

**United States Court of Appeals  
for the Federal Circuit**

---

**SUPERMUS PHARMACEUTICALS, INC., UNITED  
THERAPEUTICS CORPORATION,**  
*Plaintiffs-Appellants*

**v.**

**ANDREI IANCU, UNDER SECRETARY OF  
COMMERCE FOR INTELLECTUAL PROPERTY  
AND DIRECTOR OF THE UNITED STATES  
PATENT AND TRADEMARK OFFICE,**  
*Defendant-Appellee*

---

2017-1357

---

Appeal from the United States District Court for the  
Eastern District of Virginia in No. 1:16-cv-00342-GBL-  
IDD, Judge Gerald Bruce Lee.

---

Decided: January 23, 2019

---

DOUGLAS H. CARSTEN, Wilson, Sonsini, Goodrich &  
Rosati, PC, San Diego, CA, argued for plaintiffs-  
appellants. Also represented by VERONICA SUSANA  
ASCARRUNZ, ADAM WILLIAM BURROWBRIDGE, Washington,  
DC.

SHAUN R. SNADER, United Therapeutics Corporation, Washington, DC, for plaintiff-appellant United Therapeutics Corporation.

R. TRENT MCCOTTER, Office of the United States Attorney for the Eastern District of Virginia, Alexandria, VA, argued for defendant-appellee Andrei Iancu. Also represented by KAKOLI CAPRIHAN, BRIAN RACILLA, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA.

---

Before DYK, SCHALL, and REYNA, *Circuit Judges*.

REYNA, *Circuit Judge*.

Supernus Pharmaceuticals, Inc. and United Therapeutics Corp. appeal the entry of summary judgment by the U.S. District Court for the Eastern District of Virginia. The district court determined that, based on this court's decision in *Gilead Sciences, Inc. v. Lee*, the U.S. Patent and Trademark Office's calculation of the patent term adjustment for the patent at issue was correct, and that summary judgment was warranted as a matter of law. We reverse the district court's grant of summary judgment because the patent term adjustment in this case went beyond the period during which the applicant failed to undertake reasonable efforts and thereby exceeded the limitations set by the patent term adjustment statute.

## BACKGROUND

### I.

The life of a patent, the period of time during which the exclusive nature of a patent is in effect, is measured in years and days and is referred to as the "term" of the patent or "patent term." Prior to June 8, 1995, the term of a patent was seventeen years, measured from the date that the patent issued to its expiration date seventeen

years later. *See Merck & Co. v. Kessler*, 80 F.3d 1543, 1547 (Fed. Cir. 1996).

When the United States entered the World Trade Organization, it assumed certain obligations and commitments under the terms of the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights. *See Agreement on Trade-Related Aspects of Intellectual Property Rights*, 33 I.L.M. 1197 (1994). As a result, Congress changed the patent term from seventeen years to twenty years, measured from the filing date of the earliest United States non-provisional application for the patent. *See Pub. L. No. 103-465*, § 532, 108 Stat. 4809, 4984 (1994) (codified at 35 U.S.C. § 154(a)(2)).

In addition to extending the patent term from seventeen years to twenty years, Congress passed the patent term adjustment (“PTA”) statute in 1999 in an effort to discourage delay in the patent application process. *See Pub. L. No. 106-113*, § 1000(a)(9), 113 Stat. 1501, 1536 (1999) (codified at 35 U.S.C. § 154(b)). Specifically, § 154(b) grants the U.S. Patent and Trademark Office (“USPTO”) authority to adjust the patent term by adding days to account for delays caused by the USPTO. *See id.* §§ 154(b)(1)(A)–(C). Such adjustments are favorable to an applicant because they extend the life of the patent. But the USPTO may also reduce the PTA in order to account for delays caused by the applicant. *Id.* § 154(b)(2); *see, e.g., Gilead Scis., Inc. v. Lee*, 778 F.3d 1341, 1343–45 (Fed. Cir. 2015).

