

No. 17-1357

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

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.

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

**REPLY 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*

June 7, 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 and owns 10 percent or more of Supernus Pharmaceuticals, Inc. 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.

June 7, 2017

/s/Douglas H. Carsten
Douglas H. Carsten
WILSON SONSINI GOODRICH & ROSATI
Attorney for Plaintiffs-Appellants
*Supernus Pharmaceuticals, Inc., and
United Therapeutics Corporation*

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INTRODUCTION

The PTO fails to give effect to the plain language of the PTA statute in favor of elevating the PTO's own regulations over Congressional intent. Thus, the PTO fails to address the question at issue and highlights the PTO's prejudicial error.

The PTO disagrees with the most basic aspects of the PTA statute. For example, 35 U.S.C. § 154(b)(2)(C)(i) unambiguously states that patent term “shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts” Each of these words, chosen by Congress, is to be understood by its plain and easily discernable meaning in order to give the statute its intended effect. The PTO, however, fails to give any legal effect to these terms. Tellingly, the PTO's framing of its “precise question” admits that the PTA charged against Appellants is not—*in fact*—“equal to the period of time during which the applicant failed to engage in reasonable efforts.” In other words, the PTO admits that it reduced Appellants' patent term in excess of the period “equal to” the amount of time “during which” applicants “failed to engage in reasonable efforts.”¹ Faced with statutory language that exposes the PTO's contrary practice, the PTO largely relies on policy arguments not raised in the record. However, no PTO

¹ The PTO concedes that applicants only fail to engage in “reasonable efforts” for the time “more than 30 days after the applicant came into possession of the information,” meaning 70 days (100 days from the EPO Communication minus the PTO's 30 day allowance). Red Br. at 29-30; *infra* n.2.

policy “choice” can excuse such a stark disconnect between an agency’s practice and the fundamental requirements of the agency’s authorizing statute.

Under the plain language of the statute, and even the PTO’s own “precise question,” applicants can only fail to engage in “reasonable efforts” from, at earliest, the time an applicant possesses information it could potentially disclose.² At most, for Appellants, this period is 100 days – from August 21, 2012, when the EPO communication issued, to November 29, 2012, when Applicants filed its IDS with the PTO. The PTO, however, reduced Applicants’ patent term by 546 days, 426 days (from June 22, 2011 to August 21, 2012) of which the PTO itself admits delay. Undaunted by this contradictory juxtaposition of statutory language and agency practice, the PTO urges this Court to affirm its practice of reducing applicants’ patent term for a period *in excess* of the time an applicant failed to engage in reasonable efforts to advance prosecution. The PTO’s erasure and reassignment of admitted PTO delay as fictional applicant delay, when the applicant could do nothing to advance prosecution, is contrary to law.

² The PTO’s “precise question” is “whether an applicant’s filing of a post-RCE IDS, more than 30 days after the applicant came into possession of the information it is disclosing through that IDS, constitutes a ‘failure of [the] applicant to engage in reasonable efforts to conclude processing or examination of an application.’” Red Br. 29-30. Thus the PTO acknowledges that an applicant only fails to engage in reasonable efforts upon filing a post-RCE IDS “more than 30 days after the applicant came into possession of the information.”

The PTO focuses its case on Section 1.704(d)(1)—despite the agency having decided the case under Section 1.704(c)(8)—the PTO thus shortcuts its analysis and fails to fully respond to many of Appellants’ Section 1.704(c)(8) arguments. In order to reconcile the divergent views of the appeal, Appellants first directly reply to the PTO’s “Summary of Argument.” Second, Appellants address critical aspects of the appeal that the PTO does not contest. Finally, Appellants establish that the PTA statute sets the bounds of the PTO’s rules and respectfully requests this Court to correct the PTO’s practice where its PTA reduction under Section 1.704(c)(8) exceeds those Congressionally mandated bounds.

ARGUMENT

I. The PTO’s Argument Avoids the Relevant Issue

First, as discussed above, the PTO’s “precise question” side-steps the dispositive issue on appeal. Specifically, the PTO assumes that it has the authority to define a period of time during which applicants could do nothing more to advance prosecution as applicant’s “fail[ure] to engage in reasonable efforts.” This runs counter to the plain language of the statute, the legislative history, and *Gilead*. *Gilead Sciences, Inc. v. Lee*, 778 F.3d 1341, 1347 (Fed. Cir. 2015) (“the statute’s ‘reasonable efforts’ language focuses on *applicant conduct* as opposed to the results of such conduct.”) (emphasis added) (citing 35 U.S.C. § 154(b)(2)(C)(i)). The PTO proposes a “precise question” that asks “whether an applicant’s filing of

a post-RCE IDS, more than 30 days after the applicant came into possession of the information it is disclosing through that IDS, constitutes a ‘failure of [the] applicant to engage in reasonable efforts to conclude processing or examination of an application.’” Red Br. at 29-30 (citing 35 U.S.C. § 154(b)(2)(C)(iii)).

