

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

INTRA-CELLULAR THERAPIES, INC.,
Plaintiff-Appellant

v.

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

2018-1849

Appeal from the United States District Court for the
Eastern District of Virginia in No. 1:17-cv-00776-CMH-
IDD, Senior Judge Claude M. Hilton.

Decided: September 18, 2019

THOMAS HOXIE, Hoxie & Associates, LLP, Millburn,
NJ, argued for plaintiff-appellant.

ANDREW SUN HAN, Office of the United States Attorney
for the Eastern District of Virginia, Alexandria, VA, argued
for defendant-appellee. Also represented by G. ZACHARY
TERWILLIGER; KAKOLI CAPRIHAN, THOMAS W. KRAUSE,
JOSEPH MATAL, BRIAN RACILLA, Office of the Solicitor,

United States Patent and Trademark Office, Alexandria, VA.

Before WALLACH, CHEN, and HUGHES, *Circuit Judges*.

CHEN, *Circuit Judge*.

Intra-Cellular Therapies, Inc. (Intra-Cellular) appeals the summary judgment decision of the United States District Court for the Eastern District of Virginia affirming the patent term adjustment (PTA) determination made by the United States Patent and Trademark Office (Patent Office). During prosecution of Intra-Cellular's patent application, the Patent Office issued a final Office action rejecting some claims and objecting to the others. A final Office action, as opposed to a non-final Office action, marks the end of formal prosecution of an application. On the three-month deadline for responding to the final Office action, Intra-Cellular filed its first response. While timely, this initial response continued to argue the merits of the examiner's final rejections and failed to comply with the Patent Office's regulatory requirements for what constitutes a proper "reply" to a final Office action. For that reason, the Patent Office concluded that Intra-Cellular's first response did not prevent the accrual of applicant delay for purposes of calculating PTA for the resulting patent. Twenty-one days after filing its unsuccessful first response, Intra-Cellular tried again by filing a second response. This time, Intra-Cellular successfully overcame all outstanding rejections and objections. Adopting all of the examiner's suggestions, the second response capitulated to all of the examiner's rulings by canceling or amending every rejected or objected to claim based on the examiner's positions. As a result of these amendments, the Patent Office issued a Notice of Allowance and concluded that this second response stopped the accrual of any further applicant delay. In calculating PTA, the Patent Office determined that the extra 21 days it took Intra-Cellular to file a successful

response after the three-month deadline for responding to the final Office action constituted applicant delay. Because we find that determination of applicant delay was based on a permissible interpretation of statute and proper reading of the regulations, we affirm the district court's grant of summary judgment in favor of the Patent Office.

BACKGROUND

I. Statutory Framework

Patent term constitutes the period of exclusivity in which a patent is in effect. In 1994, Congress amended the law to change the period of patent term from 17 years from issuance to 20 years, measured from the earliest filing date of the application for patent. *See* Pub. L. No. 103-465, § 532, 108 Stat. 4809, 4984 (1994) (codified as amended at 35 U.S.C. § 154(a)). Due to this change in the law, if the Patent Office issued a patent two years after its filing date, the resulting patent would enjoy 18 years of patent term. But if a favorable patent examination took, say, seven years to complete, then there would only be 13 years of patent term remaining after issuance, far less than the 17-year term provided for under the prior law. To protect patent owners against loss of patent term due to agency delay in the patent examination process, Congress amended § 154 in 1999 to restore patent term under certain circumstances. *See* Pub. L. No. 106-113, § 4402, 113 Stat. 1501, 1501A-557 (1999) (codified as amended at 35 U.S.C. § 154(b)) (PTA statute). Under the PTA statute, the term of a patent can be extended to compensate for lost patent term due to statutorily-defined agency delay. *See* § 154(b)(1)(A)–(C). But, at the same time, PTA can be reduced for delays caused by the applicant. *See* § 154(b)(2)(C).