Section 154(b)(1) outlines three types of delays caused by the USPTO, known as Types A, B, and C, that can result in a PTA. Adjustments for a Type A delay apply when the USPTO fails to provide a notification under 35 U.S.C. § 132 or a notice of allowance within fourteen months of an application’s filing. 35 U.S.C. § 154(b)(1)(A)(i). The statute provides that “the term of

the patent shall be extended 1 day for each day” the USPTO does not meet its response deadlines. *Id.* § 154(b)(1)(A). Similarly, Type B adjustments extend the patent term by one day for every day that the USPTO fails to issue a patent after three years have passed between the filing date of the application and the date of allowance. *Id.* § 154(b)(1)(B). Finally, Type C adjustments are for delays that are excluded from the Type B delay due to derivation proceedings, secrecy orders, or successful appeals. *Id.* § 154(b)(1)(C).

As noted above, the statute recognizes that conduct by the applicant may also cause delay in the examination or prosecution of the application. Section 154(b)(2)(C) authorizes the USPTO to reduce the total amount of PTA for Type A, B, and C delays by deducting the number of days equal to the period of time that “the applicant failed to engage in reasonable efforts to conclude prosecution of the application.” *Id.* § 154(b)(2)(C)(i). An applicant is deemed to have failed to engage in reasonable efforts for the cumulative time in excess of three months that the applicant takes to respond to a notice of rejection, objection, argument, or other request from the USPTO. *Id.* § 154(b)(2)(C)(ii). The statute provides that the Director of the USPTO “shall prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.” *Id.* § 154(b)(2)(C)(iii).

The Director of the USPTO has promulgated such regulations: 37 C.F.R. § 1.704, titled “Reduction of period of adjustment of patent term.” 37 C.F.R. § 1.704 (2015). Relevant here is § 1.704(c)(8), which regulates the calculation for reduction of PTA in instances where the applicant submits a supplemental paper to the USPTO. Section 1.704(c)(8) provides:

Submission of a supplemental reply or other paper, other than a supplemental reply or other pa-

per expressly requested by the examiner, after a reply has been filed, in which case the period of adjustment set forth in § 1.703 [that extends the patent's term due to USPTO delay] shall be reduced by the number of days, if any, beginning on the day after the date the initial reply was filed and ending on the date that the supplemental reply or other such paper was filed . . . .

*Id.*

The USPTO has also promulgated regulations that permit an applicant to file an information disclosure statement (“IDS”) up to the end of the patent examination process, while providing incentives for an applicant to submit any necessary IDS promptly. *Id.* §§ 1.97(a)–(d). As relevant here, the USPTO will accept without condition an IDS that is filed before notice of the first office action after the applicant has filed a request for continued examination (“RCE”). *Id.* § 1.97(b)(4). Also relevant here, when an applicant submits an IDS disclosing a communication from a foreign patent office, there is a thirty-day safe harbor that exempts reduction of PTAs under § 1.704(c)(8), provided that the IDS is submitted within thirty days of the applicant receiving the information from the foreign patent office that is eventually contained in the IDS.<sup>1</sup> *Id.* § 1.704(d)(1).

---

<sup>1</sup> There are various requirements that apply to a submission of an IDS that are independent of the PTA. For example, during prosecution, the applicant generally has a duty of candor and good faith that includes a duty to disclose all information known to the applicant to be material to the patentability of the claims. *See* 37 C.F.R. § 1.56(a). Specifically, applicants are encouraged to “carefully examine” prior art cited in search reports of a

## II.

The relevant facts in this case are not in dispute. Appellant Supernus Pharmaceuticals, Inc. (“Supernus”) is the owner and assignee of the patent at issue, U.S. Patent No. 8,747,897 (“the ’897 patent”), titled “Osmotic Drug Delivery System.” Co-Appellant United Therapeutics Corp. (“UTC”) is the exclusive licensee of the ’897 patent. UTC assisted in the prosecution of the patent application and took action as the applicant in that capacity. Supernus and UTC are collectively referred to herein as “Supernus.”

