

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
Alexandria Division**

**IDORSIA PHARMACEUTICALS LTD.,**     )  
    **Plaintiff,**                             )  
            **v.**                                 )  
   )  
**ANDRE IANCU,**                             )  
    *Under Secretary of Commerce for Intellectual*     )  
    *Property and Director of the United States*         )  
    *Patent and Trademark Office,*                     )  
    **Defendant.**                             )  
   )

**Case No. 1:17-cv-922**

**ORDER**

For the reasons stated in the Memorandum Opinion of even date.

It is hereby **ORDERED** that plaintiff's cross-motion for summary judgment (Dkt. 27) is **DENIED**.

It is further **ORDERED** that defendant's cross-motion for summary judgment (Dkt. 30) is **GRANTED**.

The Clerk is directed to enter Rule 58, Fed. R. Civ. P., judgment in favor of defendant and to place this matter among the ended causes.

The Clerk is further directed to send a copy of this Order to all counsel of record.

Alexandria, Virginia  
July 22, 2019

  
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T. S. Ellis, III  
United States District Judge

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FOR THE EASTERN DISTRICT OF VIRGINIA  
Alexandria Division**

**IDORSIA PHARMACEUTICALS LTD.,**     )  
    **Plaintiff,**                             )  
            **v.**                                 )  
   )  
**ANDRE IANCU,**                             )  
*Under Secretary of Commerce for Intellectual*     )  
*Property and Director of the United States*     )  
*Patent and Trademark Office,*                     )  
    **Defendant.**                             )  
   )

**Case No. 1:17-cv-922**

**MEMORANDUM OPINION**

Plaintiff, a Swiss limited liability company, brings this action pursuant to 35 U.S.C. § 154(b)(4)(A), the Administrative Procedures Act (“APA”),<sup>1</sup> and the Fifth Amendment of the United States Constitution, challenging the United States Patent and Trademark Office’s (“PTO”) calculation of the length of a patent term adjustment (“PTA”) for plaintiff’s patent, U.S. Patent No. 8,518,912 (“the ’912 Patent”). In total, plaintiff seeks an additional 102 days of A-Delay PTA to be added to the term of the ’912 Patent, which would increase the total PTA from 311 to 413 days. At issue in this matter are the parties’ cross-motions for summary judgment with respect to plaintiff’s challenge to the PTO’s PTA determination.

**I.**

The APA confines judicial review of agency decisions to the administrative record of proceedings before the agency. *See* 5 U.S.C. § 706; *see also Camp v. Pitts*, 411 U.S. 138, 142 (1973). Put another way, “when a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal.” *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C.

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<sup>1</sup> 5 U.S.C. § 701 *et seq.*

Cir. 2001). Given the district court's limited role in reviewing the administrative record, the ordinary summary judgment standard does not apply. The key difference in an APA case is that "the presence or absence of a genuine dispute of material fact is not in issue, as the facts are all set forth in the administrative record." *Hyatt v. U.S. Patent & Trademark Office*, 146 F. Supp. 3d 771, 780 (E.D. Va. 2015). Therefore, in a review of agency action under the APA, "[t]he 'entire case' on review is a question of law." *Am. Bioscience, Inc.*, 269 F.3d at 1083.

The administrative record pertaining to the PTO's determination of the correct amount of PTA to be awarded to the '912 Patent reflects the following relevant facts.