Section 154(b)(1) provides three types of statutorily-defined delay caused by the Patent Office that will lead to accrual of PTA for the resulting patent, outlined in § 154(b)(1)(A), (B), (C). “A Delay” accrues when the Patent

Office fails to act by certain examination deadlines. § 154(b)(1)(A). “B Delay” accrues when the Patent Office fails to “issue a patent within 3 years after the actual filing date of the application.” § 154(b)(1)(B). “C Delay” accrues during the pendency of interferences, secrecy orders, and appeals. § 154(b)(1)(C).

On the other hand, when *applicant* conduct causes delay in the examination process, any PTA that has accumulated is reduced by that amount of applicant delay. *See* § 154(b)(2)(C); *Gilead Scis., Inc. v. Lee*, 778 F.3d 1341, 1344–45 (Fed. Cir. 2015). Under § 154(b)(2)(C)(i) of the PTA statute, a patent’s PTA “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.”

Section 154(b)(2)(C)(ii) provides an instance of what constitutes “fail[ure] to engage in reasonable efforts” based on how long it takes for an applicant to respond to certain Office actions. In particular, “an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of 3 months that are taken to respond to a notice from the [Patent] Office making any rejection, objection, argument, or other request, measuring such 3-month period from the date the notice was given or mailed to the applicant.” § 154(b)(2)(C)(ii).

Section 154(b)(2)(C)(iii) authorizes the Patent Office to promulgate regulations providing further details and examples of what constitutes “fail[ure] to engage in reasonable efforts.” This regulation provides that the “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.” § 154(b)(2)(C)(iii).

II. Regulatory Framework

Pursuant to its congressional authority, the Patent Office promulgated regulations for determining PTA reduction due to applicant delay. Relevant to this appeal is 37 C.F.R. § 1.704(b), which closely tracks the language in § 154(b)(2)(C)(ii). This regulation provides that “*an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of three months that are taken to reply to any notice or action by the [Patent] Office making any rejection, objection, argument, or other request . . .*” § 1.704(b) (emphases added). In other words, if an applicant takes longer than three months to file a “reply” to an Office action, applicant delay will accrue. Applicant delay begins accruing from the day after the three-month deadline for responding to an Office action and stops accruing the “date the reply was filed.” § 1.704(b). But § 1.704(b) itself does not define what constitutes a proper “reply” for cutting off applicant delay.

Section 1.704(b) was promulgated against a backdrop of long-existing regulations governing patent prosecution practices. One fundamental principle that pervades these regulations is that a “final” Office action marks the end of normal prosecution as of right. *See* 37 C.F.R. § 1.113(a), (c); § 1.114(b) (“Prosecution in an application is closed as used in this section means . . . that the last Office action is a final action . . .”); MPEP § 714.12 (“Once a final rejection that is not premature has been entered in an application, applicant or patent owner no longer has any right to unrestricted further prosecution.”). Before a final Office action is issued, an applicant has more leeway to argue its case and amend its claims in a reply. To properly respond to a non-final Office action, a “bona fide attempt to advance the application” is required. *See* 37 C.F.R. §§ 1.111(b), 1.135(c). Once examination proceeds into after-final Office action territory, however, § 1.113(a) restricts the options that are available to the applicant, and the patent

examiner is not obligated to engage in further examination and review of the patent application or applicant arguments. Each of the applicant's options, discussed below, is subject to its own requirements and potential PTA consequences.

One option is to file a § 1.113(c) reply. § 1.113(a). Pursuant to § 1.113(c), a “[r]eply to a final rejection or action must include cancellation of, or appeal from the rejection of, each rejected claim. If any claim stands allowed, the reply to a final rejection or action must comply with any requirements or objections as to form.” Thus, filing a § 1.113(c) reply is an action an applicant can take to conclude prosecution before the examiner, but importantly, no claim amendments or arguments are allowed, as prosecution “is closed” once a final Office action has issued. § 1.114(b). It is undisputed that filing a § 1.113(c) reply will cut off accrual of applicant delay under § 1.704(b).

