**No. 17-1357**

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**IN THE 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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# CORRECTED BRIEF FOR THE DEFENDANT-APPELLEE – MICHELLE K. LEE, DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY

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## STATEMENT OF RELATED CASES

No other appeal in or from the present civil action has previously been before this or any other appellate court. No case of which Defendant is aware in this or any other court will be directly affected by this Court's decision in the pending appeal.

## STATEMENT OF JURISDICTION

This case involves a challenge to the patent term adjustment determination of the Director of the United States Patent and Trademark Office ("PTO" or "USPTO") under 35 U.S.C. § 154(b). Plaintiffs invoked the jurisdiction of the district court under 28 U.S.C. §§ 1331, 1338(a), and 35 U.S.C. § 154(b). The district court entered final judgment for the Director on October 18, 2016, and Plaintiffs filed a timely notice of appeal on December 7, 2016. This Court has appellate jurisdiction under 28 U.S.C. § 1295(a)(4)(C).

## STATEMENT OF THE ISSUE

Whether the USPTO properly determined that a patent applicant's filing of an Information Disclosure Statement ("IDS") both (1) after the applicant has filed a Request for Continued Examination ("RCE"), and (2) outside of the 30-day "safe harbor" provision of 37 C.F.R. § 1.704(d)(1), categorically constitutes a "failure of

[the] applicant to engage in reasonable efforts to conclude processing or examination of an application." 35 U.S.C. § 154(b)(2)(C)(iii); 37 C.F.R. § 1.704(c)(8).

## STATEMENT OF THE CASE

This case concerns a challenge to the USPTO's patent term adjustment ("PTA") determination for U.S. Patent No. 8,747,897 ("the '897 patent"). When calculating the term of a patent, the USPTO is statutorily required to account, where applicable, both for delays in the USPTO's examination of the patent application, as well as for any amount 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); *see generally* 35 U.S.C. § 154(b) ("the PTA statute"). While the PTA statute itself defines one such "circumstance" constituting what is commonly—albeit imprecisely—referred to as "applicant delay," *see id.* § 154(b)(2)(C)(ii), it further mandates that the UPSTO 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." *Id.* § 154(b)(2)(C)(iii).

Pursuant to this express delegation of substantive rulemaking authority, the USPTO promulgated two regulations that are relevant to the instant case. First, 37 C.F.R. § 1.704(c)(8) ("Section 1.704(c)(8)") defines one such circumstance as the submission of certain kinds of supplemental papers *after* an applicant has already filed a "reply" to a USPTO office action. Section 1.704(c)(8) thus applies, for example, when an applicant files an IDS after having already filed an RCE. Generally speaking, Section 1.704(c)(8) reflects the USPTO's determination that an applicant's piecemeal or interstitial filing of certain kinds of supplemental papers, while the proverbial "ball" is in the USPTO's "court" to respond to an earlier-filed paper from the applicant, has the tendency to interfere with the agency's ability to efficiently move examination forward. In *Gilead Scis., Inc. v. Lee*, 778 F.3d 1341, 1349-50 (Fed. Cir. 2015), this Court expressly upheld this rule and its stated rationale, holding that (1) the USPTO had validly determined that interstitial applicant filings tend to interfere with the agency's examination process, and (2) it is irrelevant, for the valid application of Section 1.704(c)(8), whether the interstitial filing in question caused any *actual* examination delay.

Plaintiffs' arguments on appeal are substantially based on their contention that Section 1.704(c)(8) "assumes that at the time of filing a reply an applicant

could have but failed to file the information contained in [the later-filed] supplemental reply"—*i.e.*, that the regulation fails to account for situations in which an applicant, through no fault of its own, acquires certain types of additional information it must disclose to the USPTO only *after* it has a filed a reply with the agency. Bl. Br. p. 45; *see also id.* p. 13, 48. However, Section 1.704(c)(8) is not a stand-alone or inflexible rule, but to the contrary works in tandem with a second regulation that qualifies Section 1.704(c)(8) *in order to account for precisely such a situation*. Specifically, 37 C.F.R. § 1.704(d)(1) ("Section 1.704(d)(1)") creates an important exception to the general rule set forth by Section 1.704(c)(8), in instances in which the applicant (1) does not receive certain specified types of information until after it has filed its reply, and (2) discloses the new information to the USPTO promptly, within 30 days of receiving the new information. Where both of these conditions are met, Section 1.704(d)(1) waives the general rule set forth by Section 1.704(c)(8), and no PTA deduction will be made.

As the district court noted, *see* Appx11, had Plaintiffs simply availed themselves of the "safe harbor" provided by Section 1.704(d)(1), they would have avoided the PTA deduction they have initiated this litigation to challenge. Having

failed to take advantage of this grace period, Plaintiffs now seek to absolve themselves of the consequences of their own entirely avoidable error.

"Regulation, like legislation, often requires drawing lines," *Mayo Found. For Med. Educ. & Research v. United States*, 562 U.S. 44, 59 (2011), and both the U.S. Code and the Code of Federal Regulations are replete with "filing deadlines … [that,] like statutes of limitations," can "operate harshly," *United States v. Locke*, 471 U.S. 84, 101 (1985). However, "if the concept" of regulatory standards and deadlines "is to have any content," such lines "must be enforced." *Locke*, 471 U.S. at 101. Here, the lines that the USPTO has drawn in Sections 1.704(c)(8) and 1.704(d)(1), in furtherance of its statutory obligation to uniformly calculate PTA across the hundreds of thousands of patents that the agency issues every year,[1] are imminently reasonable. It was entirely within Plaintiffs' control to avoid the PTA consequences that ensued from their delay in filing their IDS, and the district court's decision should be affirmed.

## I. STATUTORY AND REGULATORY BACKGROUND

### A. Patent Application and Prosecution Process

[1] *See* http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm (last visited May 8, 2017).

All applications for U.S. patents are assigned to patent examiners for processing and examination. *See* 35 U.S.C. §§ 111, 131. Upon review of an application, the examiner may allow claims, reject claims, or issue an objection or other requirement concerning the application. 35 U.S.C. § 132(a); 37 C.F.R. § 1.104(a). Any such action, when taken by the examiner, is commonly known as an "Office action." If at any time the examiner determines that the claims in an application are entitled to a patent, the examiner will send a written notice of allowance ("NOA") to the applicant. 35 U.S.C. § 151. After the applicant pays the requisite fees, the USPTO will then issue the patent unless the application is withdrawn. 37 C.F.R. § 1.314.

If, however, the examiner's action is adverse, the applicant has the right to challenge the various rejections or requirements, and/or to amend the claims. 35 U.S.C. § 132; 37 C.F.R. §§ 1.111, 1.112. On or after the second examination or consideration, the examiner may make any prior rejection or requirement "final," 37 C.F.R. § 1.113; however, upon receiving a final rejection, an applicant has several options to pursue his application further. As relevant to this case, these options include the ability to file a "request for continued examination" ("RCE") of the application, an action which removes the finality of the preceding final

rejection and allows the examiner to consider additional information submitted by the applicant. 35 U.S.C. § 132(b); 37 C.F.R. § 1.114.

### B. Applicants' Duty of Candor

Because "[a] patent by its very nature is affected with public interest," the USPTO has determined that "the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability." 37 C.F.R. § 1.56(a) ("Rule 1.56"). The USPTO therefore requires applicants, as well as their agents, to disclose to it any material information concerning the patentability of each claim contained within an application. Specifically, Rule 1.56 provides that "[e]ach individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability[.]" *Id.* The rule applies not only to the named inventor, but also to each attorney who prepares or prosecutes the application, as well as "[e]very other person who is substantively involved in the preparation or prosecution of the application …" *Id*. § 1.56(c)(1)-(3); *see* MPEP § 2732 (discussing application of

37 C.F.R. § 1.56(c) to PTA regulation 37 C.F.R. § 1.704(d) and providing illustrative examples).

### C. Information Disclosure Statements

One of the ways that an applicant complies with its duty of candor is through an IDS, which is a statement listing patents, publications, patent applications, or other information that may be relevant to the patentability of claims within the application at issue. *See* 37 C.F.R. § 1.98. Because of the strong public interest in the examiner reviewing all material that is relevant to a given application, the USPTO has promulgated regulations that permit an applicant to file an IDS up until the end of the patent examination process, while simultaneously providing incentives for an applicant to submit any necessary IDS promptly. 37 C.F.R. § 1.97(a)-(d).