- Actelion Pharmaceutical, Ltd. ("Actelion"), plaintiff's predecessor in interest in the '912 Patent, filed United States Patent Application No. 12/745,358 ("the '358 Application") as an international application pursuant to the Patent Cooperation Treaty. The '358 Application claimed priority to International Patent Application No. PCT/IB2007/054850, which was filed on November 29, 2007.
- The '358 Application disclosed an independent compound claim 1, which recited the formula  $P(O)R^5R^8$ .
- On March 14, 2012, the PTO examiner issued the first restriction requirement for the '358 Application. All pending claims (claims 1-14 and 16) were made subject to the restriction requirement. The examiner identified six distinct inventive groups for all the claims based upon possible composition variations for the  $P(O)R^5R^8$  chemical structure disclosed by the '358 Application. The examiner explained his view that the restriction was necessary because "[t]he inventions of Groups I-VI [were] independent and distinct from each other because they [were] directed to structurally dissimilar compounds that lack[ed] a common core as noted [sic] the various  $P(O)R^5R^8$ ." AR426.<sup>2</sup>
- After the PTO issued the first restriction requirement, Actelion notified the examiner via telephone call that the first restriction requirement omitted subject matter from the claims. The examiner agreed that the restriction requirement omitted subject matter from the claims and indicated that a new restriction requirement would be issued to supersede the first restriction requirement. Actelion did not elect any of the invention groups in the first restriction requirement or oppose the restriction requirement on the merits.
- The PTO issued a second restriction requirement for the '358 Application on April 18, 2012. The second restriction requirement superseded and replaced the first restriction requirement, and it divided the '358 Application's claims into eight invention groups.

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<sup>2</sup> References to "AR" followed by a number indicate the page in the Administrative Record (Dkts. 18-2 & 18-3) on which the cited information may be found.

- After the PTO issued the second restriction requirement, Actelion notified the examiner via telephone call that the second restriction requirement omitted subject matter from the claims. The examiner agreed that the restriction requirement omitted subject matter from the claims and indicated that a third restriction requirement would be issued to supersede the second restriction requirement. Actelion did not elect any of the invention groups in the second restriction requirement or oppose the restriction requirement on the merits.
- The PTO issued a third restriction requirement for the '358 application on June 21, 2012. The third restriction requirement superseded and replaced the first restriction requirement, and it divided the '358 Application's claims into three invention groups.
- Actelion filed a response to the third restriction requirement on July 23, 2012, in which Actelion elected one of the invention groups defined in the third restriction requirement, made an election of species, and traversed.
- The '358 Application issued as the '912 Patent on August 27, 2013. The PTO issued an initial PTA determination on August 27, 2013, totaling 314 days of PTA, including 229 days of A-Delay.
- In response, Actelion filed an application for Patent Term Adjustment followed by a Request for Reconsideration of Patent Term Adjustment in view of the AIA Technical Corrections Act. On September 29, 2014, the PTO issued a recalculation of 311 days of PTA. This recalculation reduced the amount of A-Delay from 229 days to 226 days, by redetermining the national stage commencement date to be June 1, 2010, the next PTO business day after May 29, 2010.
- Actelion filed an Application for Patent Term Adjustment in response to the PTO's PTA determination of 311 days. On November 10, 2014, the PTO determined the PTA to be 346 days on the ground that the accrual of A-Delay was stopped by the second restriction requirement issued by the PTO, but not by the first restriction requirement. On April 7, 2015, the PTO issued a final decision on PTA for the '912 Patent upholding the PTO's calculation of 346 days of PTA, including 261 days of A-Delay.
- On October 1, 2015, Actelion filed suit in the Eastern District of Virginia pursuant to 35 U.S.C. § 154(b)(4)(A) to challenge the PTO's determination of PTA for the '912 Patent. On March 26, 2016, the District Court remanded the case to the PTO to reconsider its determination of PTA for the '912 Patent in light of the Federal Circuit's recent decision in *Pfizer v. Lee*, 811 F.3d 466 (Fed. Cir. 2016).
- On February 16, 2017, the PTO's issued its final determination of PTA for the '912 patent, which totaled 311 days of PTA, including 226 days of A-Delay.

## II.

The Patent Act grants a patentee rights in the patent for a term of twenty years from the date the patent application was filed. 35 U.S.C. § 154(a)(2). As a result, the enforceable term of an

issued patent will vary depending on the length of the PTO's examination of the patent application prior to issuing the patent.