A second option for the applicant when confronted with a final Office action is to file a Request for Continued Examination (RCE) under § 1.114. § 1.113(a). An RCE involves filing a “submission” and paying additional fees. § 1.114(a). Such a “submission” includes, but is not limited to, “amendment[s] to the written description, claims, or drawings,” and “new arguments.” § 1.114(c). An RCE “withdraw[s] the finality of any Office action” and re-opens normal prosecution, once again requiring the examiner to engage in a substantive examination of the application, but this time in light of the applicant's RCE submission. *Id.* In return for this extended substantive examination, the filing of an RCE stops the accrual of B Delay, thereby cutting off a potential significant source of PTA if the patent is ultimately granted. *See* § 154(b)(1)(B)(i); *Novartis AG v. Lee*, 740 F.3d 593, 601 (Fed. Cir. 2014). Thus, unlike a § 1.113(c) reply, an RCE permits much more flexibility in responding on the merits to a final Office action, but at the cost of losing PTA.

A third option is to file a 37 C.F.R. § 1.116 amendment. § 1.113(a). Under § 1.116, three types of amendments are permitted. § 1.116(b)(1)–(3). First, an applicant is permitted to file a limited amendment “canceling claims or complying with any requirement of form expressly set forth in a previous Office action.” § 1.116(b)(1). Second, an applicant is permitted to file an “amendment presenting rejected claims in better form for consideration on appeal.” § 1.116(b)(2). And third, an “amendment touching the merits of the application . . . may be admitted upon a showing of good and sufficient reasons why the amendment is necessary and was not earlier presented.” § 1.116(b)(3). Thus, § 1.116 permits an applicant to file certain minor amendments after a final Office action; a substantive amendment requiring a substantive examination is permitted only in exceptional circumstances. Importantly, the filing of a § 1.116 amendment will not alone “save the application from abandonment.” § 1.116(c). “The admission of, or refusal to admit, any amendment after final rejection . . . will not operate to save the application from abandonment.” § 1.135(b). Only a “complete and proper reply” to the final Office action within the statutory time period to act will save the application from abandonment. *Id.* Thus, per the Patent Office’s regulations, the acceptance of any after-final amendment by itself is not regarded as a “complete and proper reply.” *Id.*

III. Prosecution History

Intra-Cellular is the owner and assignee of U.S. Patent No. 8,648,077 (’077 patent). On September 10, 2010, Intra-Cellular filed the application leading to the ’077 patent. On October 9, 2012, the Patent Office issued a non-final Office action. The non-final Office action raised various issues with the application, including rejections under 35 U.S.C. § 103 and § 112 and objections due to various informalities. In response, Intra-Cellular argued against the § 103 rejections without amendment and attempted to

overcome the other rejections and objections through amendment.

On April 17, 2013, the Patent Office mailed a final Office action. No claims were allowed. Unpersuaded by Intra-Cellular's arguments against the § 103 rejections, the examiner repeated the same § 103 rejections from the prior non-final Office action. The examiner also found that Intra-Cellular's amendments did not successfully overcome the other rejections and objections raised in the non-final Office action but instead introduced new informalities leading to new objections. On July 17, 2013, Intra-Cellular responded to the final Office action by filing a submission entitled "Amendments and Response Under 37 C.F.R. 1.116."¹ This submission was filed three months after the final Office action issued, marking the last day for Intra-Cellular to file a "reply" to the final Office action without accruing applicant delay. *See* § 1.704(b); *see also* § 154(b)(2)(C)(ii). In this after-final response, Intra-Cellular continued to dispute the § 103 rejection using the same arguments that were previously found unpersuasive by the examiner, and amended claims to address other objections and rejections. Intra-Cellular also added a new claim.