Importantly, the question implicitly concedes that it is only an applicant’s failure to engage in reasonable efforts when filing a post-RCE IDS “more than 30 days after the applicant came into possession of the information.” Red Br. at 29.

But the PTO’s framing avoids the fundamental issue – whether the PTO’s actions are consistent with the statute, which must be the starting point of the analysis. The PTO asks only whether it duly promulgated a regulation, not whether that regulation, and its application, is consistent with the plain language of the statute. Even when answered in the affirmative, the PTO’s question fails to answer the question on appeal – how much reduction of patent term does the statute permit and has the PTO exceeded its statutory authority? The PTO’s question concedes that applicants only fail to engage upon “30 days after . . . *c[oming] into possession* of the information it is disclosing through that IDS” *Id.* at 29 (emphasis added). Indeed, even before the district court, the PTO admitted that “under the plain language of the PTA statute, any and all deductions of PTA must be ‘equal’ to ‘the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.’” Appx653

(citation omitted). Accordingly, when applying the PTA statute, any term reduction should be “equal to” the period of failure beyond the 30 days, here 70 days. Certainly, at most, no reduction should exceed the time during which the applicant was in possession of the new prior art and submitted the IDS, here, at most 100 days. *See* 35 U.S.C. § 154(b)(2)(C)(i) (“The period of adjustment . . . 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.”). *See infra* Part III.B.

The PTO’s second and fourth points that “Section 1.704(d)(1) is ultimately [] fatal to the entirety of [Appellants’] claims” is legally flawed. Red Br. at 28. The PTO’s June 10, 2014 “Decision on Patent Term Adjustment” stated that “[t]he Office’s position remains the same” and held that “[t]he 646-day reduction is warranted pursuant to 37 C.F.R. § 1.704(c)(8).” Appx535. As support for its determination, the PTO cited *Gilead* stating “the Federal Circuit determined that submission of an IDS after the filing of a response to an election or restriction requirement is a reduction under 37 CFR 1.704(c)(8).” *Id.* It is this PTO decision that is under review. *See Power Integrations, Inc. v. Lee*, 797 F.3d 1318, 1326 (Fed. Cir. 2015) (citing *Camp v. Pitts*, 411 U.S. 138, 142 (1973) (“emphasizing that under the APA, ‘the focal point for judicial review should be the administrative record already in existence, not some new record made initially in

the reviewing court”). Accordingly, Section 1.704(c)(8) is the operative regulation under which the PTO decided Appellants’ case and despite the PTO’s attorney argument, this appeal does not rest on the application of Section 1.704(d)(1).³ “We have no warrant to ‘accept [the government’s] appellate counsel’s *post hoc* rationalizations for agency action, or to supply a reasoned justification for an agency decision that the agency itself has not given.” *Power Integrations*, 797 F.3d at 1326 (citations omitted).

The PTO argues that Appellants “waived” Section 1.704(d)(1) argument, however, the agency did not decide this case on Section 1.704(d)(1) grounds. The PTO cannot have it both ways arguing, on the one hand, that Plaintiffs raised the Section 1.704(c)(8) but waived any discussion of Section 1.704(d)(1), and on the other hand that Section 1.704(d)(1) and Section 1.704(c)(8) “must be read in tandem.” Red Br. at 49; *see also id.* at 50 (“Section 1.704(c)(8) (and qualified by Section 1.704(d)(1))”). *See infra* Part III.D.

Third, *Gilead* does not control the outcome of this case. As discussed at length in Appellants’ opening brief (Bl. Br. at 52-58), the Court in *Gilead* did not consider whether the PTA statute authorizes the PTO to sanction applicants in

³ To the extent the Court considers Section 1.704(d)(1)’s effect on Section 1.704(c)(8), the purported reasonableness of Section 1.704(d)(1) cannot cure Section 1.704(c)(8)’s punitive effect, admitted infirmity, and direct conflict with Section 154(b)(2)(C)(i). *See* Bl. Br. at 5 n.2, 45-46; Red Br. at 39.

excess of the time during which the applicant failed to engage in reasonable efforts. In *Gilead*, this Court held that “Congress intended to sanction not only applicant conduct or behavior that result in actual delay, *but also those having the potential to result in delay* irrespective of whether such delay actually occurred.” *Gilead*, 778 F.3d at 1349 (emphasis added). Here, there was no Applicant delay or potential for delay prior to issuance of the EPO communication that could feasibly “force[] an examiner to *go back* and review the application again[.]” *Id.* at 1350 (citation omitted); Red Br. at 28.

The PTO thus essentially argues that *Gilead* created a new standard and enlarged the statute’s grant of authority. Though the statute permits 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,” (35 U.S.C. § 154(b)(2)(C)(iii)) the PTO reads *Gilead* as granting it the authority to read out of the statute the requirement of unreasonable applicant conduct and reduces patent term in excess of any alleged conduct. This Court has never concluded that the PTA statute authorizes such punitive sanctions. Unabated, the PTO sanctioned applicants for 456 days before it had any ability or potential to delay prosecution. *See infra* Part III.C.