To compensate patent applicants for reductions in their patent terms resulting from undue delays by the PTO in patent examination, the Patent Term Guarantee Act provides that patent terms be lengthened by awarding PTA in three specific circumstances. First, "A-Delay" PTA is awarded for delay arising from the PTO's failure to act by certain examination deadlines. *Id.* § 154(b)(1)(A). Second, "B-Delay" PTA is awarded for the amount of time a patent application has been pending in excess of three years. *Id.* § 154(b)(1)(B). Third, "C-Delay" PTA is awarded for delays due to interferences, secrecy orders, and appeals. *Id.* § 154(b)(1)(C).<sup>3</sup>

Prior to the issuance of a patent, the PTO determines whether any PTA delay has accrued and informs the patentee about the length of any term to be restored to the issued patent. The PTO's initial determination of PTA is calculated by a computer program. *See* Manual of Patent Examining Procedure § 2734(I). The patentee can request reconsideration of the PTO's initial PTA determination, in which case the PTO will conduct a manual redetermination of the correct amount of PTA. The patentee can then appeal the PTO's final determination of PTA by filing an action in the United States District Court for the Eastern District of Virginia. *Id.* § 154(b)(4). On appeal, the district court must review the PTO's PTA determination in accordance with the framework governing review of agency action provided by the APA. *Id.* § 154(b)(4)(A).

Pursuant to the APA, a "reviewing court shall . . . 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)(A). In this respect, the reviewing court is limited to

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<sup>3</sup> The Patent Term Guarantee Act further provides that any award of PTA must be reduced by a period of time equal to (i) the extent that periods of A-, B-, and C-Delay overlap in a particular case and (ii) "the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." 35 U.S.C. § 154(b)(2).

examining “whether the agency conformed with controlling statutes, and whether the agency has committed a clear error of judgment.” *Holly Hill Farm Corp. v. United States*, 447 F.3d 258, 263 (4th Cir. 2006) (internal quotation marks omitted). The scope of this review is “narrow,” as “[t]he court is not empowered to substitute its judgment for that of the agency.” *Id.*

In the instant case, plaintiff challenges the PTO’s calculation of PTA only with respect to the amount of A-Delay determined by the PTO. In pertinent part, the Patent Term Guarantee Act and the relevant regulations provide that A-Delay is equal to the period of time (i) beginning on the day after the date that is 14 months after the date of commencement of the national stage under 35 U.S.C. § 371 in an international application and (ii) ending on the date that “one of the notifications under [35 U.S.C. § 132] is mailed by the PTO.” *Id.* § 154(b)(1)(A); 37 C.F.R. § 1.703(a)(1).

Plaintiff advances two arguments to contest the PTO’s calculation of A-Delay PTA with respect to the ’912 Patent. Plaintiff first argues that A-Delay continued to accrue for an additional 99 days after the date calculated by the PTO in its final decision because the first and second restriction requirements issued by the PTO did not constitute a qualifying notification under § 132. Second, plaintiff argues that A-Delay PTA began to accrue 3 days earlier than the date calculated by the PTO in its final decision because it was arbitrary and capricious for the PTO to correct its previous, erroneous calculation of the date on which PTA began to accrue after plaintiff challenged the PTO’s overall PTA determination. Each of these challenges to the PTO’s calculation of A-Delay is addressed in turn below

#### A.

Plaintiff first claims that the PTO erred in concluding that the PTO’s initial restriction requirement stopped the accrual of A-Delay PTA for the ’912 Patent. According to plaintiff, the

PTO's initial restriction requirement failed to satisfy the notice requirement of § 132, and A-Delay thus continued to accrue for another 99 days until the PTO issued the third restriction requirement.

As explained above, A-Delay will stop accruing when the PTO "provide[s] at least one of the notifications under Section 132." 35 U.S.C. § 154(b)(1)(A)(i). Section 132 in turn provides that if the PTO determines that a patent application does not comply with the standards of patentability, the PTO must issue an office action "stating the reasons for such rejection . . . together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application." *Id.* § 132.

