

No. 17-1357

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**UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT**

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SUPERNUS PHARMACEUTICALS, INC., and  
UNITED THERAPEUTICS CORPORATION,

*Plaintiffs-Appellants,*

– v. –

MICHELLE K. LEE,

DIRECTOR, U.S. PATENT AND TRADEMARK OFFICE, UNDER  
SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY

*Defendant-Appellee.*

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

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**PRINCIPLE BRIEF OF SUPERNUS PHARMACEUTICALS, INC. AND  
UNITED THERAPEUTICS CORPORATION**

Douglas H. Carsten  
Wilson Sonsini Goodrich & Rosati, PC  
12235 El Camino Real  
Suite 200  
San Diego, CA 92130  
(858) 350-2300

Veronica S. Ascarrunz  
Adam W. Burrowbridge  
Wilson Sonsini Goodrich & Rosati, PC  
1700 K Street NW  
Washington, DC 20006  
(202) 973-8800

*Counsel for Plaintiffs-Appellants  
Supernus Pharmaceuticals, Inc., and  
United Therapeutics Corporation*

Shaun R. Snader  
United Therapeutics Corporation  
1735 Connecticut Avenue, NW  
Washington, DC 20009  
(202) 304-1701

*Counsel for Plaintiff-Appellant  
United Therapeutics Corporation*

February 27, 2017

## CERTIFICATE OF INTEREST

Counsel for Plaintiffs-Appellants certifies the following:

1. The full name of every party represented by the undersigned counsel in this case is: Supernus Pharmaceuticals, Inc., and United Therapeutics Corporation.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is: N/A.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the parties represented by me: Black Rock Inc. collectively through different BlackRock entities, may own 10 percent or more of United Therapeutics Corporation stock. Supernus Pharmaceuticals, Inc. does not have any parent corporations or publicly held companies that own 10 percent or more of its stock.

4. The names of the law firms and the partners and associates that have appeared for Supernus Pharmaceuticals, Inc., and United Therapeutics Corporation in the District court or are expected to appear for Plaintiffs-Appellants in this Court and who are not already listed on the docket for the current case are: N/A.

February 27, 2017

/s/Douglas Carsten

Douglas Carsten

WILSON SONSINI GOODRICH & ROSATI

Attorney for Plaintiffs-Appellants

*Supernus Pharmaceuticals, Inc., and  
United Therapeutics Corporation*

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## **STATEMENT OF RELATED CASES**

Pursuant to Fed. R. App. P. 47.5, Counsel for Appellants states that there have been no prior appeals in this same civil action and that no case in this or any court will directly affect or be directly affected by this Court's decision in the pending appeal. Appellants note that U.S. Patent No. 8,747,897 is currently asserted in *United Therapeutics Corp. v. Actavis Laboratories Fl. Inc.*, C.A. Nos. 16-cv-01816 and 03642 (D.N.J.).

## **JURISDICTIONAL STATEMENT**

This is an appeal from a final judgment of the District Court for the Eastern District of Virginia pursuant to 28 U.S.C. § 1295(a)(1). The underlying action challenges the U.S. Patent and Trademark Office's patent term adjustment determination for U.S. Patent No. 8,747,897. The district court had jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) because 35 U.S.C. § 154(b)(4)(A) permits Plaintiffs to challenge the PTO's patent term adjustment in the United States District Court for the Eastern District of Virginia. On October 2, 2015, the district court entered final judgment. Appellants filed the Notice of Appeal on December 7, 2016, within 60 days of the judgment, making it timely under Federal Rule of Appellate Procedure 4(a)(1)(B).



## **STATEMENT OF THE ISSUES**

1. Whether 35 U.S.C. § 154(b) permits the Patent and Trademark Office to reduce an applicant's patent term adjustment by a period of time exceeding a "period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application."

## STATEMENT OF THE CASE

The U.S. Patent and Trademark Office’s (“PTO”) reduction of Appellants’ Patent Term Adjustment (“PTA”) is directly contrary to the PTA statute. 35 U.S.C. § 154(b). The PTA statute unambiguously permits reduction of PTA only if “an applicant failed to engage in reasonable efforts to conclude prosecution” and only for “a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.” *Id.* at (b)(2)(C)(i). Here, the PTO has reduced Appellants’ patent term and PTA by a period of 546 days during which it admits the applicant could do nothing—meaning the applicant did not and could not “fail to engage in reasonable efforts.”

The effect of the PTO’s and district court’s holdings is a PTA reduction of patent term *in excess* of any “period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application,” despite the statute’s explicit language requiring that the PTO shall only reduce patent term “by a period equal to” applicant’s failure to reasonably engage.

Despite the unambiguous statutory language limiting the permissible reduction of PTA, the PTO promulgated and applied regulations exceeding its authority. The district court erred by failing to first examine the language of the statute and concluding incorrectly that its analysis was foreclosed by this Court’s decision in *Gilead Scis., Inc. v. Lee*, 778 F.3d 1341 (Fed. Cir. 2015) (“*Gilead*”).

By starting its analysis with the presumed reasonableness of the PTO’s regulations, rather than the text of the PTA statute, the district court failed to appreciate the statutory limits on the PTO’s authority. Section § 154(b)(2)(C) makes two points clear. First, Congress did not authorize the PTO to levy punitive PTA reductions for time during which the PTO admits Applicants could not more fully engage in prosecution. *Id.* at (C)(i). Second, Congress only permitted the PTO to “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,”—it did not permit the PTO to *redefine* a period of adjustment to retroactively include time during which an applicant actively and reasonably engaged in prosecution. *Id.* at (C)(iii) (emphasis added). Upon giving the statute its plain meaning, and congressionally intended effect, this case of patent term mis-adjustment is naturally corrected.

Because the PTO’s actions under 37 C.F.R. § 1.704(c)(8) exceed the PTO’s statutory authority and contravene the plain language of 35 U.S.C. § 154(b)(2)(C), Plaintiffs appeal.

## **I. DISTRICT COURT OPINION**

Plaintiffs-Appellants Supernus Pharmaceuticals, Inc. (“Supernus”) and United Therapeutics Corporation (“UTC”) (collectively “Appellants” and

“Applicants”<sup>1</sup> brought suit in the U.S. District Court for the Eastern District of Virginia and moved for summary judgment to correct the PTO’s PTA calculation for U.S. Patent No. 8,747,897 (“the ’897 patent”). Appellants challenged, *inter alia*, the permissibility and application of 37 C.F.R. §§ 1.704(c)(8) and (d)(1) in light of 35 U.S.C. § 154(b). The PTO filed a cross-motion for summary judgment. Relevant to this appeal, the district court held: (1) *Gilead* foreclosed Appellants challenge to § 1.704(c)(8); and (2) Plaintiffs did not demonstrate that § 1.704(d)(1) reflects an inappropriate interpretation of the PTA statute.<sup>2</sup>

The district court begins its analysis not with the language of the statute in question, § 154(b)(2)(C)(i), but instead with the conclusion that “Plaintiff’s claim that 37 C.F.R. § 1.704(c)(8) is arbitrary, capricious, or otherwise not in accordance with law is foreclosed by the Federal Circuit’s decision in *Gilead*.” Appx9. The district court concluded that “[t]he facts from *Gilead* are similar to the facts presented in this case.” Appx10. The district then court reasoned that “[t]he Federal Circuit in *Gilead* upheld the reasonableness of the PTO’s interpretation of

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<sup>1</sup> For some of the period during prosecution, UTC took over the right to prosecute the patent application and took actions as the Applicant in that capacity. Accordingly, for the sake of clarity and simplicity, “Applicants” is used herein to refer to Supernus and/or UTC as appropriate for the given time frame.

<sup>2</sup> On appeal Appellants do not challenge directly the reasonableness of § 1.704(d)(1). Rather Appellants argue that § 1.704(d)(1) alone cannot salvage the PTO’s interpretation of the PTA statute, § 154(b)(2)(C)(i), where the PTO’s regulation, § 1.704(c)(8), exceeds its statutory authority.

35 U.S.C. § 154 by finding that § 1.704(c)(8) is not arbitrary, capricious, or otherwise not in accordance with law” and “[a]ccordingly, because § 1.704(c)(8) applies squarely to this case, Plaintiffs claim must fail as a matter of law.”

Appx12. Therefore, because the Plaintiff in *Gilead* also challenged § 1.704(c)(8), and this Court upheld the reasonableness of the regulation on Gilead’s challenge, the district court did not independently examine the text of the controlling statute.

## **II. UNDISPUTED FACTS RELATING TO THE EXAMINATION OF THE ’100 APPLICATION**

The facts in this case are not in dispute and generally relate to two corresponding applications, U.S. patent application number 11/412,100 (“the ’100 application) and its related European application, number 07755989.6. The ’100 application issued as the ’897 patent on June 10, 2014 (Appx102; Appx26), and the European application issued on October 13, 2011 as European Patent EP2010189 (“the EP patent”). Supernus, the original Applicant and assignee of the ’897 patent, provided UTC an exclusive license of the ’897 patent.

On August 20, 2010, during prosecution of the ’100 application, the PTO issued a Final Rejection. Appx196-206. On February 22, 2011, the Applicant filed a request for continued examination (“RCE”), Information Disclosure Statement (IDS), amendment, and remarks responsive to the Final Rejection mailed on August 20, 2010. Appx207. Almost 18 months later, on August 21, 2012, and prior to any response from the PTO, the EPO issued a Communication (“the EPO

Communication”) of a Notice of Opposition concerning an opposition filed by Sandoz AG. The EPO Communication reported an opposition against the EP patent filed by Sandoz AG on August 8, 2012 (“the Sandoz Opposition”).