On July 26, 2013, the Patent Office mailed an "Advisory Action" indicating that Intra-Cellular's July 17, 2013 after-final submission overcame some of the previous § 112 rejections and formality objections but failed to overcome the § 103 rejection for the prior "reasons of the record." J.A. 204. To "place the application in better condition for

¹ We note that despite being labeled as an amendment "Under 37 C.F.R. 1.116," Intra-Cellular's July 17, 2013 submission does not appear to comply with any of the permitted amendments under § 1.116(b)(1)–(3), at least because this submission continued arguing the § 103 rejection repeated in the final Office action from the non-final Office action without amendment.

allowance,” the examiner suggested “amend[ing] or canceling” certain claims to overcome the outstanding § 103 rejection and amending other claims based on specific suggestions proposed by the examiner to overcome the outstanding § 112 rejections and new formality objection. J.A. 205. Intra-Cellular complied. On August 7, 2013, choosing to no longer resist the § 103 rejections, Intra-Cellular filed its second after-final submission adopting all of the examiner’s suggestions for overcoming the outstanding rejections and objections. This second after-final submission led directly to a Notice of Allowance, which was mailed on August 20, 2013. The application subsequently issued as the ’077 patent.

IV. Determination of PTA by the Patent Office

On January 9, 2017, the Patent Office issued a “Final Agency Decision” determining that the ’077 patent was entitled to 264 days of PTA. This number was computed by subtracting total delay attributed to the applicant from total delay attributed to the agency. Of the total applicant delay, the Patent Office attributed 21 days of applicant delay to the time it took Intra-Cellular to file its second after-final submission after the three-month deadline for responding to the final Office action. Though Intra-Cellular’s first after-final submission was filed right on the three-month mark, the Patent Office found that it did not constitute a proper “reply” under § 1.704(b). The Patent Office justified this determination based on two independent reasons. First, the Patent Office found that Intra-Cellular’s first submission “fail[ed] to comply with 37 C.F.R. § 1.113.” J.A. 242. Second, the Patent Office alternatively found that the first submission constituted a “[s]ubmission of a reply having an omission (§ 1.135(c))” under 37 C.F.R. § 1.704(c)(7).² J.A. 242–43. Because the Patent Office

² The Patent Office’s alternative reliance on § 1.704(c)(7) to justify accrual of applicant delay resulting

determined that Intra-Cellular's first after-final submission was not a proper after-final reply, the clock on applicant delay started ticking the day after the three-month deadline. The Patent Office stopped that clock when Intra-Cellular filed its second after-final submission 21 days later. Unlike its first after-final submission, this second submission capitulated to each of the examiner's objections and rejections to the claims set forth in the final Office action and directly led to allowance.

V. District Court Proceedings

On July 7, 2017, Intra-Cellular filed a complaint in the United States District Court for the Eastern District of Virginia seeking judicial review of the Patent Office's PTA determination. The district court granted summary judgment in favor of the Patent Office.

The district court considered the Patent Office's PTA determination to involve a question of statutory interpretation performed by the agency and applied *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467

from an improper reply to a *final* Office action is questionable. Section 1.704(c)(7) appears to apply only to replies to *non-final* Office actions. According to § 1.704(c)(7), a “[s]ubmission of a reply having an omission (§ 1.135(c))” constitutes a “circumstance[] that constitute[s] a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application” under § 1.704(c). But § 1.135(c) only addresses omissions made in a reply to a “non-final Office action.” § 1.135(c) (referring to a situation where a “reply by the applicant is a bona fide attempt to *advance the application to final action*, and is substantially a complete reply to the *non-final Office action*, but consideration of some matter or compliance with some requirement has been inadvertently *omitted*” (emphasis added)).

U.S. 837 (1984). The district court framed the question at issue to be “whether a submission filed after a final Office action that fails to place the application in condition for allowance (such as the [first after-final] submission) constitutes a ‘fail[ure] to engage in reasonable efforts to conclude prosecution’” under § 154(b)(2)(C). J.A. 9–10. At Step 1 of *Chevron*, the district court rejected Intra-Cellular’s contention that the plain language of the statute answered this question. The court noted that “nothing in the plain language of the statute indicates that ‘reasonable efforts to conclude prosecution’ should be read to include an incomplete submission which fails to place the application in condition for allowance, but in some manner advances it closer to allowance.” J.A. 10.