The parties here dispute whether the initial restriction requirement issued by the PTO complied with § 132. In this respect, the Federal Circuit has held that a restriction requirement issued by the PTO meets the notice requirement of § 132 if the restriction requirement informs the applicant "of the broad statutory basis for [the rejection of] his claims, so that he may determine what the issues are on which he can or should produce evidence." *Pfizer, Inc. v. Lee*, 811 F.3d 466, 472 (Fed. Cir. 2016) (alteration in original). On the other hand, a restriction requirement violates § 132 when it "is so uninformative that it prevents the applicant from recognizing and seeking to counter the grounds for rejection." *Id.*

The Federal Circuit's analysis in *Pfizer* is instructive on the issue whether the initial restriction requirement in the instant case met the notice requirement of § 132. In *Pfizer*, the Federal Circuit held that the first restriction requirement in that case gave the applicants notice of the reasons for the PTO's restriction requirement, in satisfaction of § 132, because the first restriction requirement in that case (i) asserted that all of the pending claims of the patent application were "subject to restriction and/or election requirement," (ii) defined the invention groups available for election and further prosecution, and (iii) articulated the reasons the PTO

believed the patent application constituted multiple separate and independent inventions. *Id.* at 472–73. Based on those factors, the Federal Circuit in *Pfizer* concluded that the first restriction requirement “provided both the ‘broad statutory basis’ for the examiner’s rejection, namely, that ‘[r]estriction to one of the following inventions [was] required *under 35 U.S.C. § 121*,’ and was sufficiently informative to allow [the applicant] to counter the grounds for rejection,” satisfying the notice requirement of § 132. *Id.* at 473–74 (emphasis in original). Importantly, the fact that the PTO accepted the applicant’s argument that the first restriction requirement omitted certain claims and issued a second restriction requirement did not undermine this conclusion. To the contrary, the Federal Circuit found that the applicant’s success in convincing the PTO to reclassify the claims provided further evidence that the initial restriction requirement was sufficiently informative to enable the applicant to “recognize[] and seek[] to counter the grounds for rejection.” *Id.* at 473.

The Federal Circuit’s holding in *Pfizer* is controlling here and confirms that the first restriction requirement issued by the PTO to Actelion, plaintiff’s predecessor in interest in the ’912 Patent, met the notice requirement of § 132 and thus stopped the accrual of A-Delay PTA. The restriction requirement restricted all of the claims pending in the ’358 Application into six clearly defined, distinct invention groups. Thus, here, as in *Pfizer*, the PTO’s restriction requirement gave Actelion clear notice of the “‘broad statutory basis’ for the examiner’s rejection,” namely that the ’358 Application improperly included multiple distinct inventions in violation of 35 U.S.C. § 121. *Id.* Indeed, the PTO’s first restriction requirement expressly identified § 121 as the statutory provision requiring restriction of the ’358 Application.

In addition, the first restriction requirement issued by the examiner in this case adequately articulated the reasons the examiner concluded the ’358 Application contained six separate



inventions. Specifically, the restriction requirement explained that restriction was necessary because “[t]he inventions of Groups I-VI [were] independent and distinct from each other because they [were] directed to structurally dissimilar compounds that lack[ed] a common core as noted [sic] the various P(O)R<sup>5</sup>R<sup>8</sup>.” AR426. And as already noted, the restriction requirement also described the six invention groups that the examiner believed were included in the ’358 Application. Therefore, here, as in *Pfizer*, the first restriction requirement issued to Actelion “was sufficiently informative to allow [the applicant] to counter the grounds for rejection.” *See Pfizer*, 811 F.3d at 473–74. Indeed, this conclusion finds further support in the fact that here, as in *Pfizer*, Actelion was in fact able to respond to the restriction requirement and oppose the PTO’s description of the various invention groups, which confirms that Actelion was able to understand the proposed groups of the restriction requirement and to craft arguments in response against such groups. *See id.* at 473 (holding that the applicant’s “success in convincing the examiner to reclassify one of the omitted claims after the issuance of the correction further evidences that the initial restriction requirement . . . was not so uninformative that it prevent[ed] the applicant from recognizing and seeking to counter the grounds for rejection.”) (internal quotation marks omitted; alteration in original).

