

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

ARQULE, INC.,

Plaintiff,

v.

HON. DAVID J. KAPPOS,

**Under Secretary of Commerce for
Intellectual Property & Director of the
United States Patent & Trademark
Office,**

Defendant.

Civil Action No. 10-1904 (ESH)

MEMORANDUM OPINION

Plaintiff ArQule, Inc., a Delaware corporation with its principal place of business in Massachusetts, has sued David J. Kappos, the Under Secretary of Commerce for Intellectual Property and the Director of the U.S. Patent and Trademark Office (“PTO”), in his official capacity. Plaintiff brings this suit under 35 U.S.C. § 154 and the Administrative Procedure Act (“APA”), 5 U.S.C. §§ 701-706, claiming that defendant erroneously charged plaintiff with one day of applicant delay in its calculation of the patent term adjustment on United States Patent No. 7,713,969 (“the ‘969 patent”) because defendant misinterpreted 35 U.S.C. § 154(b)(2)(C)(ii). Before the Court are defendant’s motion for summary judgment and plaintiff’s cross motion for summary judgment. For the reasons set forth below, defendant’s motion will be denied and plaintiff’s cross motion will be granted.

BACKGROUND

I. LEGAL FRAMEWORK

When a patent issues, the patentee has “the right to exclude others from making, using, offering for sale, or selling the invention” “for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed.” 35 U.S.C. § 154(a)(1)-(2). That twenty-year term, however, is subject to a patent term adjustment that factors in several actions that might have caused delay during the patent process. *See* 35 U.S.C. § 154(b). Four of those adjustments are relevant to this case. The first adjustment, “A delay,” favors the patentee by counting those days attributable to delay in the PTO’s examination of the patent. 35 U.S.C. § 154(b)(1)(A). The second adjustment, “B delay,” favors the patentee by creating a stopgap measure that counts those days attributable to delay in the issuance of a patent beyond three years of the application filing date. 35 U.S.C. § 154(b)(1)(B). The third adjustment discounts any redundant days between A delay and B delay so that the patentee is not rewarded with more days than the patent was actually delayed. 35 U.S.C. § 154(b)(2)(A). Finally, the fourth adjustment, “applicant delay,” disfavors the patentee by discounting those days during which the applicant did not make reasonable efforts to “conclude processing or examination of an application,” which is defined as any period of time beyond three months. 35 U.S.C. § 154(b)(2)(C).

II. FACTUAL HISTORY

Chiang J. Li, Mark A. Ashwell, Jason Hill, Magdi M. Moussa, and Neru Munshi invented a method to treat cancer entitled “Compositions and Methods for Treatment of Cancer” that was initially filed on February 9, 2006, as United States Patent Application No. 11/350,335, and issued as the ‘969 patent on May 11, 2010. (Complaint [“*Compl.*”] at ¶¶ 8, 16, & Ex. A.) Plaintiff is the assignee of the ‘969 patent and the real party in interest. (*Id.* at ¶ 9.)

When it issued on May 11, 2010, the ‘969 patent was granted a patent term adjustment of 1,127 days. (*Id.* at ¶ 15, & Ex. A at 1.) The adjustment was determined by adding 675 days of A delay and 456 days of B delay while subtracting 3 days of overlap and 1 day of applicant delay. (*Id.* at ¶¶ 17-20.) The PTO determined that the ‘969 patent was subject to one day of applicant delay because the applicant responded to an August 11, 2009 PTO office action on November 12, 2009, three months *and one day* after the August 11 action. (*Id.* at ¶ 20.) The day defendant contends the response was due, Wednesday, November 11, 2009,¹ was Veterans Day, which is a federal holiday when the PTO is closed. (Pl.’s Cross Mot. at 3 & Ex. A.)

Before the patent issued, plaintiff filed a Patent Term Adjustment Petition on March 15, 2010, arguing in part that the calculation of applicant delay was incorrect because the three-month deadline fell on a federal holiday. (Compl. at ¶ 12 & Ex. B at 4-6.) In a letter dated July 8, 2010, the PTO denied plaintiff’s request to reduce applicant delay from one day to zero. (*Id.* at ¶ 12 & Ex. C.) On August 6, 2010, plaintiff filed a Request for Reconsideration of Patent Term Adjustment that was denied by the PTO on November 19, 2010. (*Id.* at ¶ 12 & Ex. D; Defendant’s Motion for Summary Judgment [“Def.’s Mot.”] at Ex. B.)