In this sense, this case falls squarely within the reasoning in *Wyeth* and *Novartis* where this Court found the PTO’s redefinitions of delay to be wholly

inconsistent with the statutory language. Except to dismiss the cases summarily as irrelevant, the PTO did not even address them, assuming as the underpinning of its entire argument that the PTO's rules are immutable.

But this Court has held otherwise. In *Wyeth*, this Court declined to give deference to the PTO's regulations as clearly contrary to Section 154(b)'s clear and unambiguous language. *Wyeth v. Kappos*, 591 F.3d 1364, 1370 (Fed. Cir. 2010) (“The problem with the PTO's interpretation is that it considers the application delayed . . . during the period *before it has been delayed*.”) (citation omitted). Similarly, in *Novartis*, the PTO's regulations defined time directly contrary to Section 154. *Novartis AG v. Lee*, 740 F.3d 593, 602 (Fed. Cir. 2014) (rejecting application of 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.”).

Lastly, Appellants do not request—and this case does not require—“case-by-case or *ad hoc* PTA calculations.” Red Br. at 29. To the contrary, this case only requires that the PTO's “general rules of categorical application” be consistent with the PTA statute. *Id.*; *see, e.g., Novartis*, 740 F.3d at 602. As discussed below, the PTA statute does not permit punitive sanctions that reduce patent term by more time than the period during which applicants could have, but

failed to, engage in reasonable efforts to conclude prosecution. Notably, the PTO's rules *require* it to ascertain the date on which a communication "was issued by a patent office in a counterpart foreign [application]" (37 C.F.R § 1.704(d)(1)(ii)) yet the PTO turns a blind eye to this date when applying its general rules that calculate a starting time for when an applicant could reasonably engage in efforts to conclude prosecution. This is contrary to statute. 35 U.S.C. § 154(b)(2)(C)(i). *See infra* Part III.D-E.

II. The PTO Does Not Contest Critical Aspects of this Appeal

The PTO offers no response to several arguments that expose critical deficiencies in the PTO's statutory interpretation, thus requiring reversal. As an initial matter, the PTO does not, and cannot, point to conduct before August 21, 2012 that Applicants could have taken to further engage in prosecution. In fact, the PTO admitted as much on summary judgment.⁴ Accordingly, pursuant to Section 154(b)(2)(C)(i), Applicants could not and did not in fact "fail to engage in reasonable efforts to conclude prosecution of the application" during this period. At most, Applicants only could have "fail[ed] to engage" for 100 days from

⁴ *See* Plaintiffs' Undisputed Fact No. 9, Appx552-553 ("From the filing of the RCE on February 22, 2011 at least until the August 21, 2012 EPO communication, the applicant could take no further action to advance or conclude prosecution."). The PTO further admitted that the vast majority of this period comprised its own delay (Appx535) ("Patentee and the Office are now in agreement regarding the amount of 'A' delay . . .").

August 21, 2012 (EPO communication issued) to November 29, 2012 (IDS filed at the PTO). The PTO's interpretation, which reduces Appellants' patent term by 456 additional days, amounts to punitive sanctions unsupported by statute. The PTO does not contest the punitive nature of its calculation.⁵

Underlying this punitive effect is Section 1.704(c)(8)'s attempt to replace the statute's defined "period of adjustment" with the PTO's alternate definition of the "period of adjustment." Specifically, in circumstances set forth under (c)(8), the rule attempts to redefine the "period of adjustment" as a period equal to "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." 37 C.F.R. § 1.704(c)(8).⁶ Nowhere in its brief does the PTO address this dispositive language. In circumstances where an applicant could not have been aware of information to be disclosed in the initial reply, Section 1.704(c)(8)'s alternate "period of adjustment" *necessarily exceeds* the "period of adjustment" set by statute. 35 U.S.C. § 154(b)(2)(C)(i) ("The period of adjustment . . . *shall be* reduced by a period *equal to* the period of time during which the applicant *failed to*

⁵ In fact, as addressed further in Part III.C., *infra*, the PTO embraces the "punitive" and "harsh" reality of its regulations in arguing that statutes of limitation and rules of forfeiture must function in this way.