Appx339-343. The Sandoz Opposition cited 10 documents. Appx342; Appx439.

For the about 18 months, 546 days, from the filing of the RCE on February 22, 2011, until, at earliest, the issuance of the EPO Communication on August 21, 2012, Applicants could take no further action to advance or conclude prosecution of the ’100 application. The PTO admits this fact.<sup>3</sup> The PTO also admits that most of this roughly 18 month period is PTO A Delay, *i.e.* delay caused by the PTO: from June 22, 2011 until the PTO issued an Office Action on September 10, 2013 (811 days and nearly 27 months). For any period of A Delay, the PTO must grant PTA in an amount equal to “1 day for each day” “the issue of an original patent is delayed” beyond the 4 month period guaranteed in the statute.

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<sup>3</sup> Appellants’ Undisputed Fact No. 9 (Appx552-553) remained undisputed by the PTO during Summary Judgment Briefing. *See* E.D. Va. L. Civ. R. 56. During the 546 days, of the 646 days charged against Applicants, it is undisputed that there was no conduct Applicants could have taken to conclude prosecution. Indeed, Applicant could more accurately not take any action for 547 days. As the PTO itself noted “the earliest [the 30-day period] may have commenced was a day later, when Plaintiffs’ European attorney *received it.*” Appx608 at n.16 (emphasis added).

The timeline below reflects the events relevant to the 546 days<sup>4</sup> of applicant delay charged against Applicants:



On September 11, 2012, 21 days after issuance of the EPO Communication, the Applicant received a letter from its European patent attorney providing notice of the Sandoz Opposition (“the Foreign Attorney Letter”). Appx456-457. In response, Applicant submitted a timely-filed IDS to the PTO under 37 C.F.R. § 1.97(b)(4) on November 29, 2012, nearly 10 months before the mailing of a first Office action after the RCE. The IDS provided to the PTO 8 documents cited in the Sandoz Opposition, the EPO Communication dated August 21, 2012, and the Foreign Attorney Letter dated September 11, 2012. Appx209. Over 27 months from submission of the RCE, and almost 10 months after submission of the IDS

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<sup>4</sup> All other periods of PTO and applicant delay not in dispute occurred before the time reflected in the timeline.

and references from the Sandoz Opposition, the PTO issued the first Office action after the filing of the RCE on September 10, 2013. Appx462-471.

On January 10, 2014, Applicant filed a response to the first Office action after the filing of the RCE. Appx472-495. The PTO subsequently allowed the application, which issued as the '897 patent on June 10, 2014, reflecting a PTA of 1,260 days. Appx553 at ¶ 15. The patentee timely filed a Request for Reconsideration of Patent Term Adjustment under 37 C.F.R. § 1.705(d) to revise the PTA to 2,030 days. Appx509-513. The patentee argued that the PTA reduction of 646 days, that is, from the date the RCE was filed to the filing date of the IDS triggered by the EPO Communication, as applicant delay under 37 C.F.R. § 1.704(c)(8) was improper. The patentee also argued that it was entitled to an additional 126 days of PTA under 35 U.S.C. § 154(b)(1)(B). Appx512.

The PTO issued a Redetermination of Patent Term Adjustment, in which the PTO found the patentee's arguments partially persuasive. Appx516-522. The PTO awarded an additional 126 days of PTA as B Delay under 35 U.S.C. § 154(b)(1)(B), yielding a total PTA of 1,386 days, but rejected the request to eliminate the 646 days of reduction as applicant delay under 37 C.F.R. § 1.704(c)(8). Appx518-522.

The Appellants subsequently timely filed a second Request for Reconsideration of Patent Term Adjustment under 37 C.F.R. § 1.705(d) to request the PTO to revise the PTA of 1,386 days to 2,032 days. Appx523-530. The



patentee argued that the deduction of 646 days from the PTA as applicant delay under 37 C.F.R. § 1.704(c)(8) was improper and that the applicant delay was zero days. Appx523-529. The PTO responded with a Decision on Patent Term Adjustment denying the patentee's request with respect to the PTA reduction of 646 days as applicant delay and affirming the PTA of 1,386 days. Appx533-537. During at least 546 days of the PTA at issue, it is undisputed that Applicants could do nothing more to conclude prosecution. Appx552-533 at ¶ 9. Appellants, accordingly, focus on the 546 days to simplify this appeal.<sup>5</sup>

The PTO thus admits A and B delay of 1,656 and 791 days, respectively, for a total PTO Delay of 2,272 days,<sup>6</sup> or 6.22 years. The results of the PTO's adjustment of PTA is a patent term for Appellants of 15.3 years, following over 8 years of prosecution before the PTO.

### **SUMMARY OF THE ARGUMENT**

The plain language of the PTA statute authorizes reduction of PTA only by "a period equal to" the time "during which" the applicant "failed to engage in

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<sup>5</sup> The PTO, however, acknowledged one additional day where Applicants could not act. Appx608 at n.16. Moreover, Applicants should not be charged for the 30-day period permitted in § 1.704(d)(1) which is explicitly defined as not unreasonable. Thus, at most, Applicants delayed 69 days from the earliest possible date following the end of the 30-day deadline until the filing of the IDS on Nov. 29, 2012.

<sup>6</sup> As per the PTO's calculations: 1,656 (A Delay) + 791 (B Delay) – 175 (Overlap) = 2,272 days. Appx536.

reasonable efforts to conclude prosecution of the application.” 35 U.S.C. § 154(b)(2)(C)(i). Here, the PTO has reduced Appellants’ patent term and PTA by a period of 546 days during which it admits the Applicants could do nothing—meaning the Applicants did not and could not “fail to engage in reasonable efforts.” The PTO’s actions are in direct conflict with the controlling statute, Congress’s intent, and this Court’s holding in *Gilead*.

The district court erred by (1) failing to first examine the language of the PTA statute prior to considering the reasonableness of the PTO’s regulations, (2) concluding that the PTO’s application of 37 C.F.R. § 1.704(c)(8) is neither arbitrary, capricious, nor contrary to law, and (3) concluding that *Gilead* forecloses Appellants’ arguments.

First, 35 U.S.C. § 154(b)(2)(C)(i) limits any reduction of patent term to “*a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.*” (emphasis added). The statute thus defines the maximum period of time for which the PTO may reduce PTA to the time during which “the applicant failed to engage in reasonable efforts to conclude prosecution of the application.” Therefore, PTO interpretations, such as Rule 1.704(c)(8), that seek to define Applicant’s behavior as unreasonable—when it could do nothing—and seeks to impose a reduction beyond a period “equal to” any arguable period of applicant’s failure to engage in

reasonable efforts to conclude prosecution are *ultra vires*. Both the statute's plain language and its Congressional intent support this conclusion. Critically, the district court failed to examine the impact of the controlling statutory language, § 154(b)(2)(C)(i), on the permissibility of the PTO's interpretation.

The PTO's application of § 1.704(c)(8) is directly contrary with law as it exceeds the limited scope of authority bestowed by Congress to "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." 35 U.S.C. § 154(b)(2)(C)(iii) (emphasis added). As set forth above, Rule 1.704(c)(8)'s attempt to redefine Applicant's conduct as unreasonable and extend the period of adjustment beyond a period "equal to" any period of applicant's failure to engage in prosecution is *ultra vires* and, thus, contrary to law.

Specifically, 37 C.F.R. § 1.704(c)(8), states that a circumstance constituting a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application includes:

Submission of a supplemental reply or other paper; other than a supplemental reply or other paper expressly requested by the examiner, after a reply has been filed, in which case the period of adjustment set forth in § 1.703 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.

The second clause of Rule 1.704(c)(8) extends beyond the PTO's limited statutory authority of establishing the meaning of a particular statutory term, *i.e.*

circumstances, and attempts to create punitive reductions in excess of the length of time prescribed by Congress in § 154(b)(2)(C)(i). Under the guise of Rule 1.704(c)(8), the PTO divorces applicant conduct constituting a failure to engage in reasonable efforts to conclude prosecution, *i.e.* submission of the “other paper,” from the “equal” reduction in patent term adjustment required by § 154(b)(2)(C)(i). In doing so, the PTO’s interpretation impermissibly assumes that an applicant has the duty, and ability, to engage in reasonable efforts during the entirety of the time after a reply has been filed. The punitive nature of Rule 1.704(c)(8), in circumstances where the applicant is unable to engage in concluding prosecution, is an impermissible overreach in patent term reduction beyond the agency’s statutory authority. Indeed, the PTO itself recognizes that “an inflexible application of this rule would sometimes unfairly penalize applicants who only learned of such information after filing (for instance) an RCE...”<sup>7</sup> Appx660.

Second, the district court erred by concluding that the PTO’s actions are neither contrary with law, nor arbitrary and capricious. The PTA statute was passed by Congress to ensure that diligent applicants would not lose patent term due to delays caused by the PTO. The text of the PTA statute as well as the legislative history explain that only applicant conduct constituting a failure of the

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<sup>7</sup> As discussed herein, the PTO’s resort to another regulation to save Rule 1.704(c)(8) from this admitted impropriety is insufficient.

applicant to engage in reasonable efforts to conclude prosecution are charged to the applicant. Nevertheless, Rule 1.704(c)(8), explicitly incentivizes applicants *to delay* in order to avoid its impermissible punitive effect. Specifically, because Applicants filed their IDS, deemed timely under the PTO's own regulations, as soon as practicable rather than waiting several months for the PTO's office action, it falls within the ambit of Rule 1.704(c)(8)'s punitive reduction. However, had Applicants intentionally delayed several months in submitting their IDS by waiting until after the PTO had issued an Office action, Applicants would have been charged zero days of negative PTA adjustment. Because the PTO's interpretation permits punishment of diligent applicants reasonably engaged and not less diligent applicants that intentionally aim to delay prosecution, Rule 1.704(c)(8) is both arbitrary and capricious.