III. PROCEDURAL HISTORY

Plaintiff filed its Complaint in federal district court on November 5, 2010. (Compl. at 1.) Attached to the Complaint were the ‘969 patent, the Patent Term Adjustment Petition, the PTO’s response to that Petition, and the Request for Reconsideration of Patent Term Adjustment. (*Id.* at Exs. A-D.) Defendant filed its Answer on January 1, 2011. (Answer at 1.) Defendant

¹ The Complaint lists November 12, 2009 as both the date that it responded to the request (Compl. at ¶ 20) and the date on which the response was due (*id.* at ¶ 21). The latter is clearly a typographical error; plaintiff’s substantive arguments (and the entire case) are completely based on a due date of November 11, 2009, and subsequent pleadings and exhibits refer to November 11, 2009, as the actual due date. (Pl.’s Cross Mot. at 3 & Ex. A; Def.’s Mot. at Ex. B.) The Court will therefore proceed using the due date of November 11, 2009.

subsequently filed a Motion for Summary Judgment on March 15, 2011. (Def.'s Mot at 1.) Attached to the motion were the electronic receipt for plaintiff's electronic submission of its November 12, 2009 response; the November 19, 2010 PTO letter denying plaintiff's Request for Reconsideration of Patent Term Adjustment; and a copy of the Federal Register containing the final rule promulgated to implement the change in the patent term adjustment for twenty-year terms, which is entitled "Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term," 65 Fed. Reg. 56,366, 56,366-94 (Sept. 18, 2000) (codified at 37 C.F.R. pt. 1). (Def.'s Mot. at Exs. A-C.)

Plaintiff filed a Cross Motion for Summary Judgment on April 14, 2011. (Plaintiff ArQule, Inc.'s Cross-Motion for Summary Judgment ["Pl.'s Cross Mot."]). Attached to the Cross Motion were the PTO's August 11, 2009 office action; an itemized Patent Term Adjustment Summary; the same November 19, 2010 PTO letter denying reconsideration; and a November 9, 2009 PTO notice detailing changes in the calculation of patent term adjustment for international applications. (*Id.* at Exs. A-D.) On May 11, 2011, defendant filed an Opposition to plaintiff's Cross Motion and a Reply to plaintiff's Opposition to its Motion. (Defendant's Consolidated Opposition to Plaintiff's Cross-Motion for Summary Judgment & Reply to Plaintiff's Opposition to Defendant's Motion for Summary Judgment ["Def.'s Opp."]). On May 31, 2011, plaintiff filed a Reply to defendant's Opposition. (Plaintiff's Reply Memorandum of Points & Authorities in Support of Plaintiff's Cross-Motion for Summary Judgment ["Pl.'s Rep."]). Attached to plaintiff's Reply were several sections of the PTO's Manual of Patent Examining Procedure. (*Id.* at Exs. E-H.)

ANALYSIS

I. LEGAL STANDARDS

A. Judicial Review of Patent Term Adjustments

The APA provides judicial review of an agency action to a party who has suffered a legal wrong because of that action. 5 U.S.C. § 702. The laws governing patent term adjustment outline the judicial review process, allowing aggrieved applicants to seek review of the decision in the U.S. District Court for the District of Columbia:

An applicant dissatisfied with a determination made by the Director [during the patent term adjustment process] shall have remedy by a civil action against the Director filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent. . . . Any final judgment resulting in a change to the period of adjustment of the patent term shall be served on the Director, and the Director shall thereafter alter the term of the patent to reflect such change.

35 U.S.C. § 154(b)(4)(A). Further, this Court has “original jurisdiction of any civil action arising under any Act of Congress relating to patents.” 28 U.S.C. § 1338(a).