As relevant here, the USPTO will accept, without condition, an IDS that is filed, *inter alia*, before the first Office Action after the applicant has filed an RCE. 37 C.F.R. § 1.97(b). However, this rule operates wholly independently from the USPTO's PTA regulations, discussed in detail below.[2]

[2] More specifically, compliance with 37 C.F.R. § 1.97(b) is not relevant to the independent question of whether an applicant qualifies for the PTA safe harbor provided by Section 1.704(d)(1).

### D. Patent Term Adjustment Statute

In 1994, Congress amended the patent laws and changed the length of a patent term from seventeen years, measured from the *issue* date of the patent, to twenty years, measured from the earliest United States non-provisional *filing* date of the application for the patent. Generally speaking, Congress intended these two periods to be roughly equivalent, with the expectation that it would generally take about three years from filing to issuance of a patent. However, because delays in issuing a patent could reduce the effective patent term of that patent, the 1994 amendments included provisions allowing a patent owner to seek additional patent term from the USPTO for delays caused by certain specified events during the examination and prosecution of the patent. *See* 35 U.S.C. § 154(b) (1995). In the American Inventors Protection Act ("AIPA") of 1999, Congress revisited the issue and both (1) prescribed additional circumstances warranting patent term adjustment ("PTA"), *see id.* § 154(b)(1)(A)-(C), and (2) specified certain limitations in the PTA calculation, *id.* § 154(b)(2); *see generally*, *e.g.*, *Gilead*, 778 F.3d at 1343-45.

Taken together, these amendments create three broad categories of PTA for which a given patent is eligible. *See* 35 U.S.C. § 154(b)(1)(A)-(C). The first

category, codified at 35 U.S.C. § 154(b)(1)(A) and commonly known as "A delay," extends the patent term one day for each day that the USPTO fails to meet prescribed deadlines for certain events during the examination and prosecution of the patent. *Id.* § 154(b)(1)(A). As relevant here, among those statutorily-prescribed deadlines is a requirement that, when an applicant files an RCE, the examiner respond to that filing within four months; if the examiner fails to do so, the applicant will accrue PTA from that four-month deadline until such time as the examiner issues his response. *Id.* § 154(b)(1)(A)(ii).

The second category of PTA, codified at 35 U.S.C. § 154(b)(1)(B) and commonly known as "B delay," extends the patent term one day for each day that the USPTO fails to issue the patent after the end of a three-year application pendency period, exclusive of time consumed by certain specified events. *Id.* § 154(b)(1)(B). The third and final category, codified at 35 U.S.C. § 154(b)(1)(C) and commonly known as "C delay," extends the patent term one day for each day of the pendency of an interference proceeding, a secrecy order, or successful appellate review by the Board or a Federal court. *Id.* § 154(b)(1)(C).

On the reverse side of the equation, 35 U.S.C. § 154(b)(2) places certain limitations on the PTA calculation. First, the statute provides that, to the extent that

periods of A, B, and C delay overlap for a given patent, its PTA "shall not exceed the actual number of days the issuance of the patent was delayed." *Id.* § 154(b)(2)(A). Second—and relevant here—the statute provides that a PTA award must be reduced by any amount of time "during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." *Id.* § 154(b)(2)(C)(i). In the PTA statute, Congress specified that one such qualifying instance occurs when an applicant fails to "respond to a notice from the [USPTO]" within three months of the mailing of such notice. *Id.* § 154(b)(2)(C)(ii). Beyond this sole circumstance, however, 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. 35 U.S.C. § 154(b)(2)(C)(iii); *see also Gilead*, 778 F.3d at 1349 (noting that the "broad language" employed by 35 U.S.C. § 154(b)(2)(C)(iii) "indicates [that] Congress intended the PTO to employ its expertise in identifying applicant conduct" that qualifies for this consequence). In addition, Congress separately provided that "[t]he [USPTO] Director shall prescribe regulations establishing procedures for the application for and determination of patent term adjustments under [the PTA statute]." *Id.* § 154(b)(3)(A).

### E. Implementing Regulations

Pursuant to these delegations of mandatory rulemaking authority, promptly after the passage of AIPA the USPTO promulgated regulations for the assessment and computation of PTA, codified at 37 C.F.R. §§ 1.702-1.704.[3] The USPTO fulfilled its rulemaking duties under 35 U.S.C. § 154(b)(2)(C)(iii) by promulgating 37 C.F.R. § 1.704, which sets forth various circumstances that *per se* "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).

The conduct here at issue—*i.e.*, an applicant's filing of an IDS after the filing of an RCE—falls squarely under one of the enumerated circumstances:

> 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 … [an applicant's PTA] 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[.]

37 C.F.R. § 1.704(c)(8).[4]

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[3] *See* Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 Fed. Reg. 56366 (Sept. 18, 2000) (final rules); 65 Fed. Reg. 17215 (Mar. 31, 2000) (proposed rules).

[4] Although 37 C.F.R. § 1.704(c)(8) does not specifically employ either the term "information disclosure statement" (IDS) or "request for continued examination" (RCE), an IDS qualifies as an "other paper," and an RCE as a "reply," under this

As the USPTO explained when it promulgated the regulation, the rationale for this rule is simple. First, and as a general matter, "[a]n applicant who is engaging in actions or inactions that *prevent or interfere with the Office's ability to process or examine* an application cannot reasonably be characterized as 'engag[ing] in reasonable efforts to conclude processing or examination of an application.'" 65 Fed. Reg. at 56379 (emphasis added). Second, and applying this principle, "[t]he submission of a supplemental reply or other paper (e.g., an information disclosure statement (IDS) or petition) after an initial reply was filed requires the [USPTO] to restart consideration of the initial reply in view of the supplemental reply or other paper, which will result in a delay in the [USPTO's] response to the initial reply." 65 Fed. Reg. at 56372.

However, the USPTO did not simply promulgate Section 1.704(c)(8) as an inflexible, stand-alone rule. Rather, precisely in order to account for situations in which an applicant receives new material information from either a foreign patent

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rule, and Plaintiffs have not—at least in the judicial proceedings—contended otherwise. *See Gilead*, 778 F.3d at 1349 (noting that "the filing of a[n] … IDS" after a reply is the "precise situation" contemplated by Section 1.704(c)(8); 37 C.F.R. § 1.113 (providing that "*[r]eply* to a final rejection or action must comply with [37 C.F.R.] § 1.114 …") (emphasis added); *id.*§ 1.114 (setting forth requirements for initiation of an RCE).

office, or from the USPTO itself (*e.g.*, via an Office action in a related patent application) only *after* filing a reply with the agency, the USPTO additionally promulgated Section 1.704(d)(1). Although an interstitial applicant filing is no less likely to interfere with examination in this scenario, Section 1.704(d)(1) establishes an exception to the general rule set forth by Section 1.704(c)(8)—on the condition that, having received the new information, the applicant acts *promptly* to disclose it to the USPTO.

Specifically, Section 1.704(d)(1) establishes a "safe harbor" or "grace period" for applicants who promptly file an IDS within 30 days of receiving the specified forms of new information. 37 C.F.R. § 1.704(d)(1);[5] *see also* 65 Fed. Reg. at 56373 (explaining that an applicant may "submit information cited in a communication from a foreign patent office," or from the USPTO itself, "without a reduction in patent term adjustment" so long as an IDS "is *promptly* (within thirty days of receipt of the communication) submitted to the Office.") (emphasis added);

[5] As originally promulgated in 2000, Section 1.704(d)(1) applied only to an IDS that disclosed information received from a foreign patent office; in 2011, the USPTO expanded the rule to also include information first cited by the Office itself in another application. *See* Revision of Patent Term Adjustment Provisions Relating to Information Disclosure Statements, 76 Fed. Reg. 74700 (Dec. 1, 2011) (final rules); 76 Fed. Reg. 18990 (April 6, 2011) (proposed rules).

76 Fed. Reg. at 74701 (noting that "[t]he USPTO does not consider an information disclosure statement filed more than 30 days after the information has been brought to the applicant's attention to be promptly submitted"). Per the express terms of the regulation, the 30-day safe harbor "is not extendable." 37 C.F.R. § 1.704(d)(2).