Accordingly, the initial restriction requirement issued to Actelion by the PTO met the notice requirement of § 132 because the restriction requirement “provided both the ‘broad statutory basis’ for the examiner’s rejection, namely, that ‘[r]estriction to one of the following inventions [was] required *under 35 U.S.C. § 121*,’ and was sufficiently informative to allow [the applicant] to counter the grounds for rejection.” *Id.* at 473–74 (emphasis in original). The PTO was therefore

correct to conclude that the accrual of A-Delay ceased on March 14, 2012, the date that the PTO mailed the initial restriction requirement to Actelion.<sup>4</sup>

Seeking to avoid this conclusion, plaintiff argues that the first restriction requirement was not sufficiently informative because the restriction requirement did not include certain claimed subject matter of the invention in any of the six invention groups described in the restriction requirement. This asserted deficiency, according to plaintiff, prevented Actelion from electing for prosecution one of the invention groups because none of the six invention groups defined in the restriction requirement covered the scope of the invention that Actelion wished to elect.

This argument fails because a restriction requirement does not violate § 132 simply because the restriction requirement is erroneous or incomplete. *See Univ. of Massachusetts v. Kappos*, 903 F. Supp. 2d 77, 86 (D.D.C. 2012) (“The statute does not require that the first Office action be correct. The statute does not require that the first Office action ultimately stand, either completely unaltered or with only minor tweaks.”). Rather, the notice requirement of § 132 requires a restriction requirement to provide the broad statutory basis for the examiner’s rejection and to be sufficiently informative to allow the applicant to counter the grounds for rejection. *Pfizer*, 811 F.3d at 473–74. Indeed, as the Federal Circuit observed in *Pfizer*, the “purpose of PTA is to compensate patent applicants for *certain reductions* in patent term that are not the fault of the applicant, not to guarantee the correctness of the agency’s every decision.” *Id.* at 476 (quoting *UMass*, 903 F. Supp. 2d at 86) (emphasis in original; internal quotation marks omitted). Here, for the reasons already stated, the first restriction requirement provided Actelion with the notice required under § 132.

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<sup>4</sup> It is worth noting that plaintiff contends that the second restriction requirement suffers from the same alleged deficiency as the first restriction requirement, namely that it too failed to give Actelion the requisite notice under § 132. Because it is decided here that the first restriction requirement constituted a notification under § 132 and thus stopped the accrual of A-Delay, it is unnecessary to consider whether the second restriction requirement issued by the PTO satisfied the notice requirement under § 132.

Although the issuance of the patent may have been further delayed by the PTO's subsequent modification of the restriction requirement, undertaken at the request of the applicant, the Federal Circuit's holding in *Pfizer* makes clear that such delay is not the sort that is entitled to A-Delay PTA. Rather, an applicant and examiner's exchange concerning the correctness or completeness of the restriction requirement after the issuance of the restriction requirement constitutes the "typical 'back and forth' process of patent prosecution" and is not entitled to PTA. *Id.* at 475–76. Thus, plaintiff's argument that the first restriction requirement violated § 132 fails. Accordingly, the PTO's determination of the date on which A-Delay ceased to accrue for the '912 Patent is upheld as correct.

## B.

Plaintiff next claims that it was arbitrary and capricious for the PTO to correct its computer program's previous, erroneous calculation of the date on which A-Delay PTA began to accrue. According to plaintiff, plaintiff is entitled to the benefit of the earlier, incorrect determination calculated by the computer program and must therefore be awarded three additional days of A-Delay PTA.