On April 27, 2006, Supernus filed U.S. Patent Application No. 11/412,100 (“the ’100 application”). On August 20, 2010, the USPTO issued a final rejection. On February 22, 2011, Supernus filed an RCE, which removed the finality of the rejection and permitted the examiner to consider additional information submitted by Supernus. 35 U.S.C. § 132(b); 37 C.F.R. § 1.114. The ’100 application issued on June 10, 2014, as the ’897 patent.

On the same day it filed the ’100 application, Supernus filed international application PCT/US2007/009969, claiming priority from the ’100 application. The international application gave rise to European Application No. 07755989.6. On October 13, 2011, the European Patent Office (“EPO”) issued the European application as European Patent EP2010189 (“the EP patent”). On August 21, 2012, the EPO notified Supernus’s European patent counsel that a Notice of Opposition was filed by Sandoz

---

foreign patent office in a counterpart application “to make sure that any material information contained therein is disclosed” to the USPTO. *Id.* Such disclosure can be submitted in the form of an IDS. *See id.* § 1.98.

AG to the EP patent, citing 10 documents (“the Sandoz Opposition”).

On September 11, 2012, Supernus received a letter from its European patent counsel disclosing the EPO notification and the Sandoz Opposition. Seventy-nine days later, or 100 days from the EPO notification of the Sandoz Opposition, Supernus submitted a supplemental IDS on November 29, 2012, informing the USPTO of the Sandoz Opposition and providing the documents cited in the Sandoz Opposition, the Sandoz Opposition itself, the EPO notification, and the letter from Supernus’s European patent counsel.<sup>2</sup>

On September 10, 2013, the USPTO issued a first Office Action responding to Supernus’s RCE. On January 10, 2014, Supernus filed a response. On February 4, 2014, the USPTO issued a Notice of Allowance. On June 10, 2014, the USPTO issued the ’897 patent, reflecting a PTA of 1,260 days, meaning that the USPTO had added 1,260 days to the patent’s twenty-year term.

In calculating the PTA, the USPTO attributed 2,321 days to USPTO delay: 1,656 days for Type A delays (for the USPTO’s failure to meet the mandated statutory response deadlines), and 665 days for Type B delays (for the USPTO’s failure to issue the patent within three years of the application’s filing date). *See* J.A. 80. Next, the USPTO reduced the PTA of 2,321 days by 175 days to account for overlapping Type A and Type B delays, and by 886 days for applicant delay to arrive at the total 1,260-day PTA. Relevant here, of the 886 days attributed to applicant delay, 646 days were assessed for the period

---

<sup>2</sup> Supernus did not attempt to invoke the protections of the thirty-day safe harbor established by 37 C.F.R. § 1.704(d)(1).

between the February 22, 2011 filing of the RCE and the November 29, 2012 submission of the IDS. This appeal focuses on this 646-day reduction in the PTA due to purported applicant delay.

Supernus filed a request for Reconsideration of Patent Term Adjustment on grounds that the deduction of the 646-day period was improper.<sup>3</sup> Supernus argued that “37 C.F.R. § 1.704(c)(8) does not govern post-RCE submissions.” J.A. 510–11. According to Supernus, another regulation—37 C.F.R. § 1.704(c)(6)—should apply instead.