## II. FACTUAL BACKGROUND AND RELEVANT ADMINISTRATIVE PROCEEDINGS

### A. Patent Prosecution History

This case generally concerns United States Patent No. 8,747,897 ("the '897 patent"), which the USPTO issued on June 10, 2014. Appx85. Plaintiff-Appellant Supernus Pharmaceuticals, Inc. ("Supernus") was the original assignee of the '897 patent, and Plaintiff-Appellant United Therapeutics Corporation ("UTC") holds the exclusive license to the same. Appx45-46 ¶¶ 11-12, 85.[6]

[6] The Complaint alleges that UTC conducted portions of the prosecution of the underlying patent application, and is currently the exclusive licensee of the '897 patent. Appx45-46 ¶ 12; *see also* Bl. Br. p. 5 n.1. While these assertions are neither confirmed nor contradicted by the Administrative Record, the USPTO has no basis to dispute their accuracy. Accordingly, for ease of reference, the USPTO will generally refer to Supernus and/or UTC collectively as "Plaintiffs" when describing or referring to the actions taken by the patent applicant in this matter.

On April 27, 2006, Supernus applied for the '897 patent by filing Application No. 11/412,100 ("the '100 application") with the USPTO. Appx102-145; *see* Appx80. On August 20, 2010, the USPTO issued a final rejection as to the application, Appx196-206, and on February 22, 2011, Plaintiffs filed an RCE. Appx207.

Concurrently with prosecuting the '100 application before the USPTO, Plaintiffs pursued a patent on the same technology before the European Patent Office ("EPO"). This patent issued in 2011, as European Patent EP2010189 (the "EP patent"). *See* Appx340. On August 21, 2012, the EPO issued a communication (the "EPO communication") to the effect that Sandoz AG had filed with that office a Notice of Opposition (the "Sandoz Opposition") to the EP patent. Appx339. Plaintiffs' foreign counsel, Louis, Pohlau, Lohrentz, located in Nuremburg, Germany, received the Sandoz Opposition one day later, on August 22, 2012. *Id*. Plaintiffs allege that they did not directly receive the Sandoz Opposition until September 11, 2012, Appx47 ¶ 19, Appx456-457, *see also* Bl. Br. p. 8, but did not dispute (at least in the district court proceedings) the applicability of the well-settled rule that "[a] notification given to an agent is effective as notice to the principal if the agent has actual or apparent authority to receive the notification[.]"

Restatement (Third) of Agency § 5.02 (2006); *but see* Bl. Br. p. 58 (referring to their European attorney as a "third party," and averring that they were not on notice of the Sandoz Opposition until the date on which they physically received a copy of this document).

On November 29, 2012—99 days after they received constructive notice of the Sandoz Opposition through their attorney, as well as a full 79 days after they received "actual," physical notice of the same—Plaintiffs submitted to the USPTO the one-page IDS form and related attachments. Appx209-461. Plaintiffs did not include with this IDS a "30-day certification," as specified by Section § 1.704(d)(1)(i)-(ii)—*i.e.*, they did not attempt to invoke the protections of the 30-day safe harbor established by Section 1.704(d)(1).

On February 4, 2014, the USPTO issued a notice of allowance. Appx496-497; *see also* Appx505-507 (correcting an administrative error). On June 10, 2014, various specified claims in the '100 application issued as the '897 patent. Appx85-101.

**B. Administrative Exhaustion**

The USPTO originally granted 1,260 days of PTA for the '897 patent. Appx85. This calculation included a total of 2,146 days of non-overlapping "A

delay" and "B delay" on the part of the USPTO, less 886 days for time in which Plaintiffs failed to engage in reasonable efforts to conclude examination of an application, as defined by 37 C.F.R. § 1.704. *See* Appx80-84. Pursuant to Section 1.704(c)(8), the 886 days that the USPTO deducted from Plaintiffs' overall PTA included 646 days for the interval of time between (a) the February 22, 2011 filing of the RCE, and (b) the November 29, 2012 filing of the IDS. *See* Appx82 (Entry No. 59).

On August 5, 2014, Plaintiffs filed a Request for Reconsideration of Patent Term Adjustment. Appx509-515. In the petition, Plaintiffs argued for two categories of PTA adjustment. First, Plaintiffs argued that they were entitled to the restoration of the 646 days of PTA that had been subtracted pursuant to Section 1.704(c)(8). Plaintiffs based this contention on a misapprehension that a different regulation, 37 C.F.R. § 1.704(c)(6) ("Section 1.704(c)(6)"), was the relevant rule for their circumstances. Appx510-511. Secondly, Plaintiffs argued that under this Court's recent holding in *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014), they were entitled to an additional 126 days of "B delay." Appx511-512. On July 2, 2015, the USPTO responded to Plaintiffs' petition. Appx516-522. The USPTO granted Plaintiffs' second request, recalculating the proper amount of "B delay" to

include an additional 126 days. Appx518-519. The parties now agree on this portion of the PTA calculation, which is not at issue in this case.

However, the USPTO rejected Plaintiffs' first request, explaining that the 646-day deduction was required under the plain terms of Section 1.704(c)(8), which had been recently upheld by this Court in *Gilead*, 778 F.3d 1341.[7] As the USPTO explained:

> In *Gilead*, the court noted that the conduct of filing an IDS after the submission of a response to an election or restriction requirement interferes with the PTO's ability to conclude the application process …. Because the 'A' Delay provision … penalizes the PTO if the examiner fails to respond within four months of the applicant's response to the restriction requirement, any relevant information received after an initial response to a restriction requirement interferes with the [PTO's] ability to process an application. A supplemental IDS may force an examiner to go back and review the application again, while still trying to meet his or her timeliness obligations under § 154.
>
> The same analysis applies to the submission of an IDS document after the filing of an RCE. The Office must respond to the submission of an RCE within four months of the filing of the RCE or provide additional 'A' delay. Any IDS submission by patentee after the filing of a[n] RCE interferes with the PTO's ability to process an application because the examiner may be forced to go back and review the application again.

Appx521 (internal citations and alterations omitted).

[7] *Gilead* is discussed in detail in Section I.B of the Argument, *infra*.

On July 9, 2015, Plaintiffs requested reconsideration. Appx523-532. In this filing, Plaintiffs again relied primarily on the mistaken understanding that Section 1.704(c)(6), instead of Section 1.704(c)(8), supplied the relevant rule for their application. Appx525-527. In addition, Plaintiffs asserted a version of the argument regarding Section 1.704(c)(8) that they have advanced in these judicial proceedings. Appx528-529. However, at no point in the administrative process did Plaintiffs challenge, set forth any argument regarding—or indeed, so much as mention—Section 1.704(d)(1).

On September 30, 2015, the USPTO denied the application for reconsideration. Appx533-537.

## III. THE DISTRICT COURT PROCEEDING

Plaintiffs timely challenged the USPTO's PTA determination in the Eastern District of Virginia. Following briefing and argument on the parties' cross-motions for summary judgment, the district court granted summary judgment in favor of the USPTO. Appx1; Appx2-18.

*First*, the district court noted that in *Gilead*, 778 F.3d 1341, this Court had already sustained against an earlier attack on the exact same regulation challenged here by Plaintiffs, *i.e.*, Section 1.704(c)(8), and thus foreclosed such a challenge.

Appx9-10. Analyzing this opinion, the district court noted that *Gilead* had applied *Chevron* deference, Appx10, *en route* to concluding that a "'reasonable interpretation of the [PTA] statute is that Congress intended to sanction not only applicant conduct or behavior that result in delay, but also those having the potential to result in delay irrespective of whether such delay actually occurred,'" *id.* (quoting *Gilead*, 778 F.3d at 1349). After determining that the category of conduct penalized by Section 1.704(c)(8)—the interstitial filing of certain kinds of supplemental or other papers, such as an IDS, not expressly requested by an examiner—carried precisely such potential, *Gilead* upheld this regulation as well within the bounds of the USPTO's discretionary authority. 778 F.3d at 1349-50.

Applying these holdings, the district court found that *Gilead* was preclusive of Plaintiffs' claims, as their IDS was "a supplemental paper filed in the absence of a request from the PTO," and therefore, just as in *Gilead*, bore (as a categorical matter) the potential to force the examiner to restart or re-do aspects of his examination process. Appx11. Further, the district court held that when Section 1.704(c)(8) "is viewed in conjunction with the … safe harbor provision of [Section] 1.704(d)(1)," there is "nothing arbitrary, capricious, or unreasonable about reducing PTA … given that [Section] 1.704(d)(1) allows an applicant to file

… an [interstitial] IDS without penalty if filed during the stated 30 day grace period." Appx11.