Finally, the district court erred in concluding that this Court's *Gilead* decision "forecloses [Appellants]' claim." Appx9. *Gilead* does not, and could not, foreclose Appellants' arguments for several reasons. Most importantly, the issue raised in *Gilead* is wholly distinct from the issue here. The issue in *Gilead* was "whether a failure to engage in reasonable efforts requires conduct that *actually causes delay*," as opposed to threatened delay. 778 F.3d at 1349 (emphasis added). Here, Appellants' arguments do not depend on any distinction between actual and threatened delay. Further, "Gilead d[id] not contend that the plain language of the

statute answers the precise question at issue.” *Id.* at 1347. Nor did Gilead argue that the PTO’s regulations were directly inconsistent with the text of the statute. Appellants’ argument in chief, however, is that the plain language of the statute answers the precise question at issue and that the PTO’s interpretation is directly contrary to the language of the statute. The district court thus erred in concluding that a single challenge to 37 C.F.R. § 1.704(c)(8), under *Gilead’s* separate facts and posture, forecloses future challenges to § 1.704(c)(8). This error is particularly palpable where, as Appellants contend, the PTO lacks rulemaking authority for aspects of its regulation not previously challenged in *Gilead* and advance arguments wholly distinct from those previously decided.

Accordingly, Appellants respectfully requests that this Court correct the patent term adjustment for ’897 in accordance with 35 U.S.C. §154(b)(2)(C)(i).

## **ARGUMENT**

### **I. LEGAL STANDARDS**

#### **A. Summary Judgment**

Summary judgment is appropriate where the moving party demonstrates that there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). Here, the facts related to the calculation of PTA under 35 U.S.C. § 154(b) for the ’897 patent are undisputed. Therefore, only purely legal

issues remain, namely whether the PTO's refusal to accord Plaintiffs PTA is in excess of statutory authority, arbitrary and capricious, or otherwise not in accordance with the law. *See* 5 U.S.C. § 706(2)(A), (C).

**B. Standard of Review**

The PTO provides a specific procedure for applicants to request reconsideration of PTA determination. *See* 37 C.F.R. § 1.705(b). Applicants that disagree with the Director's decision on the request for reconsideration may file a civil action in the U.S. District Court for the Eastern District of Virginia within 180 days of the Director's decision. 35 U.S.C. § 154(b)(4)(A). Review of the Director's decision is performed under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-706. *Id.* ("Chapter 7 of title 5 shall apply" to a district court action challenging the PTO's PTA determination).

The APA provides that the court should "set aside agency action . . . found to be "in excess of statutory . . . 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). An agency abuses its discretion "where the decision is based on an erroneous interpretation of the law, on factual findings that are not supported by substantial evidence, or represents an unreasonable judgment in weighing relevant factors." *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1281 (Fed. Cir. 2005). Where the PTO regulations defining a reduction of PTA extend beyond that

permitted by statute, the regulation is improper and must be corrected. *Novartis AG v. Lee*, 740 F. 3d 593, 602 (Fed. Cir. 2014) (rejecting application of PTO regulation to reduce PTA, where regulation defined time between allowance to issuance as “time consumed by continued examination,” as contrary to the PTA statute and where the time was “plainly attributable to the PTO.”).

“As always, the starting point in every case involving construction of a statute is the language itself.” *United States v. Hohri*, 482 U.S. 64, 69 (1987) (internal quotations omitted). “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.” *City of Arlington v. FCC*, 133 S. Ct. 1863, 1868 (2013) (internal citations omitted). To the extent that an agency’s interpretation is at odds with the plain language of an unambiguous statute no deference is afforded to that interpretation. *Smith v. City of Jackson, Miss*, 544 U.S. 228, 267 (2005) (citations omitted).

“[T]he Federal Circuit . . . has held that with respect to USPTO regulations, ‘[b]ecause congress has not vested the Commissioner with any general substantive rulemaking power,’ USPTO regulations ‘cannot possibly have the force and effect of law and ‘[t]hus, the rule of controlling deference set forth in *Chevron* does not apply.’” *Mohsenzadeh v. Lee*, 5 F. Supp. 3d 791, 801 (E.D. Va. 2014) (citations omitted). PTO regulations, however, may still qualify for some deference under



*Skidmore*, where a court looks to an agency’s basic “power to persuade.” *Id.* (citing *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)). *Skidmore* deference applies where a party challenges a PTO regulation that was established pursuant to the general procedural rulemaking authority of § 154(b)(3)(A). *Mohsenzadeh*, 5 F. Supp. 3d at 802. The Federal Circuit has explained that under *Skidmore*, a court considers “if the agency has conducted a careful analysis of the statutory issue, if the agency’s position has been consistent and reflects agency-wide policy, and if the agency’s position constitutes a reasonable conclusion as to the proper construction of the statute.” *Id.*

A higher degree of deference under *Chevron* applies only where a party challenges a PTO regulation promulgated pursuant to the specific grant of substantive rulemaking authority. *Id.* Even under the more deferential standard set forth in *Chevron*, courts must first examine the statute *de novo* to determine whether Congress has spoken directly to the question at issue. *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984). Where the statute is unambiguous or Congress’s intent can be ascertained, the language of the statute controls and the PTO is given no deference to apply a contrary interpretation. *Wyeth v. Kappos*, 591 F.3d 1364, 1372 (Fed. Cir. 2010). Only after applying the traditional tools of statutory construction and finding that the statute is silent or ambiguous, such that Congress’s intent is not clear, will courts then look

to whether the agency's interpretation is based on a permissible construction of the statute. *Chevron*, 467 U.S. at 843. The court will only defer to the agency if "the agency's position constitutes a reasonable conclusion as to the proper construction of the statute." *Cathedral Candle Co. v. United States ITC*, 400 F.3d 1352, 1366 (Fed. Cir. 2005).

### **C. Patent Term Adjustment**

The PTA statute, 35 U.S.C. § 154(b), was enacted in response to statutory changes that converted patent terms from seventeen years from patent issuance, to twenty years from the earliest claimed priority date. Calculating patent term from an applicant's priority date, rather than issuance of the patent, meant that an applicant's term could be significantly reduced due to delays completely outside the applicant's control. For instance, if the PTO delayed in examining the applicant's application, the amount of PTO delay would cause an equal reduction to the patent's term. To address this inequity, Congress enacted § 154(b) granting the PTO limited authority to adjust patent term in order to compensate for patent term lost due to PTO delay. If, however, the applicant is responsible for delaying the prosecution of its own application, the statute provides that PTA is "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." *Id.* at (2)(C)(i).

## 1. PTO Delay

The Patent Term Guarantee Act (“the Act”), 35 U.S.C. § 154(b), provides for the restoration of patent term in three circumstances:

(i) an “A-Delay,” which awards PTA for delays arising from the USPTO’s failure to act by certain examination deadlines; (ii) a “B-Delay,” which awards PTA for an application pendency exceeding three years; and (iii) a “C-Delay,” which awards PTA for delays due to interferences, secrecy orders, and appeals. The USPTO calculates PTA by adding the A-, B-, and C-Delays, subtracting any overlapping days, and then subtracting any days attributable to applicant delay.

*Pfizer, Inc. v. Lee* 811 F.3d 466, 468 (Fed. Cir. 2016). The A, B, and C designations refer to the three different subsections in 35 U.S.C. § 154(b)(1). For *each* of these types of PTO delay, the statute dictates that “the term of the patent shall be extended 1 day for each day” that the PTO delayed or failed to act. “A Delay” is particularly relevant here because the period at issue in this case occurred after the applicant’s filing of an RCE to which the PTO failed to provide a response within the statutory guaranteed period of 4 months. 35 U.S.C. § 154(b)(1)(A).<sup>8</sup> As with all of A, B, and C Delay, “A Delay” dictates that the term of the patent “shall be extended 1 day for each day” “the issue of an original patent is delayed due to the failure of the [PTO] to . . . respond to a reply . . . within 4

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<sup>8</sup> The PTO issued its first office action over 30 months after Applicants filed its RCE.

months.” *Id.* at (b)(1)(A)(ii). This day-for-a-day PTA thus applies to every day after the end of the period the PTO was given time to act.

## 2. Applicant Delay

As noted, paragraph (1) of the PTA statute titled “Patent Term Guarantees” was passed by Congress to ensure that an applicant’s patent term “shall be extended 1 day for each day” of the PTO’s failure to provide timely responses. *Id.* Paragraph (2) sets forth limitations to paragraph (1)’s guaranteed restoration of patent term. *Id.* at (b)(2). Paragraph (2) requires that “[t]he 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.” *Id.* at (b)(2)(C)(i) (emphases added).

By statute, the amount of PTA is to be reduced only by “a period equal to” the time “during which” the applicant “failed to engage in reasonable efforts to conclude prosecution of the application.” *Id.* This time is often referred to as applicant delay. *Wyeth v. Dudas*, 580 F. Supp. 2d 138, 139 n.1 (D.D.C. 2008). Thus, as with PTO delay, the provisions relating to applicant delay contemplate a day-for-a-day reduction during applicant failure.

The statute also provides that “[t]he Director 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.” 35 U.S.C. § 154(b)(2)(C)(iii) (emphasis added). Pursuant to this subsection, the PTO promulgated regulations enumerating fourteen “[c]ircumstances that constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application.” 37 C.F.R. § 1.704(c)(1)-(14).