As explained above, A-Delay PTA begins to accrue for an international application on the day after the date that is fourteen months after the date of commencement of the national stage under 35 U.S.C. § 371. *See* 35 U.S.C. § 154(b)(1)(A)(i)(II). Section 371 of the Patent Act provides, in relevant part, that "the national stage shall commence with the expiration of the applicable time limit under article 22(1) . . . of the [Patent Cooperation Treaty]." 35 U.S.C. § 371(b). The time limit provided by Article 22(1) of the Patent Cooperation Treaty ("PCT")<sup>5</sup> that is pertinent here is

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<sup>5</sup> The PCT, which the United States has ratified, provides standardized means by which inventors may seek protection for their inventions in multiple member nations by filing a single international application in any member nation. *See* PCT, Preamble, Art. 3 (2002).

that an international patent applicant “shall furnish a copy of the international application . . . and pay the national fee . . . to each designated Office not later than at the expiration of 30 months from the priority date.” PCT Art. 22(1) (2002). Importantly, regulations under the PCT adopted by member countries explain that if the expiration of a time period falls on a day on which the office is closed, on which ordinary mail is not delivered, or that is an official holiday in that country, “the period shall expire on the next subsequent day” that is a business day. Regulations under the PCT, R. 80.5.<sup>6</sup> Thus, if the date that is 30 months from the international priority date falls on a weekend or federal holiday, the national stage will not commence in the United States until “the next workday after the 30-month date that fell on a federal holiday.” *Actelion Pharm., Ltd. v. Matal*, 881 F.3d 1339, 1346 (Fed. Cir. 2018).

These authorities confirm that the national stage for the '358 Application commenced on June 1, 2010. The date that was 30 months after the '358 Application's international priority date, November 29, 2007, fell on May 29, 2010, which was a Saturday. And the following Monday, May 31, 2010 was Memorial Day, which was a federal holiday. Thus, consistent with *Actelion Pharm.*, 881 F.3d at 1346, the PTO correctly determined that the national stage commenced in the United States for the '358 Application on “the next workday after the 30-month date,” namely Tuesday, June 1, 2010, and that A-Delay PTA accordingly began to accrue the day after the date that is 14 months after June 1, 2010, *i.e.* on August 2, 2011.

Plaintiff does not contest that the PTO's final decision correctly determined the dates on which the national stage commenced and on which A-Delay began to accrue for the '358 Application. Instead, plaintiff argues that the PTO acted arbitrarily and capriciously by correcting

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<sup>6</sup> See also 35 U.S.C. § 21(b) (“When the day, or the last day, for taking any action or paying any fee in the [USPTO] falls on Saturday, Sunday, or a federal holiday . . . , the action may be taken, or the fee paid, on the next succeeding secular or business day.”).

the PTO's previous determination of the date on which A-Delay began to accrue, *i.e.* July 31, 2011, which was calculated by a computer program, to a later date, August 2, 2011, after plaintiff brought its challenge to the PTO's PTA determination.<sup>7</sup> This argument is entirely without merit; it is well-settled that "federal agencies, including the USPTO, have broad authority to correct their prior errors." *Last Best Beef, LLC v. Dudas*, 506 F.3d 333, 340 (4th Cir. 2007). It is of no consequence that the PTO corrected the computer program's erroneous determination that A-Delay PTA began to accrue three days earlier after plaintiff initiated its challenge to the PTO's overall PTA calculation.<sup>8</sup> To the contrary, the entire purpose of the PTA reconsideration procedure is to allow the PTO to review and correct its previous PTA determinations, including PTA determinations made by the PTO's computer programs. *See* 37 C.F.R. § 1.705.<sup>9</sup> Accordingly, plaintiff's remarkable claim that it should be awarded 3 additional days of PTA in accordance with the computer program's erroneous calculations, corrected by the PTO on reconsideration, fails.