*Second*, the district court also rejected Plaintiffs' challenge to Section 1.704(d)(1), on two separate grounds: (1) that Plaintiff had waived any such challenge by failing to raise it administratively, Appx16-17, and (2) that the rule is, in any event, a permissible exercise of the USPTO's rulemaking authority, Appx12-16. With respect to the former ground, the district court noted the well-established rule that "[i]ssues not raised before the federal agency during administrative proceedings, are waived and will not be considered by a court on review." Appx16 (citing *Wallaesa v. FAA*, 824 F.3d 1071, 1078 (D.C. Cir. 2016)). Further noting that the administrative record was devoid of "any semblance" of argument regarding Section 1.704(d)(1), the district court held that Plaintiffs had waived their ability to challenge this regulation. *Id.*

Notwithstanding Plaintiffs' waiver, the district court alternatively held that Section 1.704(d)(1) is also a permissible exercise of the USPTO's rule-making authority. Appx12-16. On appeal, Plaintiffs have purported to withdraw the arguments addressed and refuted in this portion of the district court's decision. *See* Bl. Br. p. 5. n.2. However, as relevant to this appeal, the district court specifically

rejected Plaintiffs' contention that "[t]he fact that an IDS may be [timely] filed for … purposes of 37 C.F.R. § 1.97 and still be untimely for § 1.704(c)(8) and 1.704(d)(1) purposes" somehow rendered the latter rule arbitrary and capricious. Appx15. To the contrary, the district court held that, taken together, these regulations "simply mean[] that if an applicant would like to maximize its patent term, it would behoove the applicant to file the IDS promptly after receiving communications for a foreign patent office." *Id.*

*Third*, the district court noted that, at bottom, Plaintiffs' argument was that "they are entitled to an individualized PTA assessment" that went beyond—and indeed, waived—application of the USPTO's duly promulgated rules of general applicability. Appx11. The district court rejected this argument, citing the well-established principle that "'even if a statutory scheme requires individualized determinations, the decision maker has the authority to rely on rulemaking to resolve certain issues of general applicability unless Congress clearly expresses an intent to withhold that authority.'" Appx12 (quoting *Lopez v. Davis*, 531 U.S. 230, 234 (2001)). As the district court stated, "[h]ere, the PTA statute does not require the PTO to make any sort of particularized determination of PTA, and instead directs the PTO to promulgate rules of general applicability that address the

circumstances that will lead to a deduction of PTA. [Section] 1.704(c)(8) is one of those rules." Appx12.

*Fourth and finally*, the district court found that Plaintiffs had failed to state a Fifth Amendment takings claim. Appx17.[8]

## STANDARD OF REVIEW

This Court reviews a district court's grant of summary judgment *de novo*, applying the same standard as the district court. *Star Fruits, S.N.C. v. United States*, 393 F.3d 1277, 1281 (Fed. Cir. 2005). Federal patent term adjustment decisions of the USPTO are reviewed in accordance with the Administrative Procedure Act ("APA"). 35 U.S.C. § 154(b)(4)(A); *Gilead*, 778 F.3d at 1346. Under the APA, a court may only set aside the USPTO's actions if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); *Gilead*, 778 F.3d at 1346. The standard of review is "narrow," and does not authorize a court "to substitute its judgment for that of the agency." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971).

[8] Plaintiffs do not appeal the district court's ruling with respect to their purported takings claim.

Further, where, as here, this Court reviews the USPTO's interpretation of a statute that it has been delegated authority to interpret, the Court applies the two-step framework established in *Chevron, U.S.A., Inc. v. Nat'l Resources Def. Council, Inc.*, 467 U.S. 837 (1984); *Gilead*, 778 F.3d at 1346. Under this framework, the Court must first "determine 'whether Congress has directly spoken to the precise question at issue.'" *City of Arlington v. FCC*, --- U.S. ---, 133 S. Ct. 1863, 1868 (2013) (quoting *Chevron*, 467 U.S. at 842). The purpose of this step is to determine whether Congress has explicitly or implicitly delegated authority to an agency to fill a statutory gap: where "Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation." *Chevron*, 467 U.S. at 843-44; *see also Cuozzo Speed Techs., LLC v. Lee*, --- U.S. ---, 136 S. Ct. 2131, 2142 (2016).

However, even when there is no express delegation, Congress may implicitly delegate authority: "a statute's silence or ambiguity as to a particular issue means that Congress has not 'directly addressed the precise question at issue' (thus likely delegating gap-filling power to the agency)." *United States v. Home Concrete & Supply, LLC*, --- U.S. ---, 132 S.Ct. 1836, 1843 (2012); *see also Chevron* 467 U.S. at 843-44 ("Sometimes the legislative delegation to an agency

on a particular question is implicit rather than explicit. In such a case, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency."); *Brownlee v. DynCorp.*, 349 F.3d 1343, 1354 (Fed. Cir. 2003) ("[T]he correct inquiry [as to whether *Chevron* deference applies] is whether Congress has left an explicit or implicit gap for the agency to fill[.]").

Regardless of whether a delegation is explicit or implicit, where one exists, it is axiomatic that the Court's role at the second step of the *Chevron* framework is *not* to determine "how best to construe an ambiguous term in light of competing policy interests," *City of Arlington*, 133 S. Ct. at 1873 (2013), but rather, and much more modestly, to determine whether the agency's interpretation constitutes a "permissible," or rational, construction of the statute. *Chevron*, 467 U.S. at 843; *see also*, *e.g.*, *Entergy Corp. v. Riverkeeper, Inc.*, 556 U.S. 208, 218 (2009) (explaining that the agency's view "governs if it is a reasonable interpretation of the statute—not necessarily the only possible interpretation, nor even the interpretation deemed *most* reasonable by the courts") (emphasis in original); *Michigan v. EPA*, --- U.S. ---, 135 S. Ct. 2699, 2708 (2015) (where *Chevron* applies, "agencies [may] choose among competing reasonable interpretations of a

statute …"); *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1341 (Fed. Cir. 2008) ("[The Court's] duty is not to weigh the wisdom of, or to resolve any struggle between, competing views of the public interest, but rather to respect legitimate policy choices made by the agency in interpreting and applying the statute.").

## SUMMARY OF ARGUMENT

The district court's entry of summary judgment on the USPTO's behalf is correct and should be affirmed, for the following reasons.

First, the PTA statute is silent as to the "precise question" that is raised here—the "circumstances" of applicant conduct that merit a reduction in PTA—and indeed, expressly delegates to the USPTO the responsibility and authority to "fill the gap" on this and other issues. 35 U.S.C. § 154(b)(2)(C)(iii). Accordingly, in resolving this case, the Court must go beyond the PTA statute itself, and examine and apply the relevant regulatory framework promulgated pursuant to this delegation. The district court thus correctly applied the *Chevron* framework in assessing the PTA regulations here at issue, Sections 1.704(c)(8) and 1.704(d)(1). Appx10.

Second, the district court also correctly held that, by failing to so much as mention Section 1.704(d)(1) in their administrative appeal of the PTA

determination, Plaintiffs waived any argument or claim respecting this rule in these judicial proceedings. Appx16-17. Plaintiffs do not appeal this aspect of the district court's holding—and because their inability to challenge the legal sufficiency of Section 1.704(d)(1) is ultimately to fatal to the entirety of their claims, this Court may affirm the district court's disposition on this independent ground alone.

Third, the district court correctly applied *Gilead* to the facts of the instant case, finding that, just like every other interstitial IDS that falls within the scope of Section 1.704(c)(8), Plaintiffs' IDS carried the inherent potential to force the patent examiner "'to *go back* and review the application.'" Appx11 (quoting *Gilead*, 778 F.3d at 1350) (emphasis in original). Accordingly, as the district court correctly determined, Section 1.704(c)(8) applies "squarely" to Plaintiffs' circumstances. Appx9.

Fourth, the district court also correctly held that Section 1.704(d)(1) is a permissible exercise of the USPTO's rule-making authority, recognizing that the safe harbor established by this rule provides a fair and reasonable opportunity for applicants in Plaintiffs' position to avoid the reduction of Section 1.704(c)(8) by disclosing their newly-acquired information promptly. Appx11, Appx12-16.