The PTA statute does not provide the Director authority to reduce PTA by any more than “a period equal to” the time that applicant “failed to engage in reasonable efforts to conclude prosecution of the application.” 35 U.S.C. § 154(b)(2)(C)(i). The PTA statute also does not provide the Director authority to define the period of adjustment. Finally, the PTA statute does not provide the Director authority to define a time period when applicants can take no action as “a failure of an Applicant to engage in reasonable efforts to conclude processing or examination of an application.”

Regulations relevant to the PTA statute and this appeal include Rule 1.704(c)(8), Rule 1.704(d)(1), and Rule 56. Rule 1.704(c)(8) provides that a circumstance of applicant delay is “[s]ubmission of a supplemental reply or other paper, other than a supplemental reply or other paper expressly requested by the examiner, after a reply has been filed.” 37 C.F.R. § 1.704(c)(8). Circumstances falling within subsection (c)(8) purport to result in a reduction of PTA for the time between the original filing and the supplemental filing. *Id.* Rule 1.704(d)(1) relates

to the filing of an IDS and provides that filing an IDS “will not be considered a failure to engage in reasonable efforts to conclude prosecution . . . of the application” if it cites information “first cited in any communication from a patent office in a counterpart foreign or international application” and “was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the [IDS].” “The thirty-day period set forth in paragraph (d)(1) of this section is not extendable.” *Id.* at (d)(2). Rule 1.704(d) requires (1) a communication from a patent office, (2) receipt of information to be disclosed in an IDS, and (3) a duty to disclose that information pursuant to § 1.56(c). Rule 1.704(d) references 37 C.F.R. § 1.56, or “Rule 56.” Rule 56 identifies “prior art cited in search reports of a foreign patent office in a counterpart application” as potential material that must be disclosed to the PTO.

## **II. PTA CANNOT BE REDUCED FOR A PERIOD EXCEEDING THE PERIOD “EQUAL TO” APPLICANT DELAY**

“It is axiomatic that the starting point in every case involving construction of a statute is the language itself.” *Landreth Timber Co. v. Landreth*, 471 U.S. 681, 685 (1985) (internal quotations and citations omitted); *Hohri*, 482 U.S. at 69;

*Sebelius v. Cloer*, 133 S. Ct. 1886, 1893 (2013).<sup>9</sup> This Court has similarly made clear that the starting point in a PTA analysis is the statute itself:

As always, the starting point in every case involving construction of a statute is the language itself. When the terms of a statute are unambiguous, judicial inquiry is complete, except in rare and exceptional circumstances. Absent a clearly expressed legislative intention to the contrary, the statute's plain language must ordinarily be regarded as conclusive.

*Wyeth*, 591 F.3d at 1369 (internal quotations and citations omitted).

The PTA scheme is wholly statutory. As such, any PTO action within the scheme must find authority in the statute. The district court's abbreviated analysis did not analyze the PTA statute and led to flawed conclusions untethered from the plain language of the statute and unsupported by law.

**A. The precise question is answered by the text of the PTA statute**

The legal analysis in this case must begin with asking whether the precise question in this case has been answered by Congress. *City of Arlington*, 133 S. Ct. at 1868. The Supreme Court's mandate is clear:

First, always, is the question whether Congress has directly spoken to the precise question at issue. 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.

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<sup>9</sup> The district court acknowledged, but failed to apply, the proper analysis in determining whether the PTO's actions are consistent with the PTA statute. *See* Appx7.

*Chevron*, 467 U.S. at 842-43. Courts are required to perform this first step because, as the Supreme Court explained, “[t]he judiciary is the final authority on issues of statutory construction and must reject administrative constructions which are contrary to clear congressional intent.” *Id.* at n.9.

Here, the precise question is whether PTA may be reduced for a period exceeding “time during which the applicant failed to engage in reasonable efforts to conclude prosecution.” The plain language of the statute answers this precise question. It may not. Section 154(b)(2)(C)(i) states in relevant part:

(b) Adjustment of patent term.—

(2) Limitations.—

(C) Reduction of period of adjustment.—

(i) The period of adjustment of the term of the 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.**

(emphases added). Accordingly, a rule promulgated by the PTO that purports to reduce the period of adjustment *in excess* of “the period of time” during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application is invalid.

From the 546-day period after the filing of the RCE on February 22, 2011, until at least the issuance of the EPO Communication on August 21, 2012, the PTO admits that there was nothing more Applicants could have done to advance prosecution of the application. Appx552-553 at ¶ 9. Applicants were simply



waiting (over 18 months) on the PTO to take necessary action. Thus this time period, where Applicants could do nothing to further prosecution, cannot comprise a “fail[ure] to engage in reasonable efforts.” The PTO’s reduction of PTA by this period is contrary to the clear mandate of Section 154, which allows the PTO to reduce PTA only for “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). Congress answered the precise question at issue within the text of the statute and Plaintiffs are entitled to at least the 546 days of PTA between the filing of the RCE and issuance of the EPO Communication.

Rather than measuring the PTO’s actions against the statute, the district court erroneously held that *Gilead* foreclosed Appellants’ arguments despite the fact that this Court heard wholly-distinct legal arguments, pertaining to undisputedly different factual circumstances, and litigated by parties not before the Court. Even if *Gilead* answered some of the questions at issue—which it does not<sup>10</sup>—the district court cannot forgo its obligation to first determine “whether Congress has directly spoken to the precise question at issue” in this case. *Chevron*, 467 U.S. at 842-43. The district court performed no analysis of the statutory interpretation issue presented and, instead, began its analysis by

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<sup>10</sup> See Section IV.

determining whether the regulation in question, 37 C.F.R. § 1.704(c)(8), is arbitrary, capricious, or otherwise not in accordance with law. *See* Appx9 (“B. Analysis”). The district court thus failed to ask, much less answer, the precise question at issue in this case and never examined the unambiguously expressed intent of Congress established in § 154(b)(2)(C)(i).

**B. The plain language of the PTA statute permits PTA reduction *only if* “an applicant failed to engage in reasonable efforts” and *only for* a “period equal to the period of time” “during which” the applicant failed to engage**

The statute’s plain language indicates that Congress intended to reduce PTA only for a period “equal to” the time during which an applicant failed to engage in reasonable efforts to prosecute its application. Subsection (C)(i) explicitly defines the “reduction of period of adjustment.” Notably, the text of the statute does not authorize **punitive** reductions *in excess* of the time during which an applicant could have actually engaged in reasonable efforts.

Each phrase of the statute has meaning and must be given effect. The PTA statute, broken into relevant phrases, specifically limits the “[r]eduction of period of adjustment” to “a period equal to” “the period of time” “during which” “the applicant failed to engage in reasonable efforts to conclude prosecution of the application.” *Id.* These terms, chosen by Congress, limit both the category of applicant conduct warranting reduction and the extent of time authorized to be assessed against the applicant for its conduct.

The category of applicant conduct warranting reduction is defined as “the applicant[’s] fail[ure] to engage in reasonable efforts to conclude prosecution of the application.” *Id.* This phrase makes clear that Congress only intended for circumstances within the applicant’s control to result in a reduction in patent term. Where an applicant cannot engage, it is axiomatic that an applicant cannot *fail* to engage. In fact, this Court explained that “the statute’s ‘reasonable efforts’ language focuses on *applicant conduct* as opposed to the results of such conduct.” *Gilead*, 778F.3d at 1347 (citing 35 U.S.C. § 154(b)(2)(C)(i)) (emphasis added).

The plain language of subsection (C)(i) also specifically defines the extent of time authorized to be assessed against the applicant for its conduct. The reduction of period of adjustment is explicitly limited to “a period equal to” “the period of time” “during which” “the applicant failed to engage in reasonable efforts[.]” 35 U.S.C. § 154(b)(2)(C)(i). Congress’s usage of the phrase “period of time,” in conjunction with “reasonable efforts,” indicates that the extent of applicant’s failure is measured by the time that the applicant could have reasonably engaged. This is further supported by the phrase “during which” (the applicant failed to engage), again indicating that the measurement of the “period of time” spans only throughout the time an applicant *in fact* “failed to engage.” Under the plain language of the statute, Applicants did not “fail to engage” for the “period of time” from the day after filing its initial reply until, at least, issuance of the EPO’s

Communication – a period equal to 546 days “during which” it undisputed that Applicants could do nothing.<sup>11</sup> It is only by regulatory fiat that the PTO determined otherwise.

The language chosen by Congress is specific and unmistakable. Congress left zero authority or discretion for the PTO to determine the extent to which an applicant’s patent term shall be reduced. Subsection (C) prescribes a 1:1—day-for-a-day—adjustment of patent term for every day “during which” “the applicant failed to engage in reasonable efforts” to conclude prosecution. Notably, this is the equivalent flip side of the day-for-a-day of PTA added for each type of PTO delay. An interpretation seeking to expand the permitted period of reduction beyond a period “equal to” the period of applicant’s failure to engage in prosecution is *ultra vires*.

The controlling language of the statute thus demands that at least the 546 days, during which Applicants had done everything in their power to conclude prosecution and neither had a duty nor an ability to engage in further prosecution of the ’100 application, be considered “reasonable efforts to conclude prosecution of the application.” Put simply, Applicants could not act for the 546 days because the EPO Communication did not yet exist giving rise to the need to file an IDS. In fact, for at least one additional day, upon receiving the EPO Communication

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<sup>11</sup> See n.3, *supra*.

Applicants could not act on the art cite in the EPO Communication.<sup>12</sup> For the statute to have any meaning at all, the PTO cannot simply *redefine* by regulation a time of adjustment period exceeding and untied to any applicant's actual conduct or failure to act. In fact, the PTO admits—that as a factual matter—Applicants could do nothing more to engage in prosecution. Appx552-553 at ¶ 9.