⁶ "The regulation constitutes only a step in the administrative process. It does not, and could not, alter the statute." *Dixon v. United States*, 381 U.S. 68, 74-75 (1965).

engage in reasonable efforts to conclude prosecution of the application.”) (emphasis added). The PTO offers no argument defending this regulatory usurpation of statutory text and Congressional intent.⁷

Moreover, the PTO attempts to avoid this Court’s directive that Section 154(b)(2)(C)(i)’s “reasonable efforts” language has legal significance independent of subsection (iii). Red Br. at 48. Specifically, “the statute’s ‘reasonable efforts’ language focuses on applicant conduct as opposed to the results of such conduct.” *Gilead*, 778 F.3d at 1347 (citing 35 U.S.C. § 154(b)(2)(C)(i)). Accordingly, the statute’s “reasonable efforts” language must be given effect in subsection (iii) “circumstances,” including Appellants’ Section 1.704(c)(8) circumstance. The PTO’s position—that the PTO need not focus on applicant conduct in this circumstance—is not only an affront to the holding of *Gilead* and the plain language of the statute, but it is also belied by the PTO’s own prior position in *Gilead*. See *Gilead*, 778 F.3d at 1347; PTO’s *Gilead* Red Br. at 32-33 (arguing that the “reasonable efforts to conclude prosecution” provision is understood by

⁷ Section 1.704(c)(8)’s “period of adjustment” also exceeds any arguable gap-filling authority under § 154(b)(2)(C)(iii) and therefore is entitled to no deference. See *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 213-14 (1976) (“The rulemaking power granted to an administrative agency charged with the administration of a federal statute is not the power to make law. Rather, it is the power to adopt regulations to carry into effect the will of Congress as expressed by the statute.”) (citation omitted).

“the plain statutory text, which focuses on the *actions* of the applicant and not the *results* of those actions.”).

The PTO now argues that it is only required to consider applicant conduct “*as a general matter*” that “ha[s] a *tendency* to interfere with the agency’s efforts to complete examination, regardless of whether that potential is borne out[.]” Red Br. at 48. This reasoning is insufficient. The PTO’s rules must be measured against subsection (iii)’s “circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application” in light of subsection (i). 35 U.S.C. § 154(b)(2)(C)(iii). The PTO, however, attempts to write out subsection (iii)’s requirements by creating its own standard by which its actions are measured. *See, e.g.*, Red Br. at 11 (“Congress expressly delegated to the USPTO both the authority and the mandatory responsibility to ‘establish[]’ all other ‘circumstances’ of applicant conduct that merit a reduction in PTA.”) (citations omitted); Red Br. at 31 (“*expressly delegates* to the USPTO both the authority and the mandatory responsibility to ‘prescribe regulations establishing the [additional] circumstances’ *that qualify for such treatment.*”) (second emphasis added) (quoting 35 U.S.C. § 154(b)(2)(C)(iii)). Congress plainly did not expressly delegate to the PTO the authority to define without limit circumstances “that qualify for such treatment,” “merit a reduction,” or “have a tendency to interfere.” Red Br. at 31, 48. Instead, Congress limited

such circumstances to those “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).

The PTO relies on its role of creating rules of general applicability, but has no answer for why it can disregard the statutory requirements where an applicant could not fail to engage as “a general matter.” Red Br. at 48. The PTO’s argument is also misleading because similarly situated applicants have no tendency and no potential to delay prosecution before possessing information by which applicants could conceivably fail to engage. Despite the PTO’s change of heart since *Gilead*, it must still account for the statute’s plain “reasonable efforts to conclude prosecution” language and focus on applicant conduct as the starting point for any PTA reduction. *Gilead*, 778 F.3d at 1347 (citing 35 U.S.C. § 154(b)(2)(C)(i)). “[A]n agency’s interpretation of a statute or regulation that conflicts with a prior interpretation is entitled to considerably less deference than a consistently held agency view.” *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 515 (1994) (citation omitted).

III. Congress Established the Period of PTA Adjustment and Category of Circumstances that Qualify for PTA Reduction

A. A Matter of Statutory Construction

The parties agree that “this case presents a question of statutory interpretation[.]” Red Br. at 29. As such, the dispositive question is purely legal

and entitled to *de novo* review. *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1281 (Fed. Cir. 2005). To the extent the PTO’s interpretation is in excess of statutory authority, arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, this Court must set it aside. 5 U.S.C. § 706(2)(A), (C). The PTO argues that “[t]he standard of review is ‘narrow’[.]” Red Br. at 24 (quoting *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971)). It is not.⁸ Instead, this Court “is the final authority on issues of statutory construction and must reject administrative constructions which are contrary to clear congressional intent.” *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 n.9 (1984) (citation omitted). Accordingly, a proper analysis must first appreciate the plain meaning of the statute while utilizing traditional tools of statutory construction to ascertain Congress’ intent. *Id.* at 842-43.