The USPTO rejected the request for reconsideration. The USPTO determined that under this court’s decision in *Gilead*, submission of an IDS after the filing of a response to an election or restriction requirement is subject to a reduction under 37 C.F.R. § 1.704(c)(8) because any relevant information submitted to the USPTO after an initial reply interferes with the USPTO’s ability to process an application. J.A. 521. The USPTO found that “[t]he same analysis applies to submission of an IDS document after the filing of an RCE” because “[a]ny IDS submission by [a] patentee after the filing of a[n] RCE ‘interferes’ with the [USPTO’s ability] to process an application because the examiner may be forced to go back and review the application again.” *Id.* The USPTO concluded that 37 C.F.R. § 1.704(c)(8) applies and that the reduction of

---

<sup>3</sup> Supernus also argued that the USPTO erred in deducting 126 days from the PTA for the period between the time of allowance and the time of issuance, following this court’s then recent decision in *Novartis AG v. Lee*, 740 F.3d 593, 602 (Fed. Cir. 2014) (holding that the time between allowance and issuance may not be reduced from the PTA). The USPTO agreed and awarded the 126 days to Supernus, which brought the final total PTA of the ’897 patent to 1,386 days.

the PTA by the 646 days due to applicant delay was proper.

Supernus appealed to the U.S. District Court for the Eastern District of Virginia and filed a motion for summary judgment on the grounds that 37 C.F.R. § 1.704(c)(8) is arbitrary, capricious, and contrary to the PTA statute. *Supernus Pharm., Inc. v. Lee*, No. 1:16-CV-00342, 2016 WL 8739331, at \*4 (E.D. Va. Oct. 18, 2016). Supernus also argued that 37 C.F.R. § 1.704(d)(1) is similarly arbitrary and capricious, and contrary to the PTA statute. *Id.* at \*6. Finally, Supernus argued that out of the 646-day period that the USPTO attributed to applicant delay, it was entitled to at least 546 of those days—i.e., the period between its filing of the RCE and the EPO notification of the Sandoz Opposition.<sup>4</sup> *Id.* The USPTO filed an opposition and cross-motion for summary judgment. *Id.* at \*2.

The district court granted summary judgment in favor of the USPTO. *Id.* at \*8. The district court concluded that the USPTO did not err in the PTA calculation for the '897 patent and that this court's decision in *Gilead* foreclosed, as a matter of law, Supernus's statutory interpretation arguments that 37 C.F.R. § 1.704(c)(8) and § 1.704(d)(1) are arbitrary, capricious, and otherwise contrary to the PTA statute. *Id.* at \*4–8 (citing *Gilead*, 778 F.3d at 1350).

---

<sup>4</sup> Supernus concedes that it failed to engage in “reasonable efforts” for the remaining 100 days of the 646-day period: from the EPO notification to Supernus's submission of the supplemental IDS. Appellant Reply Br. 2. On appeal, Supernus only challenges the USPTO's assessment of the preceding 546 days as applicant delay. Appellant Br. 59.

Supernus timely filed this appeal. We have jurisdiction pursuant to 28 U.S.C. §§ 1295(a)(1), 1295(a)(4)(C) (2012).

## DISCUSSION

### I. Standard of Review

This court reviews a district court's grant of summary judgment under the law of the regional circuit, in this case, the Fourth Circuit. *See Mohsenzadeh v. Lee*, 790 F.3d 1377, 1381 (Fed. Cir. 2015); *Charles Mach. Works, Inc. v. Vermeer Mfg. Co.*, 723 F.3d 1376, 1378 (Fed. Cir. 2013). Applying the law of the Fourth Circuit, we review the grant of summary judgment de novo. *Gallagher v. Reliance Standard Life Ins. Co.*, 305 F.3d 264, 268 (4th Cir. 2002). Patent term adjustment decisions of the USPTO are reviewed in accordance with the Administrative Procedure Act ("APA"). 35 U.S.C. § 154(b)(4)(A); *Gilead*, 778 F.3d at 1346. Under the APA, a court should set aside the USPTO's actions if found to be "in excess of statutory jurisdiction, authority, or limitations," or "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. §§ 706(2)(A), (C); *Gilead*, 778 F.3d at 1346. When reviewing an agency's statutory interpretation, this court applies the two-step framework established in *Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984). *See Gilead*, 778 F.3d at 1346.