The APA gives the Court authority to set aside the PTO’s decision if it is found to be arbitrary and capricious:

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law

5 U.S.C. § 706.² The arbitrary and capricious standard “presumes the validity of agency action, requiring [the court] to determine whether the agency has considered the relevant factors and

² Because the Court’s scope of review is limited to “decid[ing] all relevant questions of law, interpret[ing] constitutional and statutory provisions, and determin[ing] the meaning or applicability of the terms of an agency action,” 5 U.S.C. 706, it cannot consider defendant’s

‘articulate[d] a rational connection between the facts found and the choice made.’” *AT&T Corp. v. FCC*, 220 F.3d 607, 616 (D.C. Cir. 2000) (quoting *Motor Vehicle Mfrs. Ass’n of the U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). The court “may reverse only if the agency’s decision is not supported by substantial evidence, or the agency has made a clear error in judgment.” *Id.* (quoting *Kisser v. Cisneros*, 14 F.3d 615, 619 (D.C. Cir. 1994)).

B. Motion for Summary Judgment

Normally, a motion for summary judgment under Rule 56 shall be granted if “the pleadings, depositions, answers to interrogatories, . . . admissions on file, . . . [and] affidavits . . . show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986) (quoting Fed. R. Civ. P. 56(c)). “In a case involving review of a final agency action under the [APA], however, the standard set forth in Rule 56(c) does not apply because of the limited role of a court in reviewing the administrative record.” *Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 89 (D.D.C. 2006) (citation omitted).

Under the APA, it is the role of the agency to resolve factual issues to arrive at a decision that is supported by the administrative record, whereas “the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did.”

Id. at 90 (quoting *Occidental Eng’g Co. v. INS*, 753 F.2d 766, 769-70 (9th Cir. 1985)).

“[W]hen an agency action is challenged” solely with “arguments about the legal conclusion to be drawn about the agency action,” then the “case on review is a question of law, and only a question of law.” *Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226

arguments that plaintiff’s interpretation “would create a sizable administrative burden . . . by requiring the USPTO to track multiple document submission dates . . . for each of the millions of pieces of correspondence it receives each year.” (*See* Def.’s Mot. at 18.)

(D.C. Cir. 1993). Thus, the entire case can be resolved on the administrative record under a motion for summary judgment. *Id.* In that instance, a “district court[] reviewing agency action under the APA’s arbitrary and capricious standard do[es] not resolve factual issues, but operate[s] instead as [an] appellate court[] resolving legal questions.” *James Madison Ltd. by Hecht v. Ludwig*, 82 F.3d 1085, 1096 (D.C. Cir. 1996).

C. Chevron Deference

The Supreme Court’s opinion in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), outlines a two-step process courts must follow in determining whether to defer to an agency’s interpretation of a statute. “Under *Chevron* Step One, the court examines the statute *de novo*,” applying “the traditional tools of statutory construction in order to discern whether Congress has spoken directly to the question at issue.” *Eagle Broad. Group, Ltd. v. FCC*, 563 F.3d 543, 550, 552 (D.C. Cir. 2009) (citing *Chevron*, 467 U.S. at 842-43). “If this ‘search for the plain meaning of the statute . . . yields a clear result, then Congress has expressed its intention as to the question, and deference is not appropriate.’” *Eagle Broad.*, 563 F.3d at 552 (quoting *Bell Atlantic Tel. Cos. V. FCC*, 131 F.3d 1044, 1047 (D.C. Cir. 1997)). Under that circumstance, “the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.” *Chevron*, 467 U.S. at 842-43. Because it is a federal agency, this applies to the PTO: “[T]he PTO contends that its interpretation is entitled to deference under either *Chevron* . . . or *Skidmore v. Swift & Co.* Because the language of the statute itself controls this case and sets an unambiguous rule for overlapping extensions, this court detects no reason to afford special deference to the PTO’s interpretation.” *Wyeth v. Kappos*, 591 F.3d 1364, 1372 (Fed. Cir. 2010) (internal citations omitted).

“If, however, the court determines Congress has not directly addressed the precise question at issue,” then it moves to Step Two. *Chevron*, 467 U.S. at 843. Under *Chevron* Step

Two, “the question for the court is whether the agency’s answer is based on a permissible construction of the statute.” *Id.* “If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute.” *Id.* at 843-44. If the delegation of power to the agency is implicit, “a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency.” *Id.* at 844.