The PTO prefers to explain the meaning of the statute through the lens of its promulgated regulations, but this turns the analysis on its head. *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.”) (citation omitted). Specifically, the purpose of the PTA statute is to “compensate patent

⁸ The “narrow” standard of review addressed in *Citizens* relates only to the “inquiry into the facts.” *Citizens*, 401 U.S. at 416. Here, the facts related to the calculation of PTA under 35 U.S.C. § 154(b) for the ’897 patent are undisputed. *See, e.g.*, Bl. Br. at 5-7.

applicants for certain reductions in patent term that are not the fault of the applicant.” H.R. Rep. No. 106-287, at 48-50 (1999); *Novartis*, 740 F.3d at 596 (stating that the PTA statute provides “extensions of patent terms to compensate for certain application-processing delays caused by the PTO.”) (citation omitted). This purpose is expressly reflected through the statute’s legislative history, the statute’s title (“The Patent Term Guarantee Act”), the statute’s basic framework of extending patent term by one day for each day of patent office delay (§ 154(b)(1)(A)), and more specifically § 154(b)(2)(C)’s text. The PTO refuses to defend the language and effect of Section 1.704(c)(8) within the framework of the pertinent statutory context.

B. The PTA Statute Limits The PTO’s Authority

As every question of statutory interpretation must, the proper legal analysis must start with, and be grounded in, the statute. *United States v. Hohri*, 482 U.S. 64, 69 (1987). 35 U.S.C. § 154(b)(2)(C)(i) mandates:

(C) Reduction of period of adjustment.--

(i) The period of adjustment of the term of a patent under paragraph (1) shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.

Under the first step of *Chevron* the Court must determine whether Congress has answered the “precise question at issue.” *Chevron*, 467 U.S. at 842-43. The PTO argues that the “precise question” is “whether an applicant’s filing of a post-RCE

IDS, more than 30 days after the applicant came into possession of the information it is disclosing through that IDS, constitutes a ‘failure of [the] applicant to engage in reasonable efforts to conclude processing or examination of an application.’”

See Red Br. at 29-30 (quoting 35 U.S.C. § 154 (b)(2)(C)(iii)).

First, as discussed above, the PTO’s formulation concedes that applicant’s failure to engage in reasonable efforts only begins upon coming “into possession of the information it is disclosing.” Accordingly, because Section 154(b)(2)(C)(i) only permits patent term reduction “equal to” this “failure to engage,” PTA only accrues from this applicant conduct. The PTO has reduced Applicants’ patent term for a year and a half more than a period “equal to” this time. Accordingly, the PTO’s question either concedes that the PTO impermissibly began accruing PTA before Applicants could have delayed, or the PTO’s precise question is incomplete. Second, and relatedly, the PTO’s “precise” question—even answered in the affirmative—fails to dispose of the critical question of this appeal, *i.e.*, whether PTA may be reduced for a period exceeding “time during which the applicant failed to engage in reasonable efforts to conclude prosecution.”

The PTO attempts to justify its regulatory scheme by arguing that the statute expressly authorizes the PTO to fill a gap. Red Br. at 27. Section 154(b)(2)(C)(iii), however, merely permits the PTO to “establish[] the circumstances,” or instances, of conduct that constitute a failure of an applicant to

engage. There is absolutely no support—in the statute’s text, legislative history, or reason—that authorizes the PTO to paradoxically define a period of time when an applicant *could not yet engage* as a “fail[ure] to engage” in “reasonable efforts.” 35 U.S.C. § 154(b)(2)(C)(i). At least this much is “*manifestly self-evident*” from the statute. Red Br. at 32.

The PTO’s *Chevron* Step 1 analysis is nearly nonexistent and simply interprets Section 154(b)(2)(C)(i) as a “general rule” that is “*silent*” as to what “type(s)” of applicant behavior constitute applicant delay. Red Br. at 30. Despite its repeated assertions, the PTO cannot seriously contend that Section 154(b)(2)(C)(i) is “*silent*” as to the “types” of behaviors to which Section 154(b)(2)(C) applies. Read together, as they must be, Section 154(b)(2)(C)(i) limits subsection (iii) by creating a Congressionally mandated floor that defines “circumstances” as those where (1) the applicant “failed to engage,” in (2) “reasonable efforts.” 35 U.S.C. § 154(b)(2)(C)(i). The application of Rule 1.704(c)(8) to circumstances when an applicant—admittedly and categorically—*could not* have failed to engage in reasonable efforts is thus *ultra vires*.

The PTO’s interpretation characterizes subsection (i) as only “creat[ing] a statutory gap.” Red Br. at 30. By characterizing the entirety of subsection (i) as a gap with no other significance, the PTO effectively reads out subsection (i) in favor of subsection (iii), thus eviscerating a Congressionally-mandated check to the

PTO's rule making authority. Even if Congress intended a delegation of broad authority, that authority is not limitless and Congress' words are not meaningless.

As this Court explained, Section 154(b)(2)(C)(iii) only permits the PTO to "prescribe other instances" of applicant's failure to engage, it does not allow the PTO to define an applicant's engaged behavior as a failure to engage. *Gilead*, 778 F.3d at 1348. It certainly does not allow the PTO to inflate the statutorily defined "period of adjustment" set forth in subsection (i). *See infra* Part III.C. And it does not allow the PTA to read the requirement of unreasonable applicant conduct out of the statute in favor of a nebulous new standard of circumstances with a potential or "tendency to interfere with the agency's ability to move examination forward." Red Br. at 36. To accept the PTO's statutory interpretation is to accept the conclusion that the agency's power to reduce patent term is unlimited.