**C. Traditional tools of statutory construction confirm Appellants' interpretation**

The plain language of § 154(b)(2)(C)(i) is clear – only the failure of an applicant to engage in reasonable efforts is conduct warranting a reduction, and the period of adjustment for failure to engage shall be reduced only by a period equal to the period of time during which the applicant failed to engage. The statutory text of § 154(b)(2)(C)(i) *itself* defines (1) the type of conduct warranting reduction, *i.e.* applicant's failure to engage, and (2) the period of adjustment. As discussed in Sections II.A-B the precise question at issue in this case is answered by the plain and unambiguous text of the PTA statute alone.

However, even if this Court were to determine that the statutory text of § 154(b)(2)(C)(i) does not itself answer the precise question (of whether PTA may be reduced for a period exceeding “the time during which the applicant failed to engage in reasonable efforts to conclude prosecution”) this Court does not

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<sup>12</sup> See n.3, *supra*.

automatically defer to the PTO. *Timex V.I., Inc. v. United States*, 157 F.3d 879, 882 (Fed. Cir. 1998) (“If . . . the statute’s text does not explicitly address the precise question, we do not at that point simply defer to the agency.”). Rather, this Court’s “search for Congress’s intent must be more thorough than that” because “before we can allow an agency to say what the law is, we must thoroughly investigate whether Congress had an intent on the matter.” *Id.* “The Supreme Court made this clear in *Chevron*: ‘If a court, *employing traditional tools of statutory construction*, ascertains that Congress had an intention on the precise question at issue, that intention is the law and must be given effect.’” *Id.* (quoting *Chevron*, 467 U.S. at 843 n.9) (emphasis added in *Timex*). Those “‘tools’ include examination of the statute’s structure, canons of statutory construction, and legislative history.” *Id.*; *Gilead*, 778 F.3d at 1348; *see also Dunn v. Commodity Futures Trading Com’n*, 519 U.S. 465, 470-480 (1997) (considering the overall statute, a canon of statutory construction, and legislative history to ascertain Congress’s intent, when more than one reading of the literal text of the particular statutory phrase at issue is possible).

Even when statutory language is open to multiple readings, *Chevron* deference does not apply when Congress’s intent is clear. *Timex*, 157 F.3d at 882 (citing *Dunn*, 519 U.S. at 479 n.14) (“after investigating Congress’s intent by using various tools of statutory construction beyond the literal text of the statutory

phrase, which was open to multiple readings, holding that *Chevron* deference is improper because Congress’s intent is clear”). Accordingly, prior to being able to determine that the precise question at issue has not been answered by Congress, this Court must examine the traditional tools of statutory construction, including the structure of the statute, canons of statutory construction, and legislative history.<sup>13</sup>

**1. The structure of the PTA statute confirms the plain meaning of § 154(b)(2)(C)(i)**

As discussed above, paragraphs (1) and (2) of the Patent Term Adjustment Statute, 35 U.S.C. § 154(b), work together. Paragraph (1), “Patent Term Guarantees” ensures that patent term is extended a day-for-a-day of each of Types A, B, and C of PTO delay. Paragraph (2) then sets forth certain limitations including a “reduction of period of adjustment” under paragraph 1 “equal to” the time of applicant failure to engage.<sup>14</sup>

Notably, PTO delay under paragraph (1) is only charged and converted to PTA “1 day for each day” after the end of the period during which the PTO should act (for Types A and B) or during the pendency of certain procedures (for Type C).

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<sup>13</sup> Notably, the district court failed to perform any statutory interpretation analysis and, at most, relied on the statutory analysis performed in *Gilead*, which supports Appellants’ arguments. See Section IV.

<sup>14</sup> Paragraph (2) also provides that overlaps of PTO delay are counted only once and that no PTA can be awarded beyond the date of disclaimed patent term.

For example, failure of the PTO to act within 4 months under each of subsections (ii), (iii) and (iv) is charged 1 day for each day after the end of the 4 months.

Acting within 4 months results in 0 days of PTA delay; acting within 4 months and 1 day results in 1 day of PTA delay; acting within 4 months and 100 days results in 100 days of PTA delay; and so on.

Subsection (2)(C)(i) sets forth the fundamental framework for PTA reductions. It defines, and limits, the category of applicant conduct that Congress authorized for PTA reduction as “applicant[’s] fail[ure] to engage in reasonable efforts to conclude prosecution.” Subsection (C)(i) further defines, and limits, the extent to which applicant’s conduct shall result in a patent term reduction as the “period equal to the period of time during which” the applicant failed to engage. This “period equal to the period” language takes its cue from the day-for-a-day calculation for the flip side of PTO delay.<sup>15</sup>

Subsections (C)(ii) sets forth one circumstance of applicant’s failure to engage and illustrates the mechanics of PTA reductions:

(ii) With respect to adjustments to patent term made under the authority of paragraph (1)(B), an applicant shall be deemed to have failed to engage in

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<sup>15</sup> As described herein, application of the PTO’s regulations results in an unbalanced and arbitrary result away from the day-for-a-day structure imposed by the statute. Thus, filing its IDS within the 30-day period is “reasonable efforts” and results in 0 days of applicant delay, and filing within 31 days results in 577 days of applicant delay. But waiting to file within 30 days plus 13 months results in 0 days of applicant delay.



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.*

*Id.* § 154(b)(2)(C)(ii) (emphasis added). Subsection (C)(ii) makes clear that “an applicant shall be deemed to have failed to engage” if the applicant fails to “respond to a notice from the Office” within 3 months “from the date the notice was given or mailed to the applicant.” *Id.*

Consistent with the reasonableness requirement of subsection (i), subsection (ii) confirms that a reduction of term adjustment is only appropriate when, the applicant (1) is on notice, (2) has an ability to engage with the PTO, and (3) fails to engage with the PTO to conclude prosecution. Subsection (ii) also confirms that Congress only intends for the period of PTA reduction to be equal to, and run prospectively from, the time during which the applicant actually fails to engage in concluding prosecution within the specified time. Consistent with subsection (C)(i), which only requires “reasonable efforts,” subsection (C)(ii) does not permit retroactive accrual of negative PTA. Therefore, responding within three months results in 0 days of applicant delay; responding within three months and 1 day results in 1 day of applicant delay; responding within three months and 100 days results in 100 days of applicant delay; and so on. This mirrors the day-for-a-day calculations for PTO delay.

Subsection (C)(iii) authorizes the PTO to promulgate regulations limited to 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). Consistent with subsections (i)-(ii), subsection (iii) confirms that PTA shall be adjusted only for *applicant conduct* that constitutes a failure to engage with the PTO during prosecution. *Gilead*, 778 F.3d 1341 at 1348 (Subsection (iii) “direct[s] the PTO to prescribe *other instances* in which *applicant behavior* that ‘constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.’”) (*quoting* 35 U.S.C. § 154(b)(2)(C)(iii)) (emphasis added). Subsection (iii) provides no authority to redefine the “period of adjustment” already defined in the statute as anything other than the one-to-one correlation established by the statute or reclassify the “period of time during which” applicants failed to engage in reasonable efforts. Subsection (iii) is to be interpreted, and applied consistent, with paragraph (1) and subsections (i) and (ii) of paragraph (2). *See TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001); *Res-Care, Inc. v. United States*, 735 F.3d 1384, 1388 (Fed. Cir. 2013) (“The meaning of the language is determined in the pertinent overall statutory context.”).

**2. Canons of statutory construction confirm that § 154(b)(2)(C)(i) defines the category of applicant conduct warranting reduction and the “period of adjustment”**

The plain language of § 154(b)(2)(C)(i), along with the structure of the PTA, and traditional canons of statutory interpretation, confirm that the PTO is only authorized to reduce PTA for “*a period equal to* the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.” (emphasis added); *see Dunn*, 519 U.S. at 470-478 (considering the overall statute, a canon of statutory construction, and legislative history to ascertain Congress’s intent). Accordingly, when “a court, employing traditional tools of statutory construction, ascertains that Congress had an intention on the precise question at issue, that intention is the law and must be given effect.” *Chevron*, 467 U.S. at 842-43 n.9.

The PTO’s interpretation attempts to enlarge “circumstance that constitutes a failure of an applicant to engage in reasonable efforts” and to redefine the “period of adjustment” in excess of the time period set forth in subsection (C)(i). Such a conclusion runs afoul of several traditional canons of construction that dictate the opposite outcome, *i.e.* that only subsection (C)(i) defines the category of punishable conduct (applicant’s failure to engage in reasonable efforts), and the amount of authorized PTA reduction (only “equal to” the period of time during which the applicant failed).

One such canon of construction is the rule against surplusage. It is “a cardinal principle of statutory construction” that “a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.” *Duncan v. Walker*, 533 U.S. 167, 174 (2001) (internal citations omitted); *United States v. Menasche*, 348 U.S. 528, 538-39 (1955) (“It is our duty ‘to give effect, if possible, to every clause and word of a statute.’”) (quoting *Montclair v. Ramsdell*, 107 U.S. 147, 152 (1883)).