### II. *Gilead*

As a preliminary issue, we note that this court has grappled with the reasonableness of 37 C.F.R. § 1.704(c)(8), a regulation asserted in this appeal by the USPTO. In *Gilead*, this court held that the regulation "is a reasonable interpretation of the [PTA] statute" insofar as it includes "not only applicant conduct or behavior that result in actual delay, but also those having the potential to result in delay irrespective of whether such delay

actually occurred.” *Gilead*, 778 F.3d at 1349–50. This court also acknowledged that § 1.704(c)(8) encompasses the filing of a supplemental IDS in the calculated delay period. *Id.* at 1349.

In *Gilead*, the patent owner Gilead brought an action challenging the USPTO’s assessment of a 57-day applicant delay in calculating PTA deduction, based on Gilead’s delay during examination between its initial reply to a restriction requirement and its submission of a supplemental IDS disclosing two other co-pending Gilead patent applications. *Id.* at 1345–46. The district court granted summary judgment in favor of the USPTO, and we affirmed. *Id.* at 1346, 1350–51. Engaging in the *Chevron* analysis, this court concluded that Congress did not address the precise question at issue, *i.e.*, “whether a failure to engage in reasonable efforts requires conduct that actually causes delay,” and that Congress expressly delegated authority to the USPTO to prescribe regulations establishing circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude examination. *See id.* at 1349–50. At step two of *Chevron*, we recognized that we give deference to the agency where Congress explicitly left a gap to fill and held that a reasonable interpretation of the PTA statute was that “Congress intended to sanction not only applicant conduct or behavior that result in actual delay, but also those having the potential to result in delay irrespective of whether such delay actually occurred.” *Id.* Thus, the resultant regulation, 37 C.F.R. § 1.704(c)(8), was reasonable insofar as it included both potential and actual delay. *Id.*

We conclude that *Gilead* does not foreclose Supernus’s statutory interpretation argument. Supernus’s argument is that any reduction in PTA may not exceed the “time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.” 35 U.S.C. § 154(b)(2)(C)(i). *Gilead* ruled only that the regulation reasonably drew no line between actual and poten-

tial delay and could include a supplemental IDS. It did not hold the regulation was reasonable in reducing PTA for periods during which there was no failure to engage in reasonable efforts to conclude prosecution. *Gilead* simply did not address the precondition—failure to engage in reasonable efforts—at issue here.

In *Gilead*, Appellant Gilead had two other co-pending patent applications that it disclosed in the supplemental IDS. Gilead could have submitted the supplemental IDS disclosing its co-pending applications when it filed its response to the restriction requirement. *Gilead*, therefore, involved a period of time during which the applicant could have taken identifiable efforts to conclude prosecution but did not. *Gilead* focused on whether the statute required the applicant's failure to take reasonable efforts to have resulted in actual delay, as opposed to the potential to cause delay, to count towards reduction of PTA.

In contrast, this case is not about whether efforts taken by Supernus, or those it could have taken, resulted in actual or potential delay. Supernus contends, and the USPTO does not dispute, that Supernus could not have undertaken any efforts to conclude prosecution of the '100 application during the 546-day period between the filing of the RCE on February 22, 2011, and the EPO's notification of the Sandoz Opposition on August 21, 2012. J.A. 552–53; Appellant Br. 7 n.3; Appellee Br. 16–17.

In addition, the precise question addressed in *Gilead* was not the precise question under review in this case. In *Gilead*, the “precise question” reviewed by the court in its *Chevron* analysis was “whether a failure to engage in reasonable efforts requires conduct that actually causes delay.” *Gilead*, 778 F.3d at 1349. That question fell within the USPTO's gap-filling authority to determine what constitutes “reasonable efforts.” *Id.*; 35 U.S.C. § 154(b)(2)(C)(iii). The precise question in this case is whether the USPTO may reduce PTA by a period that

exceeds the “time during which the applicant failed to engage in reasonable efforts to conclude prosecution.” 35 U.S.C. § 154(b)(2)(C)(i). *Gilead* did not decide that question.