The PTO also does not argue that traditional canons of construction or the statute's legislative history support its arguments. In fact, notably, the PTO fails to take account of either mandatory tool of statutory interpretation in this statutory construction case. The PTO instead primarily relies on *Gilead*. Appellants have addressed *Gilead* at length showing that this Court did not and could not reach the dispositive issues of this appeal in *Gilead*. *See* Bl. Br. at 52-58; *supra* Part I. Further, it is clear that the PTO's interpretation of *Gilead* is fundamentally flawed. First, the PTO argues that this Court upheld "*as a categorical matter*" the

reasonableness of Section 1.704(c)(8). Red Br. at 36.⁹ The PTO further argues, without considering the punitive circumstances raised in this appeal, that this Court categorically “upheld” that “Section 1.704(c)(8) appropriately penalizes such applicant conduct.” Red Br. at 36.¹⁰ Not so. The Court only reviews and decides, the issue raised in the administrative record. *In re Gartside*, 203 F.3d 1305, 1314 (Fed. Cir. 2000) (emphasizing that “[t]he record before us on appeal thus dictates the parameters of our review.”).

C. The PTO’s Unauthorized Punitive Sanction is Contrary to Statute, Arbitrary, Capricious, and an Abuse of Discretion

The PTO cites no statutory authority that permits punitive repercussions for applicant delay. And of course none exists because Congress did not contemplate, much less authorize, the PTO to promulgate draconian repercussions in the applicant friendly “Patent Term Guarantee Act.” As the statute’s foundational framework, the PTA statute provides that where delay is “due to the failure of the Patent and Trademark office” “the term of the patent shall be extended 1 day for each day” of delay. 35 U.S.C. § 154(b)(1). As a limited exception, Congress set forth a specific period of adjustment for *unreasonable* applicant delay. *See* 35

⁹ Notably, the PTO fails to cite any page or specific language in *Gilead* to support this ambitious conclusion.

¹⁰ The Court in *Gilead* did not consider a circumstance where Section 1.704(c)(8)’s “period of adjustment” had punitive effect by extending to a period in excess of a period equal to that of applicant’s failure to engage.

U.S.C. § 154(b)(2)(C)(i). Further, subsection (iii) permits the PTO to promulgate “circumstances” that constitute a failure of an applicant to engage in reasonable efforts to conclude prosecution of its application. *See* 35 U.S.C. § 154(b)(2)(C)(iii). Where a rule promulgated pursuant to subsection (iii) purports to retroactively define as unreasonable “the period of time during which” the PTO *admits* the applicant was fully engage to conclude prosecution, the rule is not only contrary to statute, but also arbitrary, capricious, and an abuse of discretion.

The PTO acknowledges the “conceded limitations of Section 1.704(c)(8)” and then appears to embrace them as “necessarily . . . harsh[] and arbitrar[y],” akin to statutes of limitation and deadlines that result in forfeiture of rights for “individuals who fall just on the other side of them.” Red Br. at 43, 49 (citation omitted). The PTO asserts that “[r]egulation, like legislation, often requires drawing lines,” but Congress has not authorized the PTO to draw “lines” with punitive repercussions that reduce patent term in excess of the “period equal to the period of time during which the applicant failed to engage in reasonable efforts.” *Id.* at 30, 46 (citations omitted). The PTO only has the authority to “establish[] the circumstances” under § 154(b)(2)(C)(iii).

The fact that the PTO promulgated Section 1.704(c)(8) with “conceded limitations” does not permit the PTO to subsequently concoct a “fix” that falls short of curing all Section 1.704(c)(8)’s statutory infirmities. Red Br. at 49. To be

clear, the problem is not the legal sufficiency of the PTO’s “fix,” it is the underlying “conceded limitations” of Section 1.704(c)(8) that render the rule contrary to statute. By the PTO’s reasoning, it possesses the authority to define a “circumstance” where a patent owner forfeits all of his patent term by failing to abide by the PTO’s “[f]iling deadlines, [which] like statutes of limitations, necessarily operate harshly and arbitrarily with respect to individuals who fall just on the other side of them.” Red Br. at 43 (citation omitted). The PTO’s attempt to cast the “harsh[] and arbitrar[y] effect of Section 1.704(c)(8) as normal course of business is unavailing. The PTA statute provides no authority for the punitive patent term reduction scheme manufactured by the PTO.