The PTO attempts to rewrite the statute by altering the scope of subsection (C)(i)’s “the period of adjustment” by way of regulation promulgated under subsection (iii). Allowing the PTO’s interpretation to stand requires accepting the PTO’s circular logic that renders (C)(i) surplusage. The PTO’s position is that because subsection (iii) permits the PTO Director to prescribe regulations “establishing *circumstances* that constitute a failure of an applicant to engage in reasonable efforts to conclude [prosecution],” it can also by regulation define the statute’s (C)(i) “period of adjustment” without being limited by (C)(i)’s language or an applicant’s actual conduct. (emphasis added). Specifically, under the PTO’s interpretation, it can redefine “the period of adjustment” by way of subsection (C)(iii) in a manner divorced from the “equal to” “period of time” “during which” “applicant[s] failed to engage” “in reasonable efforts.” Each of these phrases set forth a limitation that is rendered surplusage under the PTO’s interpretation if the

PTO is able to redefine 546 days—during which applicants could not do a thing—as unreasonable delay. The PTO’s interpretation is that the regulation, § 1.704(c)(8), *necessarily* defines the statute. This interpretation cannot stand.

This Court has stated that the “reasonable efforts” language of subsection (C)(i) focuses on “applicant conduct.” *Gilead*, 778 F.3d at 1347. The PTO’s interpretation that subsection (iii) permits promulgation of § 1.704(c)(8), with no regard for the applicant’s actual conduct, thus renders the statute’s “reasonable efforts” limitation superfluous and void. Because the reading proposed by the PTO and seemingly adopted by the district court, contravenes the plain language of the statute and would largely nullify subsection (i), the rule against surplusage supports the conclusion that such a reading is improper.

Traditional canons of statutory construction such as *generalia specialibus non derogant* (“the general does not detract from the specific”) and *expressio unius est exclusion alterius* (“the express mention of one thing excludes all others”) also indicate that subsection (C)(i) is not to be overridden by either the broad language of subsection (C)(iii), or more specific regulatory language purportedly promulgated under the authority of subsection (C)(iii). For example, *generalia specialibus non derogant* requires the implication that the specific period of adjustment limitations set forth in subsection (C)(i) are not to be superseded by subsection (C)(iii), which generally “directs the PTO to promulgate rules of

general applicability.” Appx12. *See Nitro-Lift Techs., L.L.C. v. Howard*, 133 S. Ct. 500, 504 (2012). Similarly, here, *expressio unius est exclusion alterius* stands for the proposition that subsection (C)(i)’s express instruction that the “period of adjustment” “shall” be reduced to a period “equal to” an applicant’s failure to engage in reasonable efforts, excludes any redefining of this reduction period via subsection (C)(iii)’s directive to “establish the circumstances that constitute a failure.” Notably, subsection (iii) is silent to, and therefore does not authorize, any alteration of the PTA “period of adjustment.”

These traditional canons of statutory construction confirm what is understood upon examining the plain language of § 154(b)(2)(C). First, only subsection (C)(i) defines the category of applicable conduct, *i.e.* applicant failure to engage in reasonable efforts to conclude prosecution. Second, only subsection (C)(i) defines the “period of adjustment” based solely on applicant conduct. The PTO cannot by regulation exceed or redefine these statutory limits.

**3. The legislative history confirms that Congress did not intend to levy punitive PTA reductions on appellants for time during which only the PTO could advance examination**

Penalizing applicants for time during which the PTO admits it delayed, and reassigning PTA adjustment to applicants for time during which applicants could not engage in prosecution, runs directly afoul of Congress’s intent in enacting the PTA statute. *See United States Nat’l Bank v. Independent Ins. Agents of Am.*, 508

U.S. 439, 455 (1993) (“Over and over we have stressed that ‘in expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy.’”). The Congressional objective of section 154 was to guarantee a 17-year patent term for any applicant acting diligently. 145 Cong. Rec. H. 6929, at \*43 (Rohrabacher). Specifically, Congress intended to prevent prejudice to patent owners from the transition from a patent term of 17 years running from issuance, to a patent term of 20 years running from the earliest claimed priority date. Under the new system prejudice to the applicant could arise due to circumstances wholly beyond applicants’ control, such as delay by the PTO in examining its application. Reflecting this intent, the Act itself was titled the “Patent Term Guarantee Act.” *Id.*

In both the House and the Senate, it was explained that “no patent applicant diligently seeking to obtain a patent will receive a term of less than [] 17 years” and “[o]nly those who purposely manipulate the system to delay the issuance of their patents will be penalized.” H.R.Rep. No. 106-287, at 48-50 (the purpose of the act is to “compensate patent applicants for certain reductions in patent term *that are not the fault of the applicant.*”) (emphasis added).<sup>16</sup> Congressman Rohrabacher, one of the sponsors in the House, further explained that calculating

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<sup>16</sup> Appellants received only 15.3 years of patent term, following over 8 years of prosecution before the PTO.

PTO delay and reducing it for any time the applicant has delayed prosecution by engaging in dilatory behavior “effectively eliminates the claimed submarine patent dilemma while providing a specific framework from which the Patent and Trademark Office must monitor and compensate the loss of any patent term due to delay for which the applicant has no responsibility.” 145 Cong. Rec. H. 6929, at \*44. These concepts are embodied in section 154(b)(1), which addresses when PTA accrues, and section 154(b)(2), which addresses when accrued PTA can be reduced.

The Federal Circuit has explained that the legislative history of the PTA statute “emphasized that the statute was intended to penalize ‘[o]nly those who purposefully manipulate the system to delay the issuance of their patents.’” *Gilead*, 778 F.3d at 1349 (citing H.R. Rep. No. 106–287, at 50) (emphasis omitted); *see* American Inventors Protection Act of 1999, H.R.1907, 106th Cong. § 302 (1999)); *see also* H.R. Rep. No. 104-784, at 67 (“The intent of the Committee is that only the most egregious and obvious delay tactics will go unrewarded by this provision”).

This Court explained that “Congress’s primary intent was to penalize applicant *conduct* as opposed to the results of such conduct.” *Gilead*, 778 F.3d at 1348 (emphasis in original). In other words, Congress’s intent was to penalize applicants for the time during which their conduct caused, or even conceivably



*could* cause, delay, not for time that has *already passed* during which engaged applicants diligently prosecuted their applications. Nevertheless, the PTO's interpretation requires that the statute authored by Congress reach the opposite result, *i.e.*, "the period of time during which the applicant failed to engage" includes periods during which the applicant was fully engaged and could do nothing more. Such a result contravenes Congress's intent in enacting Section 154(b)(2)(C) and exposes the discrepancy between the PTO's interpretation and the letter of the statute.

Moreover, the PTO's own analysis recognizes the legislative intent in creating a remedial statute to ensure that delays attributable to the PTO would not be charged to the applicant. Upon passage of the Patent Term Guarantee Act, the PTO conducted mandatory notice and rulemaking. During this notice and comment period the PTO responded to questions from stakeholders. In response to these questions the PTO relied on the section-by-section analysis of S. 1948 to explain that the statute "amends the provisions in the Patent Act that compensate patent applicants for certain reductions in patent term that *are not the fault of the applicant.*" 65 Fed. Reg. 56366, 56378 (Sept. 18, 2000) (emphasis added). Additionally, the PTO explains that "[o]nly those who *purposely manipulate the system* to delay the issuance of their patents will be penalized under subtitle D, a result that the Conferees believe entirely appropriate." *Id.* (emphasis added).

Accordingly, and as supported by the plain language of the statute as well as the legislative history, “the period of time during which the applicant failed to engage” should be given its plain meaning and should not be interpreted to include a period during which the applicant is fully engaged and could do nothing more.

The PTO’s interpretation fails to account for the statutory language set forth in § 154(b)(2)(C)(i), the traditional tools of statutory construction, and the legislative history of the PTA statute. In view of the statute, the PTO’s interpretation directly contravenes Congress’s intent. Without first examining the language of the PTA statute and Congress’s intent, the district court was ill-situated to determine whether the PTO’s interpretation conformed to the statute.

### **III. RULE § 1.704(C)(8) IS ARBITRARY, CAPRICIOUS, AND MANIFESTLY CONTRARY TO THE PTA STATUTE**

Even if the PTA statute contained some ambiguity warranting deference under *Chevron* step two, or the statute did not immediately foreclose the PTO’s interpretation, the PTO’s regulations are unreasonable, arbitrary, capricious, and in conflict with the language and intent of 35 U.S.C. § 154(b)(2)(C)(i). *See* 5 U.S.C. § 706(2). *Chevron* step two requires determination of “whether the [PTO’s] answer is based on a permissible construction of the statute. *Chevron*, 467 U.S. at 843. At this stage, the Court considers whether the agency’s actions are arbitrary, capricious, or manifestly contrary to the statute. *See Gilead*, 778 F.3d at 1349; 5 U.S.C. § 706(2).

While Congress delegated authority to “[t]he Director [to] 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,” 35 U.S. C. § 154(b)(2)(C)(iii) (emphasis added), Congress *did not* expressly delegate authority to the Director to redefine the period of adjustment. Specifically, Congress did not expressly delegate authority to the Director to define the period of adjustment in excess of “a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution or the application.” *Id.* at (b)(2)(C)(i). Certainly, Congress did not delegate authority to the Director to define as “circumstances that constitute a failure of an applicant to engage in reasonable efforts” a time period when applicants were not able to act at all.

Despite the statutory limits on the PTO’s authority the PTO’s interpretation purports to not just define “[c]*ircumstances* that constitute a failure of the applicant to engage in reasonable efforts,” but attempts to also define the “reduction of the period of adjustment,” even though that reduction is explicitly defined by § 154 (b)(2)(C)(i). The PTO’s interpretation in this case is inconsistent with the statutory definition. In addition, it is unreasonable, arbitrary, and capricious.