Because *Gilead* involved different facts and a different legal question, *Gilead* is not controlling in this action. *Cf. Fed. Election Comm’n v. Wis. Right To Life, Inc.*, 551 U.S. 449, 456, 467 (2007) (Roberts, C.J., writing in non-majority section of the opinion of the Court) (noting that upholding a facial challenge to a statute does not foreclose all future challenges to the statute in the particular circumstances of another case). The district court erred, therefore, when it granted the USPTO summary judgment on the basis of this court’s decision in *Gilead*. And because, as we next conclude, the statute plainly resolves the question at issue here against the USPTO, we reverse the district court’s grant of summary judgment.

### III. *Chevron* Framework

#### A. The PTA Statute Answers the Precise Question

This case presents a question of statutory interpretation by an agency to which we apply the *Chevron* framework. The first step of our legal analysis, therefore, is to “ask whether the statute’s plain terms ‘directly address[ ] the precise question at issue.’” *Nat’l Cable & Telecomms. Ass’n v. Brand X Internet Servs.*, 545 U.S. 967, 986 (2005) (quoting *Chevron*, 467 U.S. at 843). The precise question at issue in this case is whether the USPTO may reduce PTA by a period that exceeds the “time during which the applicant failed to engage in reasonable efforts to conclude prosecution.” 35 U.S.C. § 154(b)(2)(C)(i).

We begin by looking at the plain language of the PTA statute. *See United States v. Hohri*, 482 U.S. 64, 69 (1987) (“[T]he ‘starting point in every case involving construction of a statute is the language itself.’” (quoting *Kelly v. Robinson*, 479 U.S. 36, 43 (1986))); *Suprema, Inc.*

*v. Int'l Trade Comm'n*, 796 F.3d 1338, 1346 (Fed. Cir. 2015) (en banc) (“*Chevron*’s framework begins with the language of the statute.”). “Absent a clearly expressed legislative intention to the contrary, [the statute’s plain] language must ordinarily be regarded as conclusive.” *Consumer Prod. Safety Comm’n v. GTE Sylvania, Inc.*, 447 U.S. 102, 108 (1980).

In this case, the pertinent language of the PTA statute is plain, clear, and conclusive. “Congress has supplied a clear and unambiguous answer to the interpretive question at hand.” *Pereira v. Sessions*, 138 S. Ct. 2105, 2113 (2018); *see also Chevron*, 467 U.S. at 842–43 (“If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.”) On the basis of the plain language of the statute, we hold that the USPTO may not count as applicant delay a period of time during which there was no action that the applicant could take to conclude prosecution of the patent. Doing so would exceed the time during which the applicant failed to engage in reasonable efforts.

The PTA statute provides in pertinent part:

(b) Adjustment of patent term.—

....

(2) Limitations.—

....

(C) Reduction of period of adjustment.—

(i) The period of adjustment of the term of a patent under paragraph (1) shall be reduced by a period ***equal to*** 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)(C)(i) (emphases added).

A plain reading of the statute shows that Congress imposed two limitations on the amount of time that the USPTO can use as applicant delay for purposes of reducing PTA. First, the statute expressly requires that any reduction to PTA **be equal** to the period of time during which an applicant fails to engage in reasonable efforts. Second, the statute expressly ties reduction of the PTA to the specific time period **during which** the applicant failed to engage in reasonable efforts.