D. Canons of Statutory Interpretation

Chevron Step One requires this Court to apply traditional canons of statutory interpretation to the statutes at issue to determine if their meaning is clear. *Eagle Broad.*, 563 F.3d at 552. As the Supreme Court has noted:

canons of construction are no more than rules of thumb that help courts determine the meaning of legislation, and in interpreting a statute a court should always turn first to one, cardinal canon before all others. We have stated time and again that courts must presume that a legislature says in a statute what it means and means in a statute what it says there. When the words of a statute are unambiguous, then, this first canon is also the last: “judicial inquiry is complete.”

Conn. Nat’l Bank v. Germain, 503 U.S. 249, 253-54 (1992) (citation omitted).

“It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.” *Davis v. Mich. Dep’t of Treasury*, 489 U.S. 803, 809 (1989). Statutes are not interpreted in a vacuum, and “the meaning of statutory language, plain or not, depends on context.” *Smith v. Zachary*, 255 F.3d 446, 448 (7th Cir. 2001) (quoting *Holloway v. United States*, 526 U.S. 1, 7 (1999)). Further, “it is a traditional canon of statutory construction to construe related statutory provisions in similar fashion.” *United States v. Delgado-Garcia*, 374 F.3d 1337, 1347 (D.C. Cir. 2004). In

addition, a court “must read the statutes to give effect to each if [it] can do so while preserving their sense and purpose.” *Watt v. Alaska*, 451 U.S. 259, 267 (1981). Finally, “[a] fundamental canon of statutory construction is that, unless otherwise defined, words will be interpreted as taking their ordinary, contemporary, common meaning.” *Perrin v. United States*, 444 U.S. 37, 42 (1979).

II. CHEVRON STEP ONE

Although the litigants disagree over the meaning of § 154(b)(2)(C)(ii), both argue that the statute is unambiguous and that the inquiry should stop at Step One. (Def.’s Mot. at 10-12; Pl.’s Cross Mot. at 2-3; Def.’s Opp. at 5; Pl.’s Rep. at 7-9.) Therefore, the Court will now address Step One and the interpretation of the statute..

A. Applicant Delay and the Weekend/Holiday Exception

During the prosecution of a patent application, the PTO may issue a request to an applicant concerning an unresolved question with the application. The PTO can set a deadline from thirty days up to six months for the applicant to respond to the request. 35 U.S.C. § 133. This deadline is referred to by the government as “timeliness,” and a failure by the applicant to meet this deadline will result in abandonment of the application. (Def.’s Mot. at 2-3, 12-18.) Separate from timeliness is applicant delay, which is governed by 35 U.S.C. § 154(b)(2)(C)(ii). Applicant delay deducts days from the patent term adjustment if the applicant takes more than three months to respond to a PTO request during the prosecution of the patent application:

[A]n applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of 3 months that are taken to respond to a notice from the Office making any rejection, objection, argument, or other request, measuring such 3-month period from the date the notice was given or mailed to the applicant.

35 U.S.C. § 154(b)(2)(C)(ii). The only issue in dispute here is whether the calculation of applicant delay in § 154(b)(2)(C)(ii) is subject to the “weekend/holiday exception” in 35 U.S.C. § 21(b).

Section 21(b) allows applicants to take any action or pay any fee on the next business day if the deadline for that action falls on a weekend or a federal holiday:

When the day, or the last day, for taking any action or paying any fee in the United States Patent and Trademark Office falls on Saturday, Sunday, or a federal holiday within the District of Columbia, the action may be taken, or the fee paid, on the next succeeding secular or business day.

35 U.S.C. § 21(b). As both litigants concede, the weekend/holiday exception in § 21(b) applies to several actions applicants can take under the patent laws, including the timeliness of an applicant’s response to a PTO request. (Pl.’s Cross Mot. at 7-9; Def.’s Opp. at 2-4 & n.4.) But the issue here is whether § 21(b) applies to § 154 (b)(2)(C)(ii). If § 21(b) applies to applicant delay, as plaintiff contends, then the PTO incorrectly calculated the delay because the deadline to respond to PTO’s request was a federal holiday, which should have given plaintiff leeway to respond on the next business day. If § 21(b) does not apply to the calculation of delay, as defendant contends, then the PTO calculated applicant delay correctly by giving the ‘969 patent one day of applicant delay because plaintiff filed its response three months and a day from the date of the PTO notice.