The PTO’s interpretation of subsection (i) permits an invalid assumption in Rule 1.704(c)(8) that the timing of filing a supplemental paper, after a reply has

been filed, is factually and necessarily attributable to unreasonable applicant conduct. It assumes that at the time of filing a reply an applicant could have but failed to file the information contained in a supplemental reply. As shown by this case, that assumption is arbitrary, unfounded, and exceeds the intent of the statute. In circumstances where applicants are penalized despite their reasonable efforts to conclude prosecution, and in excess of any period during which the applicant failed to engage in reasonable efforts, Rule 1.704(c)(8) contradicts the plain language subsection (i) and Congress's purpose in enacting the PTA statute—it is also unreasonable, arbitrary, and capricious. The PTO's interpretation offers no safeguards to ensure that the reduction of PTA is "equal to" delay attributable to the applicant as required by § 154(b)(2)(C)(i).

Indeed, the PTO admitted in its briefing before the district court, "that an inflexible application of this rule would *sometimes unfairly penalize applicants* who only learned of such information after filing (for instance) an RCE . . . ." Appx660 (emphasis added). This is the very situation here. The PTO argued, however that §1.704(d) provides a solution that saves this admitted infirmity with § 1.704(c)(8).<sup>17</sup>

But Section 1.704(d)(1) cannot rescue Rule § 1.704(c)(8) from its admitted

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<sup>17</sup> The district court decided that Rule § 1.704(c)(8) is reasonable because "§ 1.704(d)(1) allows an applicant to file such an IDS without penalty if filed during the stated 30 day grace period." Appx11.

faults where (c)(8) contradicts the scope of adjustment required by statute. Indeed, Section 1.704(d)(1) merely highlights the problem with (c)(8) in at least three ways. First, it does not negate the outcome and assumption in (c)(8) that the filing of an IDS is *per se* unreasonable even where it is timely in accordance with 37 C.F.R. § 1.97 and in satisfaction of an applicant's duty of candor under Rule 56. That is, it creates a tension (and therefore unreasonable, arbitrary, and capricious requirement) where an applicant is following the PTO's rules diligently but nevertheless gets penalized. Second, it contains no protections (such as for example those in 1.704(c)(6)) to prevent an applicant from being penalized for PTO delay. Finally, and most notably, the operation of 1.704(c)(8) undoes any reasonable protections by retroactively and arbitrarily penalizing the applicant. Rule 1.704(d)(1) acknowledges that an applicant cannot act (or fail to act) with an IDS until it receives a communication from a foreign office and explicitly defines the filing of such an IDS as "not [] considered a failure to engage" up until the 30-day period runs. But these protections are decimated by as little as a single day of delay past the 30-day period when it results in transforming a time when applicant could do nothing to "applicant delay" contrary to the statute or from transforming a time explicitly defined as "not [] considered a failure to engage in reasonable efforts" to applicant delay upon missing a specified time frame.

In all other circumstances of time frames to act, a failure to act is charged

against the applicant or the PTO only by a day-for-a-day past the time frame.

Here, a failure to meet the 30-day period by as little as one day results in a forfeit of not just the day of delay, but also a forfeit of the 30-days, and, even more egregiously, a forfeit of all time dating back to an event (the filing of a reply) that admittedly “sometimes unfairly penalizes applicants.” Here, Applicants at most acted unreasonably for the 69 days following the end of the 30-day period and filing of the IDS, but the Applicants are being penalized by over 9 times that delay in contradiction with the statute.

Looking to the other “circumstances” defined by the PTO in Rule 1.704(c) further highlights the problems with Rule 1.704(c)(8). In many Rule 1.704(c) applications the “failure to engage in reasonable efforts” and the “reduction of period of adjustment” will necessarily be the same. Thus, for example where suspension of action is a “failure to engage,” the reduction of PTA is equal to the period of suspension. Rule 1.704(c)(1). Similarly, where abandonment of the application is the “failure to engage,” the reduction of PTA is equal to the period of abandonment. Rule 1.704(c)(3). Indeed, these rules reflect a reasonable day-for-a-day period of adjustment consistent with the PTA statute.

But Rule 1.704(c)(8) goes further. Where submission of a supplemental reply following RCE is the “failure to engage,” the reduction of PTA is defined as “beginning on the day after the date the initial reply [RCE] was filed and ending on

the date that the supplemental reply [IDS] . . . was filed.” 37 C.F.R. § 1.704(c)(8). This “reduction of the period of adjustment” bears no relation to “the period of time equal to the period of time during which the applicant failed to engage in reasonable efforts,” unless the applicant could have but failed to file the supplemental reply, such as an IDS, beginning on the day after the initial reply was filed. That is, the PTO’s definition of the “reduction of the period of adjustment” assumes that the entire time between the initial and supplemental reply is time during which the applicant “failed to engage” because it could have but failed to file the supplemental reply.

This assumption baked into the rule was coincidentally correct in *Gilead* where the applicant actually could have filed its IDS at the time of the reply, but failed to do so. *See* Section IV.C. The PTO’s interpretation, however, can also be wholly improper, as it is here and as the PTO itself admits. Here, the “reduction in the period of adjustment” encompasses not just the period of time when the applicant had information it could have or should have submitted in an IDS, but also encompasses the period of time when the information to submit did not yet even exist and Plaintiffs could do nothing more to “engage in reasonable efforts.” Additionally, the information had only recently been cited permitting a 30-day

period to submit the information without penalty.<sup>18</sup>

By way of illustration, had Applicants filed the IDS on day 31 following the relevant learning of the EPO Communication, their patent term would be nearly two years shorter than if they had filed one day earlier. That is, filing on day 30 would constitute “reasonable efforts” to advance prosecution, but filing on day 31 would not. That 1-day difference would constitute failure to “engage in reasonable efforts” under the PTO’s rules, and would result in a 577-day penalty of patent term in direct contravention to the statute. The PTO’s arbitrary and impermissible “period of adjustment” definition effectively converts from admitted PTO delay to applicant delay a 546-day period when Applicants could do absolutely nothing more to “engage in reasonable efforts.” Likewise, Applicants could have intentionally submitted the IDS far later in time—with their response to the next Office action—and would not have lost any days of PTA. Under no reasonable reading of the PTA statute can 1 day of delay, or for that matter 31 days of delay, be “equal to” the 546 days the PTO charged against Appellants. The PTO’s interpretation is thus directly contrary to the statute and arbitrary and capricious.<sup>19</sup>

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<sup>18</sup> At the time Applicants submitted the IDS, the PTO had already failed to act for more than 21 months and took more than another 9 months after submission of the IDS to take action.

<sup>19</sup> Had the PTO issued an Office Action within the 4 months guaranteed in the statute (or even within 21 months), the Applicants would not be charged the 646 days of delay.



The result of the PTO's regulations is that they penalize applicants for a period of time contrary to statutory language and intent. Under the PTO's interpretation even filing a paper to *expedite* examination would "constitute a failure to engage in prosecution by the applicant." *See* 65 Fed. Reg. 56366 (Comment 35).

This case is thus analogous to the Federal Circuit's findings against the PTO in *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010) and *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014). In *Wyeth*, the Federal Circuit affirmed the district court's finding that the PTO's "strained" interpretation of the statute was contrary to the plain language of the statute: "The problem with the PTO's interpretation is that it considers the application *delayed* . . . during the period *before it has been delayed*." 591 F.3d at 131368-69. Thus, *Wyeth* held that "Section 154(b)'s language is clear, unambiguous, and intolerant of the PTO's suggested interpretation. For that reason, this court accords no deference to the PTO's greater-of-A-or-B rubric." *Id.* at 1372. Analogously, Rule 1.704(c)(8)'s definition of the "reduction in the period of adjustment" as including time before any possible applicant delay is contrary to the statute. Analogously to *Wyeth*, the PTO is considering the application delayed and the applicant conduct unreasonable during a period before the applicant can even take any action.

In *Novartis*, the Federal Circuit similarly rejected PTO regulations that ran contrary to the PTA statute, finding that the reduction of PTA must be corrected.

*Novartis* rejected application of a PTO regulation to reduce PTA, which regulation defined time between allowance to issuance as “time consumed by continued examination,” as contrary to section 154 and where the delay time was “plainly attributable to the PTO.” 740 F.3d at 602. Notably, the Federal Circuit rejected the PTO’s attempt to argue its “general rule” excluding time between allowance and issuance might make sense in certain circumstances where the rule as applied in the present case was not consistent with the statute. *Id.* Here too, the PTO should not be permitted to shift its nearly 2-year admitted delay to an applicant who could do nothing to advance prosecution and, if at all, at most delayed prosecution for 69 days, to deprive the applicant of nearly 2 years of patent term for delay “plainly attributable to the PTO.” *Id.*

If Congress wanted to authorize the PTO to define the appropriate reduction in the period of adjustment or to permit it to enlarge the “equal to” language of the statute, it could easily have done so. But Congress did not. Congress only permitted the PTO to define conduct that is a “failure to engage in reasonable efforts,” not to re-define the “reduction in period of adjustment.” Congress unambiguously defined by statute the “reduction in period of adjustment”—and dictated that it be limited to only that “period equal to the period of time during which the applicant failed to engage in reasonable efforts.” 35 U.S.C. § 154(b)(2)(C)(i).

#### **IV. GILEAD DOES NOT PRECLUDE, BUT SUPPORTS, APPELLANTS' ARGUMENTS**

*Gilead* supports Appellants' arguments that Congress only intended for the PTA statute to reduce PTA for "applicant conduct" for a time "equal to" the period an applicant failed to engage in reasonable efforts to conclude prosecution.

Without identifying the precise question at-issue or examining the plain language of the PTA statute, the district court erred in concluding that *Gilead* "forecloses" the issues presented here. Appx9. *Gilead* does not, and cannot foreclose Appellants' arguments. As an initial matter, *Gilead* presented a distinct legal issue under factual circumstances wholly distinguishable from the facts of Appellants' case.