The PTA statute requires that any PTA reduction be **equal to** the period of time during which an applicant fails to engage in reasonable efforts. The word “equal” is widely understood to mean “the same in amount, number, or size.” *E.g., Equal*, Cambridge Dictionary of American English 287 (2000). Stated differently, PTA reduction cannot exceed the period of time during which an applicant failed to engage in reasonable efforts. Thus, if there is no period of time **during which** the applicant could have but failed to engage in reasonable efforts, there can be no reduction to the PTA. The word “during” is similarly understood to mean “from the beginning to the end of (a particular period)” or “at some time between the beginning and the end of (a period).” *E.g., During*, Cambridge Dictionary of American English 267 (2000). The preceding “shall” “generally imposes a nondiscretionary duty.” *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1354 (2018); *see also Kingdomware Techs., Inc. v. United States*, 136 S. Ct. 1969, 1977 (2016) (discussing that “shall” is mandatory and connotes a requirement). Thus, the statutory period of PTA reduction must be the same number of days as the period from the beginning to the end of the applicant’s failure to engage in reasonable efforts to conclude prosecution. PTA cannot be reduced by a period of time during which there is no identifiable effort in which the applicant could have engaged to conclude prosecution because such time would not be “equal to” and would instead exceed the time during which an applicant failed to engage in rea-

sonable efforts. This is consistent with the PTA extensions of “1 day for each day” granted for the A, B, and C types of USPTO delays.

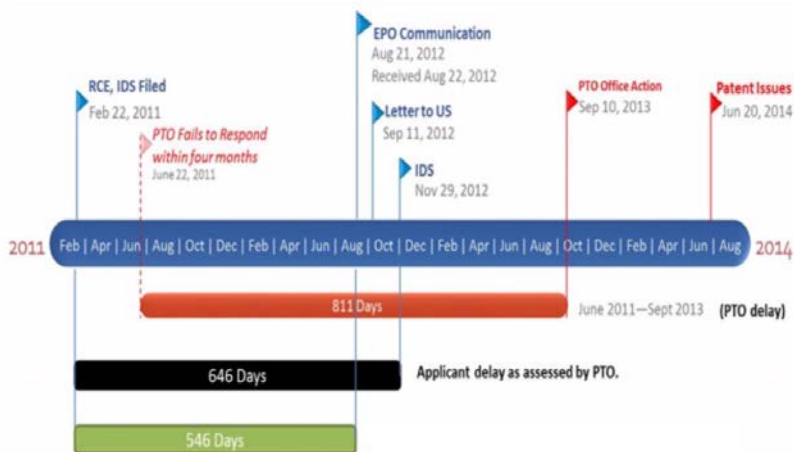
The “equal to” limitation ensures that applicants will be charged the full amount of time corresponding to their own delay. *See Gilead*, 778 F.3d at 1348–49 (“[I]t appears Congress’s primary intent was to penalize applicant *conduct* as opposed to the results of such conduct.”). By the same token, the “equal to” limitation protects applicants by ensuring that PTA can only be reduced by periods of time during which the applicant failed to engage in such efforts. *See id.* at 1344 (“[B]ecause the duration of a patent is no longer solely predicated on its date of issuance, delays in the patent examination process decrease the length of an applicant’s patent term.”); H.R. Rep. No. 106-287, pt. 1, at 50 (1999) (“[N]o patent applicant diligently seeking to obtain a patent will receive a term of less than the 17 years as provided under the pre-GATT standard.” (footnote omitted)). The expressed legislative intent is consistent with the plain language of the statute. The USPTO cannot, therefore, count as applicant delay any period of time during which there were no efforts in which the applicant could have engaged to conclude prosecution of the patent. *See SAS Inst.*, 138 S. Ct. at 1355 (“Where a statute’s language carries a plain meaning, the duty of an administrative agency is to follow its commands as written, not to supplant those commands with others it may prefer.”).

A period of time including no identifiable efforts that could have been undertaken cannot be “equal to” the period of failure to undertake reasonable efforts under the terms of the statute. To conclude otherwise renders the PTA statute’s “reasonable efforts” language superfluous. This understanding of the plain language makes practical sense and is consistent with the legislative history because Congress intended the PTA statute to discourage dilatory conduct by patent applicants and reward appli-

cants that take action to conclude prosecution of the patent. *See* H.R. Rep. 106-287, at 49–50.