Lastly, the district court also correctly recognized that the USPTO is not only permitted, but expressly required to administer the PTA statute through general rules of categorical application, as opposed to case-by-case or *ad hoc* PTA calculations. Appx12; 35 U.S.C. §§ 154(b)(2)(C)(iii), 154(b)(3)(A). Accordingly, to the extent that Plaintiffs' arguments amount, at bottom, to a claim of entitlement to a particularized PTA determination that goes beyond the terms of the agency's general rules, their challenge must also be denied on this ground.

## ARGUMENT

### I. THE DISTRICT COURT CORRECTLY UPHELD SECTIONS 1.704(c)(8) AND 1.704(d)(1) AS PERMISSIBLE CONSTRUCTIONS OF THE PTA STATUTE

#### A. The PTA Statute Does Not Address "The Precise Question at Issue"

As this case presents a question of statutory interpretation to which the *Chevron* framework clearly applies, the first step of the legal analysis is to "ask whether the statute's plain terms 'directly addres[s] the precise question at issue.'" *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Svcs.*, 545 U.S. 967, 986 (2005) (quoting *Chevron*, 467 U.S. at 843). Here, the "precise question" presented 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." The relevant statutory language is found at 35 U.S.C. § 154(b)(2)(C), and contains three pertinent sub-provisions:

*First*, 35 U.S.C. § 154(b)(2)(C)(i) sets forth a general rule: "[t]he period of adjustment of the term of a patent … shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." 35 U.S.C. § 154(b)(2)(C)(i). This principle is certainly straightforward; however, and notably, as a stand-alone proposition it is *silent* as to what type(s) of applicant behavior, precisely, constitutes an applicant's "fail[ure] to engage in reasonable efforts to conclude prosecution of the application" *in the first place.* Subsection (i) thus creates a statutory gap which, in the absence of further instruction or interpretation, would leave both the USPTO and patent applicants alike in a position of uncertainty as to which types of applicant conduct fall with the provision's ambit, and require a deduction of PTA.

*Second*, 35 U.S.C. § 154(b)(2)(C)(ii) fills that gap as to one—and only one—category of applicant behavior, providing that when an applicant takes "in excess of 3 months" to "respond to a notice from the Office," the USPTO must

deduct "the cumulative total of any [such] periods" from the applicant's PTA. 35 U.S.C. § 154(b)(2)(C)(ii). Plainly, while subsection (ii) answers *one* "precise question," that question is not the one raised by this case, and Plaintiffs do not contend otherwise.

*Third*, 35 U.S.C. § 154(b)(2)(C)(iii) makes clear that the singular circumstance defined in subsection (ii) is not the only circumstance warranting a deduction of PTA, and *expressly delegates* to the USPTO both the authority and the mandatory responsibility to "prescribe regulations establishing the [additional] circumstances" that qualify for such treatment. 35 U.S.C. § 154(b)(2)(C)(iii). In *Gilead*, this Court expressly held that the "broad language" of this "express[]" delegation "demonstrates [that] Congress intended the PTO to employ its expertise in identifying applicant conduct demonstrating a lack of 'reasonable efforts to conclude processing or examination of an application.'" *Gilead*, 778 F.3d at 1349 (quoting 35 U.S.C. § 154(b)(2)(C)(iii)); *see also id.* at 1348 (the statute's "broad language" is plainly "employ[ed]" to "direct[] the PTO to prescribe other instances" that require a PTA reduction); *cf. City of Arlington*, 133 S. Ct. at 1868 (explaining that under *Chevron*, "Congress knows to speak in plain terms when it

wishes to circumscribe, and in capacious terms when it wishes to enlarge, agency discretion").

Plaintiffs' repeated contention that the PTA statute somehow answers the "precise question" at issue here is not only erroneous, but a textbook example of circular reasoning that assumes the very conclusion it purports to prove. That is, according to Plaintiff, the "precise question" presented by this suit is "whether PTA may be reduced for a period exceeding 'time during which the applicant failed to engage in reasonable efforts to conclude prosecution.'" Bl. Br. p. 25. The fatal flaw with this framing, however, is that it assumes the "circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application" to be *manifestly self-evident* from the statute. But to the contrary, as demonstrated by the above textual analysis, with the exception of one statutorily defined "circumstance" (not relevant here), the PTA statute is silent regarding the circumstances that warrant a PTA deduction—and indeed, the statute expressly and "broad[ly]" delegates to the USPTO the mandatory authority to fill that very gap. *Gilead* 778 F.3d at 1349; *see* 35 U.S.C. § 154(C)(i)-(iii).

Accordingly, this case cannot be decided on the plain language of the PTA statute, but must proceed to an analysis of whether the specific regulations at issue here, Sections 1.704(c)(8) and 1.704(d)(1), are reasonable exercises of the USPTO's rulemaking authority. *Cf.* Bl. Br. p. 44 (conceding that Congress did indeed "delegate[]" the substantive "authority" to define "'the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing of examination of an application.'") (quoting 35 U.S.C. § 154(b)(2)(C)(iii)). And, as the district court correctly held, this Court's decision in *Gilead* has already definitively answered this question as to the first of these regulations.

### B. The Rationale of *Gilead* Applies Equally Here

In *Gilead*, 778 F.3d 1341, this Court previously considered a challenge to—and upheld—Section 1.704(c)(8). There, 57 days after responding to a restriction requirement by selecting one group of claims for further examination, the plaintiff submitted to the USPTO an IDS disclosing the existence of two other co-pending patent applications that the company had also filed. 778 F.3d at 1345. Pursuant to Section 1.704(c)(8), the USPTO deducted these 57 days from Gilead's PTA. Gilead then filed suit, arguing both that (1) Section 37 C.F.R. § 1.704(c)(8)

contravened the PTA statute, and (2) the regulation's application was arbitrary and capricious, where the company's untimely filing had not caused any actual delay in examination.

A unanimous panel of this Court affirmed the district court's rejection of this challenge. 778 F.3d 1341; *see also Gilead Scis., Inc. v. Rea*, 976 F. Supp. 2d 833 (E.D. Va. 2013) ("*Gilead I*"). First, the Federal Circuit held that neither the plain language of the PTA statute, 35 U.S.C. § 154(b), nor its legislative history, answered the question of whether "a failure to engage in reasonable efforts [to conclude prosecution of the application] requires conduct that actually causes delay[.]" 778 F.3d at 1349. Moreover, *Gilead* held that the "broad language" of the delegation set forth in 35 U.S.C. § 154(b)(2)(C)(iii) "demonstrates that Congress intended the PTO to employ its expertise in identifying applicant conduct demonstrating a lack of 'reasonable efforts to conclude processing or examination of an application.'" 778 F.3d at 1349. Accordingly, the Court held that *Chevron* deference applies to the regulations promulgated by the USPTO pursuant to this delegation, including but not limited to Section 1.704(c)(8). *Id.*

Second, applying *Chevron* deference, *Gilead* concluded that "a reasonable interpretation of the [PTA] statute is that Congress intended to sanction not only

applicant conduct or behavior that results in actual delay, but also those having the potential to result in delay irrespective of whether such delay actually occurred." *Id*.

As relevant here, the court further explained that Gilead's arguments to the contrary failed because, *inter alia*, they

> frame[d] the issue solely in terms of the patentee's application, without recognizing that an Examiner is required to review a significant number of applications during a limited period of time. As the PTO argued before the district court, 'a supplemental reply or paper often causes delay not only in processing an examination of the particular applicant's application, but also with the processing and examination of other applications before the examiner. Although an applicant's conduct may not actually result in delaying the issuance of *that* applicant's patent, such conduct may have negative externalities for other patent applicants because it could result in delaying the issuance of their patents.

778 F.3d at 1349-50 (quoting *Gilead I*, 976 F. Supp. 2d at 837) (emphasis in original).

Further, the decision explained that

> the conduct penalized under the regulation interferes with the PTO's ability to conclude the application process because of significant time constraints faced by the PTO. Because the A Delay provision of the statute penalizes the PTO if the examiner fails to respond within four months of the applicant's response to a restriction requirement, any relevant information received after an initial response to a restriction requirement 'interferes with the [PTO's] ability to process an application.' As the district court found, '[a] supplemental IDS, such as the one that Gilead submitted, [may] force[] an examiner to *go*

> *back* and review the application again, while still trying to meet his or her timeliness obligations under § 154.'

*Id.* at 1350 (quoting *Gilead I*, 976 F. Supp. 2d at 837) (emphasis in original).