B. The Applicability of 35 U.S.C. § 21(b) to Applicant Actions

Because § 21(b) applies to any action an applicant can take, it necessarily applies to a litany of actions that an applicant takes during the normal course of the prosecution of a patent application, from filing the application itself to responding to requests by the PTO, and, as defendant argues correctly, § 21(b) applies solely to actions taken by the applicant, as distinct from actions taken by the PTO. (Def.’s Mot. at 13, 15.) Defendant nonetheless argues that the

calculation of applicant delay under § 154(b)(2)(C)(ii) is exempt from § 21 because § 154(b)(2)(C)(ii) describes an internal action taken by the PTO, not an action taken by an applicant. (*Id.*) Further, defendant contends that the rigid language in § 154(b)(2)(C)(ii) protects it from § 21, and since § 154(b)(2)(C)(ii) contains the words “shall” and “any,” the PTO has no choice but to view the three-month window as static. (*Id.* at 10-12); *see* 35 § 154(b)(2)(C)(ii) (“an applicant *shall* be deemed to have failed to engage in reasonable efforts . . . for the cumulative total of *any* periods of time in excess of 3 months” (emphasis added)).

Defendant’s interpretation, however, violates two traditional canons of statutory interpretation. First, defendant’s interpretation fails to read § 154(b)(2)(C)(ii) in the context of the overall statutory scheme. *See Davis*, 489 U.S. at 809. As plaintiff demonstrates, there are several examples of applicant actions within Title 35 that are subject to the weekend/holiday exception in § 21(b), and those examples prove informative in examining whether § 154(b)(2)(C)(ii) describes an applicant action. Those examples also prove that defendant’s interpretation violates a second canon of statutory interpretation, which is “to construe related statutory provisions in similar fashion.” *Delgado-Garcia*, 374 F.3d at 1347. The applicant actions described in §§ 133, 102(b), and 119(a) illustrate the point.

First, both parties agree that the weekend/holiday exception applies to the PTO notice deadline set forth in § 133. (Def.’s Mot. at 7-8; Pl.’s Cross Mot. at 7-8.) Unambiguous language in § 133, similar to the language in § 154(b)(2)(C)(ii), is problematic for defendant’s interpretation: “Upon failure of the applicant to prosecute the application *within six months* after any action therein, of which notice has been given or mailed to the applicant, or within such shorter time, not less than thirty days . . . the application *shall* be regarded as abandoned . . .” 35 U.S.C. § 133 (emphasis added). Used as a preposition, the term “within” in its common,

ordinary meaning, *see Perrin*, 444 U.S. at 42, means “[i]nside the limits or extent of in time, degree, or distance[;] . . . not beyond.” *Webster’s II: New Riverside University Dictionary* 1324 (1994). Using defendant’s method of interpretation and viewing § 133 in a vacuum, an applicant would be given no leeway beyond a rigid six-month deadline because the word “within” creates such a limitation and “shall” compels the PTO to act. As defendant concedes, however, the seemingly unbending language in § 133 is interpreted in light of the weekend/holiday exception in § 21. (*See* Def.’s Mot. at 7-8.) Thus, the correct interpretation of § 133 reads that statute in the context of the overall statutory scheme.

Second, the statutory limit barring a patent if the invention was patented, described in a printed publication, in public use, or on sale more than one year prior to the application, as described in 35 U.S.C. § 102(b), has long been subject to § 21(b)’s weekend/holiday exception. Like other sections, its language alone seems to allow no exception for periods beyond its designated deadline: “A person *shall* be entitled to a patent unless . . . the invention was patented or described in a printed publication . . . or in public use or on sale . . . , *more than one year prior to the date* of the application for patent in the United States” 35 U.S.C. § 102(b) (emphasis added). Under the defendant’s method of interpretation, an application would be denied if any of the described events occurred more than one calendar year before the application. That, however, is not the case.