**B. The USPTO’s Assessment of Applicant Delay is Inconsistent with the PTA Statute**

As shown in the figure below, the USPTO reduced the PTA by 646 days due to applicant delay. Supernus concedes that it failed to engage in “reasonable efforts” for the last 100 days of the 646-day period. It states, however, that there was nothing it could have done during the period of time from the filing of the RCE and original IDS to the EPO communication.



Appellant Br. 8 (reproduced and modified).

We agree with Supernus that there were no efforts that it could have taken in the period of time during the preceding 546 days. The record is silent as to what Supernus could have done to conclude prosecution during the 546-day time period, beginning with the filing of the RCE/IDS on February 22, 2011, and ending on the date of the EPO notification, August 21, 2012. Nor does the USPTO contend that Supernus could have undertaken any “reasonable efforts” during the 546-day time period to conclude prosecution. To the contrary, the facts indicate

that there was no action Supernus could have taken to advance prosecution of the patent during the 546-day period, particularly because the EPO notice of opposition did not yet exist. Here, the USPTO's interpretation of the statute would unfairly penalize applicants, fail to incentivize applicants not to delay, and fail to protect applicants' full patent terms. The USPTO's additional 546-day assessment as applicant delay is contrary to the plain meaning of the statute because the 646-day total reduction is not ***equal to*** a period of time ***during which*** Supernus failed to engage in reasonable efforts to conclude prosecution of the '897 patent. The USPTO's interpretation of the PTA statute applied in these circumstances exceeds the statutory limitations for PTA reduction and therefore, the USPTO actions are "in excess of statutory . . . authority." *See* 5 U.S.C. § 706(2)(C).

This decision is consistent with the intent of Congress. Congress chose to speak plainly to the precise issue by setting limitations on the period of PTA reduction. *See City of Arlington. v. FCC*, 569 U.S. 290, 296 (2013) ("Congress knows to speak in plain terms when it wishes to circumscribe, and in capacious terms when it wishes to enlarge, agency discretion."). Congress intended that the PTA statute not adversely impact applicants like Supernus who could have done nothing to advance prosecution. To be sure, Congress expressly granted the USPTO authority to determine what constitutes reasonable efforts, but the USPTO lacks any authority to exceed the statutory "equal to" limitation by including the 546-day time period during which it does not contend that Supernus failed to undertake reasonable efforts to conclude prosecution.

#### CONCLUSION

The USPTO argues that 37 C.F.R. §§ 1.704(c)(8) and (d)(1) are reasonable exercises of its rulemaking authority. For the reasons discussed above, neither regulation

empowers the USPTO to exceed its statutory authority as it has done in these circumstances by assessing a PTA reduction that exceeds the statutory limitations. We determine that the PTA statute addresses the precise question at issue, so our inquiry ends at step one of the *Chevron* analysis. “Because the language of the statute itself controls this case and sets an unambiguous rule,” we need not go further in our analysis of the specific regulations asserted in this appeal. *Wyeth v. Kappos*, 591 F.3d 1364, 1372 (Fed. Cir. 2010) (citing *Smith v. City of Jackson*, 544 U.S. 228, 267 (2005) (Scalia, J., concurring in part and concurring in the judgment) (“Of course, it is elementary that ‘no deference is due to agency interpretations at odds with the plain language of the statute itself.’”)). Any reduction to PTA shall be “equal to the period of time during which the applicant fail[s] to engage in reasonable efforts to conclude prosecution of the application.” 35 U.S.C. § 154(b)(2)(C)(i).

We find the USPTO’s PTA reduction to be inconsistent with the PTA statute and, as a result, we accord no deference to the USPTO’s application of the regulations at issue in these circumstances. *See Wyeth*, 591 F.3d at 1372. We have considered the USPTO’s remaining arguments and find them unpersuasive. We conclude that the district court erred in granting summary judgment in favor of the USPTO. Based on the foregoing reasoning, we reverse the district court’s summary judgment order and remand for further proceedings consistent with this opinion.

### **REVERSED AND REMANDED**

#### **COSTS**

No costs.