue there to be the exclusive means for revisiting the EPA's decisions.[7] *See id.* at 18. This distinction is a reasonable and substantially

[7] Accordingly, the Court finds Ivy's complaint that the "FDA never once acknowledged or addressed the key language from *American Methyl* that Ivy relied on," Pl.'s Mem. Supp. at 14,

justified one. Indeed, the D.C. Circuit majority and dissent took starkly different positions on the proper reading of *American Methyl* as applied to this case that divided along similar grounds. The majority focused on the language Ivy has chosen to invoke, but Judge Pillard's dissent repeatedly and emphatically emphasized that she read the principle of statutory construction announced in *American Methyl* to be limited to cases in which Congress intended for a particular statutory mechanism to provide the *exclusive* means for reconsidering a particular type of decision. *See, e.g.*, *Ivy Sports Med.*, 767 F.3d at 93 (Pillard, J., dissenting). As a result, Judge Pillard concluded that the majority's holding was erroneous because "even if the agency *could* have acted under subsection (e) to change the classification . . . , *American Methyl*'s negative implication would only apply . . . if the only permissible reading for the Act is that subsection (e) is the *exclusive* means for rescinding an erroneous substantial equivalence determination." *Id.* at 101 (emphasis in original). In light of the lack of case law interpreting *American Methyl*, the FDA's position "was not 'flatly at odds with controlling caselaw.'" *Hill*, 555 F.3d at 1008 (quoting *Am. Wrecking Corp. v. Sec'y of Labor*, 364 F.3d 321, 326–27 (D.C. Cir. 2004)). And, given that Judge Pillard's dissent adopted the agency's reading, the Court is hard pressed to conclude that the FDA's position lacked substantial justification or was one that a reasonable person could not think correct.[8] *See, e.g.*, *In re Long-Distance Tel. Serv. Fed'l Excise Tax*

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unavailing. The record makes clear that the parties each viewed different language from *American Methyl* as most instructive.

[8] To be sure, the D.C. Circuit has acknowledged, citing to out of circuit cases, that some courts have held that "an earlier dissent does not conclusively show the government's position was substantially justified." *In re Long-Distance Tel. Serv.*, 751 F.3d at 636. The Circuit went on to note, however, that dissents should still properly be considered in the substantial justification inquiry, and that (in that case), the existence of several dissenting opinions was "particularly persuasive evidence of substantial justification." *Id.* As explained below, the majority here also described the FDA's position as advancing "a forceful case." That acknowledgement, along with the difficult, provision-specific question of statutory construction presented, demonstrate that the government's position in this case was substantially justified.

Refund Litig., 751 F.3d 629, 637 (D.C. Cir. 2014) ("[O]ne might also reasonably conclude that, absent other factors, dissenting opinions on difficult questions are sufficient evidence of substantial justification."); *Taucher*, 396 F.3d at 1174 (noting that a position is not unjustified "if the government lost because an unsettled question was resolved unfavorably").

Moreover, even beyond establishing *American Methyl*'s reach, the application of that principle to the specific statutory provision at issue in this case was not clear-cut. The question of whether section 360c(e), which concerned changes in classification determinations, applied to substantial equivalency determinations at all was a difficult, and nuanced one. As the majority explained it, "[i]n FDA's view, Ivy [was] conflating the underlying substantial equivalence determination with the potential consequence of that decision—classification into Class I, II, or III." *Ivy Sports Med.*, 767 F.3d at 87. The agency claimed that section 360c(e) dealt with "a different question than whether the device is substantially equivalent to a predicate." Brief for Appellees at 39, *Ivy Sports Med., Inc. v. Burwell*, No. 13-5139 (D.C. Cir. Dec. 11, 2013). And the majority conceded that "counsel for FDA has advanced a *forceful case* for the agency's position," and that "[i]t may well be correct, as FDA contends, that the statutory procedures outlined in Sections 360c(f) (for determining substantial equivalence) and 360c(e) (for reclassification) are not mirror images of one another." *Ivy Sports Med.*, 767 F.3d at 87 (emphasis added). As Judge Pillard argued, "[t]he text of subsection (e) makes no mention whatsoever of subsection (f) or substantial equivalence determinations." *Id.* at 97 (Pillard, J., dissenting). Nevertheless, the majority took a more functional view, noting that "[a]s a practical matter, the decision to revoke a substantial equivalence determination in circumstances like those present here is a de facto reclassification of the device into Class III, at least absent other FDA action." *Ivy Sports Med.*, 767 F.3d at 87.