For instance, in *Ex parte Olah and Kuhn*, the Patent and Trademark Office Board of Appeals held that § 102(b) was subject to the weekend/holiday exception when an applicant filed for a patent one year and one day after the invention appeared in a publication. *Ex parte Olah & Kuhn*, 131 U.S.P.Q. 41, 41-42, 1961 WL 7823 (P.T.O.B.A. Nov. 8, 1960). Because the one-year deadline fell on a Sunday, the court’s application of § 21 to § 102(b) prevented the application

from being barred. *Id.* Similarly, in *Orion IP, LLC v. Mercedes-Benz USA, LLC*, the court cited *Olah* when applying the weekend/holiday exception to the prior sale portion of § 102(b). *Orion IP, LLC v. Mercedes-Benz USA, LLC*, 485 F. Supp. 2d 745, 746-47 (E.D. Tex. 2007). The application at issue in *Orion* had a filing date of one year and three days after the invention was sold at a parts fair. *Id.* at 745-46. The court held that the prior sale was immaterial to the application's validity because the one-year deadline fell on a Friday that was a federal holiday, allowing the application to be filed three days later, on the following Monday. *Id.* at 746-47. Again, the seemingly unbending language of §102(b) was tempered by the weekend/holiday exception, and this section of the statute was interpreted in the context of the overall statutory scheme.

Third, the foreign filing privilege detailed in 35 U.S.C. § 119(a) is also subject to the weekend/holiday exception. Like § 133, §119(a) contains the same rigid “within” as a modifier to its time designation:

An application for patent for an invention filed in this country by any person who . . . previously regularly filed an application for a patent for the same invention in a foreign country which affords similar privileges . . . *shall* have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country, if the application in this country is filed *within twelve months* from the earliest date on which such foreign application was filed

35 U.S.C. § 119(a) (emphasis added). The Board of Patent Appeals and Interferences, however, cited *Olah* when concluding that § 119 was modified by the weekend/holiday exception in § 21. *Wingrove v. Langen*, 230 U.S.P.Q. 353, 354, 1985 WL 71903 (B.P.A.I. Nov. 13, 1985). In *Wingrove*, the applicant filed an application one year and two days after filing a similar application with the German patent office. *Id.* Because the one-year deadline fell on a Saturday, however, the Board held that the applicant had filed his application on time because § 119(a) was

subject to § 21(b)'s weekend/holiday exception. *Id.* Like §§ 133 and 102(b), the language in § 119(a) is modified by § 21 when read in context of the overall statutory scheme. Defendant's argument that the words "shall" and "any" allow for no exceptions has been rejected in these examples, all of which describe an action that an applicant can take during the prosecution of a patent application.

C. Anatomy of an "Action"

The similarity between § 154(b)(2)(C)(ii) and the actions described in §§ 133, 102(b), and 119(a) does not end with the rigid statutory language each of those sections uses to describe the period of time within which an applicant must act. Each of the four describes an action that an applicant must take within a specified period of time to avoid incurring a penalty. These compelling similarities make the action described in § 154(b)(2)(C)(ii) an applicant action that warrants the application of the weekend/holiday exception to applicant delay.

Plaintiff argues that "any action" should be interpreted broadly, capturing § 154(b)(2)(C)(ii) because that section describes an action that the applicant must take, namely responding to a PTO request before the applicant is penalized by applicant delay. (Pl.'s Cross Mot. at 9; Pl.'s Rep. at 3.) Defendant contends that § 154(b)(2)(C)(ii) does not describe an applicant action, instead serving as instructions to the PTO on how to properly calculate applicant delay. (Def.'s Mot. at 15.) In doing so, defendant attempts to distinguish § 154(b)(2)(C)(ii) from the other sections to which § 21(b) applies by arguing that all of plaintiff's examples (*e.g.*, §§ 133, 102(b), and 119(a)) describe actions taken by applicants, whereas § 154(b)(2)(C)(ii) applies to an action taken by the PTO. (Def.'s Opp. at 4 n.4.) The Court, informed by the canon of statutory interpretation to construe related statutory provisions similarly, cannot accept defendant's purported distinction.