### C.

In sum, for the reasons stated above, the PTO's determinations regarding the dates upon which A-Delay PTA began to accrue, August 2, 2011, and ceased to accrue, March 14, 2012, for

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<sup>7</sup> It appears that the initial A-Delay PTA calculation made by the PTO's computer program failed to take into account that the date that was 30 months after the '358 Application's international priority date fell on a Saturday and that the following Monday was a federal holiday. For the reasons already explained, the PTO, on reconsideration of the overall PTA determination, correctly recognized that the appropriate date of national stage commencement for the '358 Application was June 1, 2010. Thus, A-Delay PTA began to accrue on August 2, 2011, three days later than the accrual date calculated by the computer program.

<sup>8</sup> Plaintiff attempts to characterize the PTO's correction of the determination of the date upon which A-Delay PTA began to accrue as "punishing" plaintiff for seeking reconsideration of the PTA's calculation. But plaintiff has cited absolutely no evidence to support its accusation that the PTO's intent in correcting its prior, erroneous calculation was to retaliate against plaintiff rather than merely to review the accuracy of the overall PTA determination at plaintiff's invitation.

<sup>9</sup> Indeed, MPEP § 2734(I) explicitly warns patent applicants that due to the complexity of the patent term adjustment provisions under § 154(b), "a manual redetermination of patent term adjustment could result in (1) an amount of patent term adjustment that is the amount of patent term adjustment requested by the applicant; (2) the same amount of patent term adjustment as indicated in the patent (*i.e.*, there being no change); or (3) a different amount of patent term adjustment that may be higher or lower than the patent term adjustment as indicated in the patent."

the '912 Patent "conformed with controlling statutes" and do not represent "a clear error of judgment" by the PTO. *See Holly Hill*, 447 F.3d at 263. Accordingly, the PTO's calculation of the term of A-Delay PTA to which the '912 Patent is entitled, totaling 226 days, must be upheld, and plaintiff's claims brought pursuant to § 154(b)(4)(A) and the APA fail.

### III.

In addition to its challenge to the PTO's PTA determination under § 154(b)(4)(A) and the APA, plaintiff also claims that the PTO's refusal to grant plaintiff the statutorily mandated term for the '912 Patent constitutes an unconstitutional taking without just compensation in violation of the Takings Clause of the Fifth Amendment. U.S. CONST. amend. V. This argument fails. For the reasons already stated, *supra* part II, the PTO's final PTA determination (i) granted plaintiff the correctly adjusted patent term for the '912 Patent under 35 U.S.C. § 154 (ii) and did not constitute an arbitrary or capricious reduction in the term of the '912 Patent. Accordingly, plaintiff's Fifth Amendment claim fails for the same reasons as plaintiff's challenges to the PTO's PTA determination brought under § 154(b)(4)(A) and the APA.<sup>10</sup>

An appropriate order will issue.

Alexandria, Virginia  
July 22, 2019

  
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T. S. Ellis, III  
United States District Judge

<sup>10</sup> In addition, courts have sensibly expressed doubt whether the failure to award PTA to a patentee constitutes the taking of property that is cognizable under the Takings Clause. *See, e.g., Actelion Pharm. Ltd. v. Kappas*, 972 F. Supp. 2d 51, 54 (D.D.C. 2013), *aff'd sub nom., Actelion Pharm., Ltd. v. Lee*, 565 F. App'x 887 (Fed. Cir. 2014) (summarily dismissing as meritless the plaintiff's claim that the PTO's failure to correct its PTA was a "taking" of property "because plaintiff has proffered no legal support for the proposition that a patent term is a constitutionally protected property interest"); *see also Maass v. Lee*, 189 F. Supp. 3d 581, 586 (E.D. Va. 2016) ("Plaintiff's argument that the application of § 154(b) amounts to an unconstitutional taking also misses the mark, as the congressional choice not to award B-Delay for time consumed by requests for continued examination is not a taking of property, but rather a decision not to award additional property rights.").