"Undoubtedly, there will be instances in which an agency might take a position about its own statute or regulation, which, while incorrect, might appear correct to a reasonable person." *Trahan v. Brady*, 907 F.2d 1215, 1220 (D.C. Cir. 1990). Here, the FDA took the ultimately incorrect position that section 360c(e)'s focus on classification indicated that it was not intended to cover the agency's reconsideration of underlying substantial equivalency determinations. In signaling that the FDA had mounted a "forceful case for the agency's position," the majority itself indicated that the FDA's position was not an unreasonable one. *Compare, e.g.*, *Halverson*, 206 F.3d at 1211 (finding the government's position not substantially justified where the merits panel found the issue "easy," and there was "not even a wisp of a suggestion that it gave any credence to the Department's argument"). Moreover, the government's position accorded with the *presumption* that, unless the statutory text indicates otherwise, agencies are presumed to retain inherent authority to reconsider their decisions. And, as already noted, the fact that Judge Pillard accepted the agency's purported distinction between section 360c(e) and substantial equivalency determinations is a significant, although not dispositive, indication that the FDA's position was substantially justified and could appear correct to a reasonable person. *See In re Long-Distance Tel. Serv.*, 751 F.3d at 637.

Ivy seeks to limit the import of Judge Pillard's dissent by arguing that "she did not propose to adopt the agency's litigation position" and instead relied in large part on "a reading of the FDCA that was directly at odds with FDA's litigating and longstanding regulatory positions." Pl.'s Reply at 11. It is true that Judge Pillard relied on particular statutory language—such as section 360c(e)'s reference to "new information" and that the provision only addressed changing

a device's class downwards, to a less restrictive class[9]—that the agency had purported to read differently. These distinctions may have conflicted with the agency's reading of how or in what circumstances it could alter *classification decisions* through section 360c(e). But they still support the basic point on which Judge Pillard and the agency were in agreement: that the text and structure of section 360c(e) indicated that Congress did not intend for the section to have anything to say about the agency's power to revisit *underlying substantial equivalency determinations*.[10]

The FDA had also argued—and this Court accepted in large part as the grounds for its own decision[11]—that *American Methyl* was distinguishable because the FDA's report indicated that misconduct tainted the agency's procedures and affected the integrity of the agency's scientific determination. The D.C. Circuit majority also found in Ivy's favor on this ground, holding that even if *American Methyl*'s exception for fraud, ex parte contacts, or other misconduct tainting the original record was valid, it did not apply to the facts of this case. *See Ivy Sports Med.*, 767 F.3d at 88–89. The Court first noted that "it is not clear" that the exception

[9] For example, from Class III to Class I or to Class II. *See* 21 U.S.C. § 360c(e)(2) (2002 ed.). The provision has since been amended to provide for upward changes to a device's classification. *See* 21 U.S.C. § 360(e)(1)(A)(i).

[10] It is also accurate that Judge Pillard further questioned whether the agency was correct even to concede that section 360c(e) could be used to *de facto* change a device's classification by revoking a substantial equivalence determination. *See Ivy Sports Med.*, 767 F.3d at 101–02 (Pillard, J., dissenting). As Judge Pillard went on to explain, however, her "view of the statute does not rely on whether the agency was correct that it could have done so." *Id.* at 102. Similarly, the Court does not view this difference of opinion as lending support to Ivy's claim that the FDA's position was not substantially justified.