Section 154(b)(2)(C)(ii) is the only statutory provision that outlines applicant delay. Unlike the other provisions within § 154(b) that describe the elements of patent term adjustment, including A delay and B delay, § 154(b)(2)(C)(ii) hinges on actions taken by the applicant. While A delay and B delay are solely dependent upon the PTO's timely prosecution of a patent application, and thus completely independent of an applicant's actions, applicant delay by its very nature depends on the applicant failing to respond to a PTO request within a three-month window. Defendant's argument that § 154(b) functions solely as instruction to the PTO for calculating the patent term adjustment may be correct for sections such as § 154(b)(1), which outlines actions solely within the PTO's control like A delay and B delay, but it is surely incorrect as applied to § 154(b)(2)(C)(ii). In contrast, the activity described in § 154(b)(2)(C)(ii) informs PTO actions, *as well as* applicant actions. While applicants are powerless to affect other elements of patent term adjustment, applicant actions can and do impact the calculation of applicant delay.

Defendant's interpretation of § 154(b)(2)(C)(ii), if correct, would inexplicably suggest that applicants have no involvement in applicant delay because that section would merely serve as an instruction to the PTO. The Court finds plaintiff's response to this argument persuasive. (*See* Pl.'s Rep. at 3.) The activity described in § 154(b)(2)(C)(ii) contains three similarities to the other applicant actions that fall within the ambit of § 21(b). First, § 154(b)(2)(C)(ii) defines a time period. Like the "within six months" period in § 133, the no "more than one year" period in § 102(b), and the "within twelve months" period in § 119(a), § 154(b)(2)(C)(ii) sets a limit of "any periods of time in excess of 3 months." 35 U.S.C. §§ 102(b), 119(a), 133, 154(b)(2)(C)(ii). Second, § 154(b)(2)(C)(ii) defines an action to be taken by the applicant within that time period. Just as § 133 requires an applicant to respond to a PTO action during the prosecution of the

application, and § 102(b) and § 119(a) require an applicant to file the patent application in the context of previous outside actions, § 154(b)(2)(C)(ii) requires the applicant to respond to a PTO action during the prosecution of the application. 35 U.S.C. §§ 102(b), 119(a), 133, 154(b)(2)(C)(ii). Third, § 154(b)(2)(C)(ii) defines a punishment (*i.e.*, taking days away from the patent term adjustment) for the applicant should it fail to take the prescribed action within the defined time period like § 133 punishes an applicant with abandonment, § 102(b) bars the application altogether, and § 119(a) denies a right to priority. 35 U.S.C. §§ 102(b), 119(a), 133.

These similarities between the action described in § 154(b)(2)(C)(ii) and the actions described in other sections that are covered by § 21(b) are too strong for defendant to overcome. In finding that § 154(b)(2)(C)(ii) describes an action to be taken by an applicant, it falls under the umbrella of “any action” taken by an applicant. Therefore, the applicant action in § 154(b)(2)(C)(ii) is subject to the weekend/holiday exception because § 21(b) applies that exception to “any action” taken by an applicant.

D. The Interaction of Timeliness in § 133 and Applicant Delay in § 154(b)(2)(C)(ii)

During the prosecution of a patent application, the PTO may issue a request to an applicant. That request is governed by two deadlines—the timeliness deadline in § 133, which can be set from thirty days to six months and carries the penalty of abandonment, and the applicant delay deadline in § 154(b)(2)(C)(ii), which is statutorily set at three months and carries the penalty of a reduction in patent term adjustment. Though the two are separate provisions, they both describe applicant actions to which § 21(b) applies.

While defendant is correct to assert that §§ 133 and 154(b)(2)(C)(ii) outline separate actions,³ both sections define actions that an applicant must take within a specified period of time lest the applicant be penalized. To suggest that § 154(b)(2)(C)(ii) does not prescribe an applicant action is to ignore the incentive that it clearly places on applicants to respond to a PTO request to avoid accruing days of applicant delay. Under defendant's interpretation, an applicant who receives a PTO request with a three-month deadline may respond in a timely manner under § 133 *but still be charged* with applicant delay under § 154(b)(2)(C)(ii). For example, for a request with a three-month deadline ending on a Sunday, the § 21(b) weekend/holiday exception would allow an applicant to file a timely response under § 133 on Monday. Under the defendant's interpretation, however, the applicant's response would still garner one day of applicant delay under § 154(b)(2)(C)(ii) because § 21(b) would only save the response's timeliness, not its accrual of applicant delay.