Thus, *Gilead* upheld as eminently reasonable the USPTO's determination that, *as a categorical matter*, an applicant's submission of certain kinds of interstitial filings, while the USPTO is under a statutory obligation to respond to the applicant's last filing, has a tendency to interfere with the agency's ability to efficiently move examination forward—and that Section 1.704(c)(8) appropriately penalizes such applicant conduct.

As the district court correctly recognized—and, notably, Plaintiffs have not disputed—Plaintiffs' IDS carried the exact same potential to interfere with the examination process as any other interstitial filing that falls within the ambit of Section 1.704(c)(8). Appx11 (noting that "[t]he fact that Plaintiffs filed an IDS to comply with their duty of candor … does not change the notion that the IDS …was a supplemental paper filed in the absence of a request from the PTO. Such a filing forces a patent examiner 'to *go back* and review the application again, while still trying to meet his or her timeliness obligations under [the PTA statute].'") (quoting *Gilead*, 778 F.3d at 1350) (emphasis in original). Accordingly, the only relevant distinction between the instant case and *Gilead* is that Plaintiffs, unlike Gilead, had

the opportunity to benefit from the safe harbor established by Section 1.704(d)(1)—*i.e.*, to file their interstitial IDS without penalty, notwithstanding its categorical potential to interfere with the examination process, provided that they simply did so promptly.

The limited additional question presented by this case, therefore, is whether the safe harbor established by Section 1.704(d)(1) creates a reasonable exception to Section 1.704(c)(8), in situations where an applicant acquires certain types of information only after filing a "reply" paper. For the reasons set forth below, the answer to this question is in the affirmative.

### C. Section 1.704(d)(1) Reasonably Qualifies Section 1.704(c)(8)

#### 1. Plaintiffs Waived Their Ability to Challenge Section 1.704(d)(1) by Failing to Raise the Issue Administratively

As a preliminary manner—and as the district court correctly recognized—by failing to so much as mention Section 1.704(d)(1) in their administrative appeal of the PTA determination, Plaintiffs have waived any argument or claim respecting this rule in these judicial proceedings. Appx16 (citing *Wallaesa*, 824 F.3d at 1078). "It is a hard and fast rule of administrative law ... that issues not raised before an agency are waived and will not be considered by a court on review." *Nuclear Energy Inst., Inc. v. EPA*, 373 F.3d 1251, 1297 (D.C. Cir. 2004); *see also*, *e.g.*,

*Woodford v. Ngo*, 548 U.S. 81, 90 (2006) ("Courts should not topple over administrative decisions unless the administrative body not only has erred, but has erred against objection made at the time appropriate under its practice."). As the district court correctly noted:

> '[t]his rule applies with no less force to a statutory interpretation claim not brought to an agency's attention: Respect for agencies' proper role in the *Chevron* framework requires that the Court be particularly careful to ensure that challenges to an agency's interpretation of its governing statute are first raised in the administrative forum.'

Appx16 (quoting *Nuclear Energy Inst.*, 373 F.3d at 1297 (alterations in district court opinion); *see also id.* (correctly noting that the administrative record was devoid of "any semblance" of any argument regarding Section 1.704(d)(1)).

Plaintiffs, who cannot dispute that their administrative appeals were indeed wholly devoid of "any semblance" of any argument regarding Section 1.704(d)(1), do not challenge this aspect of the district court's decision on appeal; indeed, they expressly aver that they "do not challenge directly the reasonableness of [Section] 1.704(d)(1)." Bl. Br. p. 5. n.2. However, presumably recognizing that once the validity of Section 1.704(d)(1) is established or assumed, their claims must necessarily fail, Plaintiffs nonetheless attempt to improperly inject precisely such questions into this appeal. That is, notwithstanding their purported disavowal of

any challenge to Section 1.704(d)(1), Plaintiffs attempt to avoid the consequences of their acknowledged waiver by drawing a "distinction" between a "direct" attack on Section 1.704(d)(1), on the one hand, and arguments to the effect that this regulation "cannot salvage" Section 1.704(c)(8), on the other. *Id*; *see also id*. p. 45-46 (advancing various arguments regarding Section 1.704(d)(1)'s purported shortcomings as a qualification to Section 1.704(c)(8)).

This purported "distinction" is wholly illusory, and this Court should not abide these tactics. *The 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. Because *Gilead* has already upheld Section 1.704(c)(8) as a general matter, 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. Accordingly, Plaintiffs cannot evade the consequences of their forfeiture simply by drawing a false dichotomy between a "direct" attack on Section 1.704(d)(1), and "indirect" arguments as to why this regulation does not create a sufficient exception to the general rule established Section 1.704(c)(8), and upheld by *Gilead*. Where the

express purpose of Section 1.704(d)(1) is to serve as a "safe harbor" for Section 1.704(c)(8), these arguments are one and the same.

Accordingly, this Court should hold Plaintiffs to the "hard and fast" consequences of their forfeiture, *Nuclear Energy Inst.*, 373 F.3d at 1297, and affirm the disposition of the district court on this independent ground alone.

### 2. Section 1.704(d)(1) Is a Permissible Exercise of the USPTO's Rule-Making Authority

In the alternative, to the extent this Court were to reach the merits of the qualification that Section 1.704(d)(1) adds to Section 1.704(c)(8), it must affirm the reasonableness of this rule.

As the district court properly recognized, the opportunity that Section 1.704(d)(1) extends to applicants in Plaintiffs' position—namely, to avoid the reduction of PTA by Section 1.704(c)(8) by disclosing their newly-acquired information within 30 days of acquiring the same—is a fair and reasonable one. *See* Appx11 ("[W]hen [Section] 1.704(c)(8) is viewed in conjunction with the … safe harbor provision of [Section] 1.704(d)(1)," there is "nothing arbitrary, capricious, or unreasonable about reducing PTA … given that [Section] 1.704(d)(1) allows an applicant to file such an [interstitial] IDS without penalty if

filed during the stated 30 day grace period."); *see also* Appx12-16 (discussing at length why Plaintiff's challenge to the terms of the safe harbor failed).

Section 1.704(d)(1) rationally balances competing concerns. On the one hand, as *Gilead* recognized, when an applicant files certain kinds of interstitial papers in the middle of the examination process, such filings have the tendency to interfere with the agency's examination process—and this tendency is exactly the same whether the information disclosed in the interstitial filing was information the applicant had all along (the "*Gilead* scenario"), or whether the applicant only acquired the relevant information at a later point in time (Plaintiffs' scenario). *Cf.* Bl. Br. p. 56 (acknowledging the Sandoz Opposition as a "circumstance [that] ar[ose] that could potentially cause delay"). On the other hand, the USPTO recognized that in the latter situation, notwithstanding the potential for delay, the agency still holds an interest in receiving the relevant new information at the earliest possible point in the process—and thus an interest in providing an opportunity and incentive for an applicant who receives new information to promptly disclose it. Balancing these competing policy considerations, Section 1.704(d)(1) waives Section 1.704(c)(8), but only on condition that the applicant

file the newly obtained information promptly, which the agency reasonably—and, indeed, generously—defined as within a 30-day window.

Notwithstanding their waiver, Plaintiffs argue—if obliquely—that Section 1.704(d)(1) is invalid because "even where [an IDS] is timely [filed] in accordance with 37 C.F.R. § 1.97 and in satisfaction of an applicant's duty of candor under Rule 56," it may not qualify for the protection of the safe harbor. Bl. Br. p. 46. However, as the district court correctly held, there is nothing "inconsistent" about the varied time frames set forth by these rules; rather, they "simply mean[] that if an applicant would like to maximize its patent term, it would behoove the applicant to file the IDS promptly after receiving communications for a foreign patent office." Appx15. That is, taken together, these rules quite reasonably provide that, while an applicant may take longer to file an IDS, if the applicant wants to maximize its patent term, it must act with alacrity. Indeed, Congress embedded precisely this type of "dual" deadline structure within the PTA statute itself, providing in 35 U.S.C. § 133 that an applicant has a maximum of six months to reply to an Office action (on pain of having the application deemed abandoned), but providing in 35 U.S.C. § 154(b)(2)(C)(ii) that if the applicant does not wish to forfeit PTA, it must make this filing more quickly—specifically, within three

months. *Cf.* 65 Fed. Reg. at 56379 (explaining that conduct need not be "unreasonable per se" in order to carry PTA consequences).