[11] The D.C. Circuit has previously acknowledged the "delicate circumstances" under which a district court must "determine whether the very Government argument it previously accepted was not substantially justified, *i.e.*, unreasonable." *Halverson*, 206 F.3d at 1208. As noted previously, however, the undersigned was assigned to this case only after it was remanded from the D.C. Circuit. *See* note 2, *supra*.

is "anything more than dicta." *Id.* at 88. Ivy latches on to that conclusion to argue that the government's reliance on the exception was not substantially justified because the footnote "was dicta, not a holding." Pl.'s Mem. Supp. Fees at 14. But while it now embraces that conclusion, at summary judgment even Ivy accepted the footnote's limitation as settled law. *See* Pl.'s Mem. Opp'n Defs.' Cross-Mot. Summ. J. & Reply at 20, ECF No. 62 ("Again, Ivy does not dispute that evidence of fraud, ex parte contacts, or comparable misconduct may justify revocation of a prior agency decision."). An agency's reliance on the D.C. Circuit's own stated limitations of its analysis, and effort to argue that a subsequent case merits considering and accepting that limitation, does not strike the Court as unreasonable.

In any event, while the Circuit majority concluded that "'misconduct' as used in *American Methyl* connotes some clear legal or ethical violation," and that supposed mistakes in the approval process did not rise to the level of misconduct, *Ivy Sports Med.*, 767 F.3d at 88, nothing in *American Methyl* had provided further clarification on what might demonstrate misconduct tainting the original record. In this very case, the Circuit has now stated that "the term 'misconduct' as used in *American Methyl* connotes some clear legal or ethical violation." *Id.* Yet, at the time the FDA decided to rescind the CS's substantial equivalency determination, and while the government litigated this action, no case had further examined what might constitute "misconduct" under the potential *American Methyl* exception.[12] The agency was faced with a report that indicated there had been considerable departures from agency processes and practices that may have, among other things, excluded "individuals, if not viewpoints, from parts of the scientific debate," and accordingly concluded that a "scientific reevaluation of the

[12] The Circuit's holding that "'misconduct' as used in *American Methyl* connotes some clear legal or ethical violation," was accompanied neither by a citation nor further analysis. Thus, it is difficult to claim that the government was unreasonable in failing to anticipate it.

decision to clear the CS device [was] warranted." Pl.'s Mem. Opp'n Ex. B at 2. After that reevaluation, the FDA concluded that its substantial equivalency determination had been wrong, and chose to rescind it. Although the government was incorrect is anticipating how far any exception to the *American Methyl* principle might extend, the Court finds that the government's position, as applied to the facts of this case and considering the case law at the time, was substantially justified.

The substantial justification standard "does not 'require the Government to establish that its decision to litigate was based on a substantial probability of prevailing.'" *Taucher*, 396 F.3d at 1173 (quoting *Spencer v. NLRB*, 712 F.2d 539, 557 (D.C. Cir. 1983)). Moreover, the D.C. Circuit has cautioned that, "as in other areas," a court must "guard against being 'subtly influenced by the familiar shortcomings of hindsight judgment.'" *Id.* (quoting *Beck v. Ohio*, 379 U.S. 89, 96 (1964)). The reach of *American Methyl* and how to square section 360c(e)'s emphasis on classification changes with devices that had been classified only *de facto* through a substantial equivalency determination were both sufficiently uncertain and open to reasonable interpretation. Consequently, the Court concludes that the FDA's action in rescinding the CS's substantial equivalency decision, and the government's litigating position defending that action, were both substantially justified.

IV. CONCLUSION

For the foregoing reasons, Ivy's motion for attorneys' fees and expenses is **DENIED**. An order consistent with this Memorandum Opinion is separately and contemporaneously issued.

Dated: March 31, 2016

RUDOLPH CONTRERAS
United States District Judge