To the extent the district court relied on the doctrine of *stare decisis* to suggest *Gilead* is controlling, it is incorrect. *Stare decisis* applies only to legal issues "deliberately reached upon full argument" and doe "not preclude examination of new questions." *United States v. Bauer*, U.S. Cust.App. 343, 344 (Ct. Cust. App. 1912); *Beacon Oil Co. v. O'Leary*, 71 F.3d 391, 395 (Fed. Cir. 1995) (finding two issues raised by appellant were not litigated or resolved in a prior case against different claimants who did not make the same arguments). To the extent the district court determined that *Gilead*'s unsuccessful challenge to a PTO regulation nullifies all future challenges to that regulation, it is again mistaken. As explained below, the *Gilead* panel could not have considered—or

decided—the legal issues here, because the facts in *Gilead* did not permit Plaintiff to challenge a PTA reduction in excess of Plaintiff’s failure to engage in prosecution.

**A. *Gilead* presented a different legal issue**

Appellants contest whether the PTO is authorized to reduce PTA for a period exceeding the “period equal to 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 address that issue. The sole issue presented in *Gilead* was “whether a failure to engage in reasonable efforts requires conduct that actually causes delay,” as opposed to threatened delay. 778 F.3d. at 1349 (emphasis added); *Id.* at 1346 (“Gilead argues the PTA statute only allows for adjustments in instances where the applicant’s conduct ‘*actually delays* the conclusion of prosecution.’”). Appellants’ case does not rely on, and cannot be foreclosed by, the question of whether an applicant’s delay must in-turn cause “actual delay” for PTA to be reduced.

The difference between Appellants’ case and *Gilead* is illustrated by Congress’s primary intent in enacting the PTA statute. As explained by this Court, “Congress’s primary intent was to penalize applicant *conduct* as opposed to the results of such conduct.” *Id.* at 1348 (emphasis in original). Congress’s intent was fatal to *Gilead*’s legal theory that applicant delay causing no actual delay in

prosecution could not justify PTA reduction. The Federal Circuit rejected Gilead's interpretation of the PTA statute, explaining that it is the *applicant's conduct* that is the basis for PTA penalty. *Id.* at 1347 (citing 35 U.S.C. § 154(b)(2)(C)(i)) (“the statute’s ‘reasonable efforts’ language focuses on applicant conduct as opposed to the results of such conduct.”); *Id.* at 1349-50. Because Gilead in fact had the ability to engage in prosecution during the entirety of its contested 57 days, but failed to engage, this Court concluded that its conduct warranted a reduction of PTA, whether or not its conduct actually caused delay. Appellants do not here disagree with the holding in *Gilead*—Appellants’ arguments do not depend on any distinction between actual and threatened delay.

**B. Gilead did not challenge the PTO’s interpretation based on the PTA statute’s “period equal to the time” language**

Gilead’s “actual delay” theory was not grounded in the text of the statute. This Court in *Gilead* acknowledged “Gilead ‘d[id] not contend that the plain language of the statute answers the precise question at issue’.”<sup>20</sup> 778 F.3d at 1347. *Gilead* did not address, and therefore cannot foreclose a challenge based on the “equal to” the “period of time” “during which” the applicant “failed to engage in reasonable efforts” text of the PTA statute. Gilead also did not argue that the PTO’s regulations are directly inconsistent with this language of the statute.

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<sup>20</sup> Moreover, this Court determined that “nothing in the plain language of the statute [supports Gilead’s argument].” *Id.*

Indeed, Gilead could not challenge the “equal to” period of adjustment as being in excess of the time “during which” it failed to engage in prosecution because Gilead had notice of its *own* copending applications, and the ability to file an IDS, during the entirety of the PTA assessed. Accordingly, Gilead was forced to argue that its delay in filing the IDS disclosing its copending applications should not reduce PTA because it caused no “actual delay.”

Gilead also failed to show that the legislative history supported its “actual delay” interpretation. For example, this Court concluded that the legislative history “emphasized that the statute was intended to penalize ‘[o]nly those who purposefully manipulate the system *to delay the issuance of their patents.*’” *Id.* at 1349 (emphasis in original). Thus penalizing Gilead was consistent with Congress’s intended purpose because Gilead could have purposefully withheld the IDS disclosing its copending application for the entirety of the time it failed to engage in reasonable efforts, whether or not they caused actual delay. Appellants’ conduct, however, could not have purposefully manipulated the system to delay the issuance of their patents, because Appellants could not in fact have done *anything* to engage in prosecution during at least 546 days of the period in question.

Accordingly, here, unlike in *Gilead* the PTO unfairly penalized Applicants not for their *conduct*, but instead for a time period when Applicants could do nothing. In other words, the PTO interprets the PTA statute as not only addressing

“applicant conduct” or applicants that “failed to engage,” but also fully engaged applicants diligently prosecuting their applications that, due to no conduct of their own, have circumstances arise that could potentially cause delay. The PTO’s interpretation is unsupported by the statute’s plain language, the holding in *Gilead*, the statute’s legislative history and even the PTO’s implementing guidance.

**C. The factual circumstances underlying *Gilead* are wholly distinguishable from the facts of Appellants’ case**

Unlike Appellants, Gilead was able to further prosecution during the entirety of the time it was charged applicant delay. The Plaintiff in *Gilead* had notice of information necessary to disclose to the PTO, the ability to engage with the PTO, and nonetheless failed to engage in any efforts to conclude prosecution. Appellants on the other hand were assessed PTA for time during which nothing more could have been done to conclude prosecution.

Gilead’s ability to act and failure to engage doomed its PTA challenge. In relevant part, on November 18, 2009, the PTO issued a restriction requirement on Gilead’s application. Gilead responded to the restriction requirement on February 18, 2010, and selected one of the four groups of inventions for examination. *Id.* at 1345. “While waiting for the PTO to issue a first office action on the merits, Gilead filed a supplemental information disclosure statement (“IDS”) on April 16, 2010, which disclosed two other co-pending Gilead patent applications.” *Id.* After issuing a notice of allowance the PTO reduced Gilead’s patent term for the period

between Gilead's initial reply to the restriction requirement and its filing of the supplemental IDS on April 16, 2010.

Gilead thus created the circumstances by which it failed to reasonably engage in efforts to conclude prosecution of its application. The PTO's reduction of term adjustment in *Gilead* was consistent with subsections § 154(b)(2)(C)(i-iii) because the Plaintiff was (1) on notice, (2) had the ability to engage with the PTO, and (3) failed to engage with the PTO to conclude prosecution. In other words, it was the "applicant's conduct" that was found to be unreasonable. These factual circumstances were relied on and highlighted by the district court in *Gilead*:

Tellingly, at no point does Gilead attempt to explain why it did not include the information relating to *its own co-pending applications* when it replied to the restriction requirement, opting instead to wait fifty-seven days before notifying the USPTO of information it had been in possession of for approximately a year prior. Notwithstanding its theoretical argument about hypothetical non-delays, *Gilead fails to show how its failure to disclose this information when it initially responded to the restriction requirement was reasonable.*"

*Gilead Scis. Inc., v. Rea*, 976 F. Supp. 2d 833, 837 n.2. (E.D. Va. 2013) (emphasis in original, emphasis added). Accordingly, in *Gilead*, the Plaintiff was not only aware of the information to be disclosed to the PTO, but chose not to disclose that information concurrently with its initial reply to the PTO's restriction requirement. The entirety of Gilead's delay falls within § 154(b)(2)(C)(i) because the reduction of patent term is, 1:1 day-for-a-day, "equal to" the period during which the applicant failed to engage in reasonable efforts to conclude prosecution of the



application. § 154(b)(2)(C)(i). The entirety of Gilead’s conduct also falls within § 1.704(c)(8), because there is no discrepancy between Gilead’s ability to engage in reasonable efforts to conclude prosecution and the entirety of the time charged pursuant to § 1.704(c)(8), since Gilead could have filed its IDS “beginning on the day after the date the initial reply was filed and ending on the date that the supplemental [paper] was filed.” § 1.704(c)(8).

The ability for Gilead to engage with the PTO in reasonable efforts to conclude prosecution—during the entirety of time that PTA was reduced—is in stark contrast to the facts here. Appellants had no knowledge of additional information to disclose to the PTO until at least 567 days after its initial reply. Applicants were only able to engage in reasonable efforts to conclude prosecution *after* it received information from a third party via the Sandoz Opposition. Accordingly, a vast discrepancy exists between Appellants ability to “engage in reasonable efforts to conclude prosecution” and the entirety of the time charged pursuant to § 1.704(c)(8), since Appellants could *not* have filed its IDS “beginning on the day after the date the initial reply was filed and ending on the date that the supplemental [paper] was filed.” The plain language of the PTA statute alone, and reinforced by Congress’s intent in enacting the statute, distinguishes these circumstances from *Gilead*.

## CONCLUSION

For these reasons, Appellants Supernus and United Therapeutics Corporation respectfully request that this Court reverse the district court's Order and restore, at a minimum, 546 days of patent term to the '897 patent. Beyond that, at least one additional day should be granted due to the PTO's admission that Applicants could not act until receipt of the EPO Communication. Appx608 at n.16. Still further, the 30-day period of § 1.704(d)(1) should be restored because the PTO explicitly defines that time as not unreasonable.

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Respectfully submitted,

*/s/Douglas Carsten*

WILSON SONSINI GOODRICH & ROSATI  
Attorney for Plaintiff-Appellants  
*Supernus Pharmaceuticals, Inc., and  
United Therapeutics Corporation*