Plaintiffs further argue that Section 1.704(d)(1) is legally insufficient because the protections of the safe harbor it establishes "are decimated by as little as a single day of delay past the 30-day period[.]" Bl. Br. p. 46. Of course, however, this objection is simply the wholly unremarkable definition of a "deadline," and far greater consequences (*e.g.*, the total forfeiture of an individual's cause of action, no matter how valuable) routinely attach to, for instance, a failure to satisfy a statute of limitations or other legal time limit. As the Supreme Court has explained, "[f]iling deadlines, like statutes of limitations, necessarily operate harshly and arbitrarily with respect to individuals who fall just on the other side of them, but if the concept … is to have any content, the deadline must be enforced. Any less rigid standard would risk encouraging a lax attitude towards filing dates." *Locke*, 471 U.S. at 101 (internal citation omitted).

Finally, Plaintiffs also argue that the USPTO's regulations[9] are arbitrary because they present applicants in Plaintiffs' situation with the choice of waiting to

[9] Plaintiffs label this objection as one that applies to Section 1.704(c)(8), but it is in substance directed to the ways in which Sections 1.704(c)(8) and 1.704(d)(1) work in tandem.

file the newly obtained information until the applicants reach a later point in the examination process when they can submit it without incurring any PTA penalty.[10] *See* Bl. Br. p. 14, *id.* p. 49. However, there is nothing irrational about the policy trade-offs embedded in this scheme: taken together, the USPTO's regulations embody its decision to prefer, in descending order: (1) that the applicant promptly disclose the new information within 30 days; and (2) that the applicant disclose the new information only after the USPTO has completed processing of the applicant's materials that are currently before the agency, *i.e.* that the applicant wait to disclose the new information until such time as it is the applicant's "turn" to respond to the USPTO. Indeed, recognizing that an unrestrained inflow of intermittent, piecemeal filing causes significant examination difficulties, *Gilead* has already endorsed precisely these same policy preferences—which, in any event, are well within the USPTO's discretion. *Cf. Balestra v. United States*, 803 F.3d 1363, 1371 (Fed. Cir. 2015) (recognizing that "[a]gencies must draw such lines and make such choices between alternatives in drafting regulations").

[10] Specifically, Section 1.97 allows an applicant to file an IDS up until the end of the patent examination process. And, if an applicant chooses to wait until the USPTO has responded to the applicant's reply, and files its IDS together with its next filing to the agency, the applicant will have "mooted" any application of Section 1.704(c)(8).

In sum, while Section 1.704(d)(1) is not necessarily the only policy choice that the USPTO could have made, it rationally balances competing concerns, in furtherance of the agency's need to examine the approximately million pending patent applications and to uniformly administer the PTA statute across the hundreds of thousands of patents that it issues every year.[11] As explained above, the Court must uphold Section 1.704(d)(1)'s qualification to Section 1.704(c)(8) as long as "it is a reasonable interpretation of the statute—not necessarily the only possible interpretation, nor even the interpretation deemed *most* reasonable by [this] [C]ourt." *Entergy Corp.*, 556 U.S. at 218 (emphasis added); *see also*, *e.g.*, *Cooper Techs. Co.*, 536 F.3d at1341 ("[The Court's] duty is not to weigh the wisdom of, or to resolve any struggle between, competing views of the public interest, but rather to respect legitimate policy choices made by the agency in interpreting and applying the statute."). As the district court correctly held, and for the reasons set forth above, Section 1.704(d)(1) more than suffices to meet these deferential standards.

[11] *See* Fiscal Year 2016 USPTO Performance and Accountability Report, 181 (Table 5 and Table 6), *available at* https://www.uspto.gov/sites/default/files/documents/USPTOFY16PAR.pdf (last visited May 9, 2017)

### D. The PTA Statute Does Not Entitle Plaintiffs to an Individualized PTA Assessment That Goes Beyond the Application of the Agency's Uniform PTA Rules

Finally, the district court also correctly recognized that, at bottom, Plaintiffs' claims amount to an argument "that they are entitled to an individualized PTA assessment" that goes beyond—and indeed, waives—application of the USPTO's duly promulgated rules of general applicability. Appx11.

As the district court recognized, the USPTO is not only permitted, but expressly required, to administer the PTA statute through general rules of categorical application, as opposed to case-by-case or *ad hoc* PTA calculations. 35 U.S.C. §§ 154(b)(2)(C)(iii), 154(b)(3)(A); *cf.* Bl. Br. p. 42 (noting that "[u]pon passage of the Patent Term Guarantee Act, the PTO conducted mandatory notice and rulemaking."). "Regulation, like legislation, often requires drawing lines," *Mayo Found. For Med. Educ. & Research*, 562 U.S. at 59, and "'even if a statutory scheme requires individualized determinations, the decision maker has the authority to rely on rulemaking to resolve certain issues of general applicability unless Congress clearly expresses an intent to withhold that authority.'" Appx12 (quoting *Lopez*, 531 U.S. at 234); *see also*, *e.g.*, *Edwards v. Dewalt*, 681 F.3d 780, 786 (6th Cir. 2012) ("Even where Congress uses such language as 'in each case,'

the Supreme Court has repeatedly reaffirmed that 'the decisionmaker has the authority to rely on rulemaking to resolve certain issues of general applicability unless Congress clearly expresses an intent to withhold that authority.'") (quoting *Am. Hosp. Ass'n v. NLRB*, 499 U.S. 606, 612 (1991), and collecting cases).

As relevant here, *Gilead* upheld one such general rule promulgated by the agency, Section 1.704(c)(8), and for the reasons set forth above, Section 1.704(d)(1) is likewise a permissible, categorical USPTO response to a recurring structural issue in the patent examination process. Plaintiffs acknowledge, as they must, that Section 1.704(c)(8) applies on its face to the facts of this case, and that they failed to avail themselves of Section 1.704(d)(1)'s safe harbor exception to this rule. The USPTO was not required to go any further in computing PTA for the '897 patent.

### E. Plaintiffs' Remaining Arguments Are in Error

Plaintiffs' remaining arguments, not yet addressed in Sections I (A)-(D), *supra*, are in error and do not change the result of the above analysis.

#### 1. Plaintiffs' Attempts to Distinguish *Gilead* Are Unavailing

First, Plaintiffs' attempts to distinguish *Gilead* are unavailing. According to Plaintiffs, the instruction of *Gilead* is that in calculating PTA, the USPTO must

"'focus[] on *applicant conduct* as opposed to the results of such conduct." Bl. Br. p. 28 (quoting *Gilead*, 778 F.3d at 1347) (emphasis added by Plaintiffs); *see also id.* p. 35 (similar), p. 38 (similar, and arguing the USPTO's failure to take into account Plaintiffs' "actual conduct" somehow renders the PTA's reference to "reasonable efforts" "superfluous and void"). However, contrary to Plaintiffs' characterization of this directive—which is that the USPTO must focus on *their conduct* as an individualized matter—what *Gilead* plainly meant by this statement is that the USPTO is entitled to penalize *categories* of applicant behavior that, *as a general matter*, have a *tendency* to interfere with the agency's efforts to complete examination, regardless of whether that potential is borne out in a particular examination process. 778 F.3d at 1349-50; *cf.* Section I.D, *supra* (explaining why Plaintiffs are not entitled to an individualized PTA determination). Thus, just as in *Gilead*, Plaintiffs err in "fram[ing] the issue solely in terms of [their] application," 778 F.3d at 1349, as opposed to the *category* of conduct that *Gilead* affirmed the USPTO to have validly addressed in Section 1.704(c)(8).

Moreover, even if "applicant conduct" had only the narrow meaning that Plaintiffs attach to it, Sections 1.704(c)(8) and 1.704(d)(1) are targeted toward "applicant conduct" and "reasonable efforts" in the sense that Plaintiffs use those

terms. *See, e.g.*, Bl. Br. p. 38. Because Section 1.704(d)(1) expressly applies to the circumstances outlined in Section 1.704(c)(8), they must be read in tandem as if they appear together in the same paragraph. When done so, Plaintiffs' argument that Section 1.704(c)(8) has "no regard for the applicant's actual conduct" cannot stand. Plaintiffs can only maintain their argument by improperly ignoring the plain language of Section 1.704(d)(1) and reading Section 1.704(c)(8) in a vacuum. Indeed, it is up to applicants whether they comply with the thirty-day "safe harbor" afforded by the PTA regulations. Where, as here, they do not, PTA is deducted.