In this way, defendant's interpretation violates the canon of statutory interpretation that instructs the Court to read "statutes to give effect to each if [it] can do so while preserving their sense and purpose." *See Watt*, 451 U.S. at 267. In any case, where the § 133 timeliness deadline is set at three months, defendant's interpretation would functionally negate the § 21(b) weekend/holiday exception for § 133 timeliness because any applicant who did not want to be penalized with applicant delay would have no choice but to respond within § 154(b)(2)(C)(ii)'s

³ Defendant contends that plaintiff is conflating § 133 with § 154(b)(2)(C)(ii) (Def.'s Mot. at 12-16), but that is a mischaracterization of plaintiff's argument, which consistently maintains the two are separate provisions that are both subject to § 21(b). Further, defendant contends that this conflation would allow an applicant to abuse the system by filing a response several months after it was due if the applicant were lucky enough to have its deadline fall on a weekend or federal holiday. (Def.'s Mot. at 16.) This argument is also unpersuasive because defendant is mischaracterizing plaintiff's argument and the Court is not conflating the two sections.

static three-month window instead of being allowed the grace period statutorily guaranteed by § 21(b) as it is applied to § 133.⁴

E. Traditional Canons of Statutory Interpretation Reveal Plain Meaning in § 154(b)(2)(C)(ii)

Using the traditional canons of statutory interpretation, the Court finds the meaning of § 154(b)(2)(C)(ii) to be plain. Like other applicant actions described throughout Title 35, § 154(b)(2)(C)(ii) describes an action that applicants must take by a specified deadline to avoid a penalty. Because it describes an action, the language of § 21(b), applying the weekend/holiday exception to “*any* action taken” by an applicant, plainly applies. Therefore, the judicial inquiry stops here, meaning the Court and the agency must yield to the clear meaning of the statute and the intent of Congress. Because the PTO’s interpretation of § 154(b)(2)(C)(ii) contravenes the clear meaning of the statute, it violates the APA. Given that conclusion, the Court need not reach Step Two, nor does any party ask it to. Moreover, while defendant appears to offer several deference arguments,⁵ “[b]ecause the language of the statute itself controls this case and sets an

⁴ This hypothetical does not appear to be a rare occurrence. The PTO’s Manual of Patent Examining Procedure seems to suggest that requests on the merits are assigned a three-month timeliness deadline under § 133. *See* U.S. Patent & Trademark Office, Manual of Patent Examining Procedure §§ 130, 710.02(b) (8th ed. 2001, 8th rev. 2010) (outlining the special circumstances required for one month, two month, and six month deadlines while defining the three month deadline as used “[t]o reply to any Office action on the merits”).

⁵ Defendant cites several cases to show that the Court should give it deference. (*See* Def.’s Mot. at 9-10; Def.’s Opp. at 7.) However, the cases fail to prove that the PTO should be afforded special or unique deference within the *Chevron* framework, and defendant has failed to prove how any of the cases would modify the Court’s application of Step One. Further, defendant contends that Congress has delegated to it the authority to create regulations governing applicant delay, citing § 154(b)(2)(C)(iii) and 37 C.F.R. § 1.704(b). (Def.’s Opp. at 6-7.) While the PTO is charged with implementing the statutory provisions governing applicant delay, any regulation or implementing policy that contravenes the meaning of the statute violates the APA. 5 U.S.C. § 706.

unambiguous rule . . . , this court detects no reason to afford special deference to the PTO's interpretation." *Wyeth*, 591 F.3d at 1372.

CONCLUSION

For the above-stated reasons, the Court finds that the PTO's interpretation of 35 U.S.C. § 154(b)(2)(C)(ii) is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law because it contravenes the clear meaning of the statute. Accordingly, the Court finds that the patent term adjustment for the '969 patent was erroneous, and that the correct calculation for applicant delay should have been zero days instead of one day, making the correct patent term adjustment for the '969 patent 1,128 days instead of 1,127 days. Thus, plaintiff's cross motion for summary judgment is granted, and defendant's motion for summary judgment is denied. A separate order accompanies this memorandum opinion.

/s/
ELLEN SEGAL HUVELLE
United States District Judge

Date: June 22, 2011