The PTO decided applicants’ case under Section 1.704(c)(8), which contains two clauses:

[1] 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,

[2] 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 first clause is the PTO’s attempt to define a “circumstance[]” that “constitute[s] 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). This rule or “circumstance”, however, assumes—as was the case in *Gilead*—that the

applicant had the ability to engage as of the time “a reply has been filed.”¹¹ To conclude otherwise, *i.e.*, that even applicants with no ability to engage are nonetheless failing to engage, is to strip all meaning from the statute’s “failure to engage” and “reasonable efforts” requirements. *See* 35 U.S.C. § 154(b)(2)(C)(i), (iii). The PTO accepts this point and strenuously argues that Section 1.704(d)(1) “must be read in tandem” with Section 1.704(c)(8). *See* Red Br. at 49 (admitting “*the conceded limitations of Section 1.704(c)(8)*”) (emphasis added). In other words, Section 1.704(c)(8) cannot be read alone because doing so exposes its infirmity. But whether Section 1.704(d)(1) is “read in tandem” with Section 1.704(c)(8), or separately, subsection (c)(8) is critically flawed due to its inherent assumption that an applicant could act starting at the time the initial reply was filed. In such circumstances where an applicant cannot conceivably act at the time the “reply has been filed,” the first clause of Section 1.704(c)(8) is contrary to statute, arbitrary, capricious, and an abuse of discretion.

The second clause goes a dangerous step further. The second clause creates a punitive sanction for applicants that do not fall within the first clause’s assumption that the applicant was able to engage as of the time “a reply has been

¹¹ In *Gilead* the IDS was filed on material relating to applicant’s own copending applications after the PTO issued a restriction requirement. Accordingly, Gilead, was both aware and capable of filing the information contained in the later filed IDS at the time of the initial reply. *See* Bl. Br. at 56-58.

filed.” Even if the PTO has unbridled authority, under the first clause, to define any “[s]ubmission of a supplemental reply . . . after a reply has been filed” as a failure to engage in reasonable efforts to conclude prosecution—which it does not—the PTO does not *also* have limitless authority to redefine the statute’s “period of adjustment.” The second clause directly conflicts with and thus attempts to read out critical elements of Section 154(b)(2)(C)(i)’s “period of adjustment” in favor of a PTO standard wholly divorced from the statute. In short, the PTO’s interpretation of the statute’s “period of adjustment,” for purposes of Section 1.704(c)(8), is as follows:

The period of adjustment of the term of a patent under paragraph (1) ~~shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.~~ 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.

~~35 U.S.C. § 154(b)(2)(C)(i)~~ 37 C.F.R. § 1.704(c)(8).

The PTO’s interpretation of this “period of adjustment” not only reads out the entirety of subsection (i), it is also in excess of subsection (iii)’s limited authority to “establish[] circumstances.” As evidenced by Section 154(b)(2)(C)(i)’s mandatory period of adjustment (“shall be reduced”), it is clear that Congress did not intend to delegate this authority to the PTO. Indeed, nowhere in its brief does the PTO even mention the “equal to the period of time during which” statutory language at the heart of this case. There is no statutory

basis that permits the PTO to redefine the “period of adjustment.” Accordingly, the second clause of Section 1.704(c)(8) is entitled no deference.

Critically, while the first clause starts the clock of purported unreasonable applicant conduct at the “[s]ubmission of a supplemental reply,” the second clause again goes further and reduces patent term “beginning on the day after the date the initial reply was filed.” This second clause thus reaches back in time prior to any alleged failure by the applicant—having the punitive effect of transforming actual PTO delay into loss of patent term for the applicant. The rule thus has no rational relationship to the applicant’s actual conduct. There is no evidence of the PTO’s careful consideration of this second clause in these circumstances. The PTO does not address this critical language and the PTO makes no attempt to justify such an egregious overreach of statutory authority. In circumstances where an applicant cannot conceivably act at “the date the initial reply was filed,” the second clause of Section 1.704(c)(8) is an unauthorized punitive repercussion, contrary to statute, arbitrary, capricious, and an abuse of discretion.

Each clause of Section 1.704(c)(8) provides an independent ground for reversal. The first clause is impermissible as it assumes—without reason—that the applicant had the ability, but failed, to engage in prosecution as of the time “a reply has been filed.” The second clause is impermissible as it attempts to calculate the “period of adjustment” starting with, and running through, a time during which the

PTO admits it alone delayed. Both clauses of Section 1.704(c)(8), as applied in circumstances where an applicant cannot conceivably act, impermissibly punishes applicants for the PTO's delay during a time which the applicant has neither delayed nor taken any action/inaction that has the potential for delay. *See Gilead*, 778 F.3d at 1349 (“Congress intended to sanction not only applicant conduct or behavior that result in actual delay, but also those having the potential to result in delay irrespective of whether such delay actually occurred.”). The PTO's application of Section 1.704(c)(8) to applicant's in Appellant's circumstance is thus contrary to statute.

D. The PTO's Myopic Focus on Section 1.704(d)(1) Exposes Section 1.704(c)(8)'s Flaws

As discussed above, this case was decided by the PTO pursuant to Section 1.704(c)(8). The PTO now argues that “the question upon which Plaintiffs' challenge *necessarily hinges* is thus whether the exception provided by Section 1.704(d)(1) is legally sufficient to be reasonable.” Red Br. at 39. The PTO's problem is two-fold.