Plaintiffs' remaining contentions regarding *Gilead*, *see* Bl. Br. p. 53-54, amount to arguments that that decision did not encounter a situation in which the qualification to Section 1.704(c)(8) established by Section 1.704(d)(1) had any relevance. However, the import of Plaintiffs' arguments is simply that, as explained, above, the limited additional question presented by this case is whether Section 1.704(d)(1)'s safe harbor is legally sufficient to address the conceded limitations of Section 1.704(c)(8). For the reasons set forth in Section I.C.1, *supra*, to the extent that Plaintiffs take issue with the safe harbor, they were required (but failed) to say so in the proceedings before the USPTO itself in the first instance. Further, for the reasons set forth in Section I.C.2, *supra*, Section 1.704(d)(1)

rationally balances competing policy concerns, and more than suffices to meet *Chevron*'s deferential review standards.

### 2. The PTA Statute Authorizes the USPTO to Define the Period of Adjustment

Plaintiffs also argue extensively that the USPTO is attempting to alter the "period of adjustment" in a manner that somehow exceeds the agency's statutory authority, but Plaintiffs cannot seriously contend that "Congress left zero authority or discretion for the PTO to determine the extent to which an applicant's patent term shall be reduced." Bl. Br. 29; *see also id.* p. 36-39 (arguing that various canons of statutory interpretation strip the USPTO of the ability to define the period of reduction).

As Plaintiffs themselves concede, *see* Bl. Br. p. 44, Congress expressly delegated authority to USPTO to "prescribe regulations" that define the "circumstances" that *per se* constitute "a failure to reasonably engage in efforts . . ." for purposes of determining PTA. 35 U.S.C. § 154(b)(2)(C)(iii). The period of adjustment set forth in Section 1.704(c)(8) (and qualified by Section 1.704(d)(1)) simply embodies the USPTO's exercise of that delegation. Indeed, without the authority to define the period of time in which the applicant had failed to engage in reasonable efforts to conclude prosecution or examination, Congress's delegation

to the USPTO to define the circumstances constituting an applicant's "failure to engage" would be meaningless surplusage because it would have no actual consequence.

Where "a statute leaves a 'gap' or is "ambigu[ous],'" a court should "typically interpret it as granting the agency leeway to enact rules that are reasonable in light of the text, nature, and purpose of the statute." *Cuozzo Speed Techs.*, 136 S. Ct. at 2142 (quoting *United States v. Mead Corp.*, 533 U.S. 218, 229 (2001)) (alteration in original). Here, the "text, nature, and purpose" of the PTA statute plainly do not evince Congressional intent that the USPTO define the circumstances constituting an applicant's "failure to engage" as some sort of academic or theoretical exercise. Rather, this delegated authority is manifestly in the service of the related statutory directive that the USPTO "reduce[]" PTA where one or more of the defined circumstances has occurred in a given prosecution history. 35 U.S.C. § 154(b)(2)(C)(i). Making the statutorily required PTA "reduc[tions]"—at least in a uniform as opposed to an *ad hoc* manner—requires the USPTO to define the relevant period(s) of adjustment. 35 U.S.C. § 154(b)(2)(C)(i). For the reasons set forth in Sections I.B-C, *supra*, the USPTO has properly done so in Section 1.704(c)(8), as qualified by Section 1.704(d)(1).

Plaintiffs try to support their argument by narrowly focusing on and isolating the phrase "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" in Section 154(b)(2)(C)(i). However, to assert that any reduction of PTA must "equal" "the period of time during which the applicant failed to engage in reasonable efforts," 35 U.S.C. § 154(b)(2)(C)(i)), is not the end, but rather the *beginning*, of the analysis. In other words, this proposition does not answer, but to the contrary only *raises*, the relevant question of what circumstances constitute a "fail[ure] to engage in reasonable efforts" that requires a concomitantly "equal" deduction of PTA. Plaintiffs cannot and do not contend that the PTA statute speaks "directly" to this ***necessarily antecedent*** question—and indeed concede, as they must, that Congress expressly delegated the responsibility to fill this substantive statutory gap to the UPSTO. Bl. Br. p. 44.

Further, Plaintiffs' approach runs contrary to the very tenets of statutory construction they espouse in their brief. *See* Bl. Br. p. 35 (noting that one must look to the larger context of a statutory scheme when construing statutory language). When the full context of 154(b)(2)(C) is viewed, it becomes clear that this language simply requires the PTA reduction to be directly tied to a

circumstance that Congress or the USPTO has determined is "a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application" as set forth in 154(b)(2)(C). As explained at length above, *Gilead* has already upheld the PTA deduction set forth in Section 1.704(c)(8), and the limited additional question presented by this case is whether Section 1.704(d)(1) creates a reasonable safe harbor exception to this general rule. For the reasons explained above in Section I.C.2, *supra*, it does.

### 3. The Challenged PTA Deduction Was Wholly Within Plaintiffs' Control to Avoid

Throughout their brief, Plaintiffs attempt to portray themselves as the victims of a punitive PTA deduction, the imposition of which was wholly outside of their control to avoid. *See* Bl. Br. p. 28 (arguing that "Congress only intended for circumstances within the applicant's control to result in a reduction of patent term"); *id.* p. 39-43 (similar, and discussing at length the legislative history of the PTA statute which, as Plaintiffs' explain, reflects this principle).

Like much of their framing of this case, however, this characterization wholly ignores the existence of the safe harbor established by Section 1.704(d)(1). As the district court noted, *see* Appx11, had Plaintiffs simply availed themselves of this grace period, they would have avoided the challenged PTA deduction.

Plaintiffs are correct that, 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 in the iterative examination process, and thus at least potentially avoided a PTA reduction. However, the PTA regulatory scheme promulgated by the USPTO incentivizes applicants to promptly submit material information in its possession, and the USPTO has used its expertise and experience to implement an array of provisions intended to capture circumstances where applicants fail to engage in reasonable efforts to conclude prosecution. While this appeal focuses exclusively on Section 1.704(c)(8), the USPTO has taken a holistic approach to implementing the PTA statute. It simply does not matter that Section 1.704(c)(8) alone may not trigger a reduction in PTA because other provisions in 37 C.F.R. §§ 1.703 and 1.704(c) will also often apply.[12] Therefore, contrary to Plaintiffs' assertions, the incentives plainly remain for applicants to file prompt

[12] For example, an applicant risks PTA reduction by waiting until after the next Office action to disclose the material information. This is because if the next Office action is a notice of allowance, any later-filed IDS will accrue significant PTA reductions under § 1.704(c)(12). Alternatively, if the next Office action is a rejection and the later-filed IDS results in a second, final rejection, the applicant (if it even chooses to continue with its application) will accrue PTA reductions either by filing an RCE, 37 C.F.R. § 1.703(b)(1), a continuation application, *id.* § 1.704(c)(11), or an appeal to the Patent Trial and Appeal Board, *id.* § 1.704(c)(4).

IDS statements. But again, these are the type of complex policy choices that are not appropriate or relevant to the *Chevron* inquiry. *Brand X*, 545 U.S. at 982.

The administrative record strongly suggests that the reason Plaintiffs failed to avail themselves of the 30-day "safe harbor" and risked significant PTA reductions is that they simply misread the PTA regulations—specifically, that they were under, at that point in time, the mistaken impression that Section 1.704(c)(6), not Section 1.704(c)(8), would supply the relevant PTA rule for their filing. Appx430-431, 445-447. While Plaintiffs have not pursued any such argument in the judicial proceedings, they do not—and in any event, could not—contend that their initial misapprehension of the regulatory framework justifies any deviation from the same. *Cf. Covenant Med. Ctr., Inc. v. Sebelius*, 424 F. App'x 434, 439 (6th Cir. 2011) ("Just as everyone is charged with knowledge of the United States Statutes at Large, Congress has provided that the appearance of rules and regulations in the Federal Register gives legal notice of their contents.'" (quoting *Fed. Crop Ins. Corp. v. Merrill*, 332 U.S. 380, 384-85 (1947)); 44 U.S.C. § 1507.

Thus, contrary to Plaintiffs' self-portrayal, it cannot seriously be disputed they were, in point of fact, fully in control of the PTA consequences of their untimely IDS filing.

### 4. Neither *Wyeth* Nor *Novartis* Are Relevant to the Issues Presented Here

Finally, contrary to Plaintiffs' strained contentions, *see* Bl. Br. p. 51, neither *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010), nor *Novartis*, 740 F.3d 593, has any relevance whatsoever to the issues presented by this case, as neither dealt, even tangentially, with the specific regulations or issues presented here.

## CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Respectfully submitted,

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