First, the PTO admits that Section 1.704(c)(8) is fundamentally flawed. Red Br. at 49 (confessing “the conceded limitations of Section 1.704(c)(8)”).

Specifically, the PTO states “[t]he parties agree that there may be times where an applicant lacks immediate access to information such that some sort of regulatory exception or ‘safe harbor’ to the general rule of Section 1.704(c)(8) is needed.” *Id.*

at 39 (second emphasis added). This concession is fatal to the PTO's position. The PTO acknowledges that without an "exception" to Section 1.704(c)(8) applicants cannot meet the statutorily required "reasonable efforts" element because the first clause of the rule does not account for circumstances where an applicant lacks access to information at the time "a reply has been filed." The PTO's admission also concedes the point made above regarding Section 1.704(c)(8)'s first clause, *i.e.*, Section 1.704(c)(8) is flawed because it *assumes* that the applicant had the ability to engage at a time when in fact it cannot engage. Accordingly, in these situations, Section 1.704(c)(8) is contrary to the statute.

Second, the PTO's admission that Section 1.704(c)(8) "need[s]" an exception in circumstances where an applicant lacks access to information, exposes the punitive nature of Section 1.704(c)(8)'s second clause. Rather than applying Section 154(b)(2)(C)(i)'s "period of adjustment" which would account for an applicant's *inability* in such circumstances to "fail[] to engage", the PTO's rule has no such safety valve. The PTO cannot simply rely on its purported "safe harbor" rule because, as seen here, in circumstances where applicants "lack[] immediate access to information" (Red Br. at 39), Section 1.704(c)(8)'s punitive repercussions are contrary to the statute. Here, for example, despite the PTO's awareness (by way of its general rules) that Appellants lacked access to actionable information until August 21, 2012, the PTO reduced Appellants patent term as if it

could have filed the relevant information on February 23, 2011. Again, in these situations, Section 1.704(c)(8) is contrary to the statute.

E. The PTO’s “Policy Choices” Highlight the Misguided Nature of the PTO’s Statutory Interpretation

The PTO admits that Appellants could have intentionally forgone Section 107.4(d)(1), strategically delayed, and be charged *zero* patent term reduction under its rules. Red Br. at 54 (“Plaintiffs are correct, once this grace period expired, they could have waited until the USPTO had responded to their RCE, and then filed the IDS concurrently with their next filing . . .”); *see also id.* at 44 n.10. In the very next sentence, the PTO makes an about face arguing that “the PTA regulatory scheme . . . incentivizes applicants to promptly submit material information in its possession[.]” *Id.* at 54. The PTO’s admission undercuts its own “incentive” argument and highlights the arbitrary nature of its rules. In short, the PTO rules *incentivize* applicants that possess information to disclose to the PTO and that do not avail themselves to Section 107.4(d)(1) to intentionally not engage in efforts to conclude prosecution, contrary to the PTO’s stated goal and the plain language of the statute. Had Appellants filed its IDS earlier or later, the PTO would not have reduced the patent term either prospectively from issuance of the EPO communication or retroactively from filing of its initial reply. This cannot be reconciled with the statute’s purpose, legislative history, plain language, or even many of the PTO’s stated policy objectives.

The PTO attempts to justify these inconsistencies by characterizing the PTA regulatory scheme as one rife with “complex policy choices.” Red Br. at 55. By framing the scheme in this manner, the PTO attempts to shield its rules from statutory scrutiny. *Id.* (“[T]hese are the type of complex policy choices that are not appropriate or relevant to the *Chevron* inquiry.”) (citing *Nat’l Cable & Telecomms. Ass’n v. Brand X Internet Servs.*, 545 U.S. 967, 982 (2005)). Not so fast. *Brand X*’s reasoning only applies to statutory ambiguities, not situations where an agency’s rule is contrary to the plain language of the statute. *Brand X*, 545 U.S. at 980. An agency’s implementing regulations must, at all times, remain consistent with the unambiguous authorizing statute. *See Dixon*, 381 U.S. at 74-75 (“The power of an administrative officer or board to administer a federal statute and to prescribe rules and regulations to that end is not the power to make law but the power to adopt regulations to carry into effect the will of Congress as expressed by the statute. A regulation which does not do this, but operates to create a rule out of harmony with the statute, is a mere nullity.”) (citation omitted). Accordingly, Section 1.704(c)(8), with and without Section 1.704(d)(1), must at minimum comply with the PTA statute.

CONCLUSION

For the forgoing reasons, Appellants respectfully request that this Court reverse the judgment as to patent term adjustment for the '897 patent, and remand for redetermination of the proper term.

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Respectfully submitted,

/s/Douglas H. Carsten

DOUGLAS H. CARSTEN

WILSON SONSINI GOODRICH & ROSATI

Attorney for Plaintiff-Appellants

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