At Step 2 of *Chevron*, the district court upheld the agency’s interpretation under applicable regulations. In attributing the 21-day period to applicant delay, the Patent Office found that Intra-Cellular’s first after-final submission did not constitute a valid “reply” that stopped accrual of applicant delay under § 1.704(b). To determine whether Intra-Cellular’s first after-final submission was a valid “reply” to a final Office action, the Patent Office applied § 1.113(c), which sets forth the requirements for replying to a final (as opposed to non-final) Office action. Thus, the Patent Office effectively interpreted “reply” under § 1.704(b) to be a “reply” compliant with § 1.113(c). Because Intra-Cellular’s first after-final submission did not cancel or appeal every rejected claim per § 1.113(c), the Patent Office determined that the first after-final “submission was not a proper reply under § 1.113(c),” and therefore not a “reply” under § 1.704(b). J.A. 13–14. Ultimately, the district court held that the Patent Office’s determination that Intra-Cellular’s first after-final submission constituted a “fail[ure] to engage in reasonable efforts to conclude processing or examination” under § 1.704(b) “was based on a permissible construction of the relevant statutes, and

therefore should be afforded deference” under *Chevron*. J.A. 14–15.

Intra-Cellular timely filed this appeal. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

STANDARD OF REVIEW

We review a district court’s grant of summary judgment under the law of the regional circuit. *See Mohsenzadeh v. Lee*, 790 F.3d 1377, 1381 (Fed. Cir. 2015). Under Fourth Circuit law, we review the grant of summary judgment *de novo*. *Gallagher v. Reliance Standard Life Ins. Co.*, 305 F.3d 264, 268 (4th Cir. 2002). Patent Office PTA decisions “are reviewed in accordance with the Administrative Procedure Act” (APA). *Supernus Pharm., Inc. v. Iancu*, 913 F.3d 1351, 1356 (Fed. Cir. 2019); § 154(b)(4)(A). Under the APA, we set aside the Patent Office’s actions only if they are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A), (C). When reviewing an agency’s statutory interpretation, we apply the two-step framework established in *Chevron*. *Gilead*, 778 F.3d at 1346.

DISCUSSION

In dispute is whether a particular period of 21 days, following the three-month deadline for responding to a final Office action, counts as applicant delay. The Patent Office determined it was, finding that Intra-Cellular’s first after-final submission constituted a “fail[ure] to engage in reasonable efforts to conclude prosecution.” § 154(b)(2)(C)(i). We now discuss whether the district court erred in upholding the agency’s determination, which hinges in part on an interpretation of statutory text, under *Chevron*.

I. *Chevron* Step 1: The PTA Statute Does Not Answer the Precise Question.

At Step 1 of *Chevron*, we “ask whether the statute’s plain terms ‘directly address[s] the precise question at issue.’” *Nat’l Cable & Telecomms. Ass’n v. Brand X Internet Servs.*, 545 U.S. 967, 986 (2005) (quoting *Chevron*, 467 U.S. at 843). We begin with the language of the statute itself. *United States v. Hohri*, 482 U.S. 64, 69 (1987). “Absent a clearly expressed legislative intention to the contrary, [the statute’s plain] language must ordinarily be regarded as conclusive.” *Consumer Prod. Safety Comm’n v. GTE Sylvania, Inc.*, 447 U.S. 102, 108 (1980). When “deciding whether the language is plain, the Court must read the words ‘in their context and with a view to their place in the overall statutory scheme.’” *King v. Burwell*, 135 S. Ct. 2480, 2483 (2015) (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000)).

The precise question at issue is whether an applicant submission, filed after a *final* Office action, that continues to argue the merits of the examiner’s rejection, without good cause, constitutes a “fail[ure] to engage in reasonable efforts to conclude prosecution” such that applicant delay would accrue under the PTA statute. See § 154(b)(2)(C)(i). Because its first after-final submission addressed each outstanding objection and rejection to the claims made in the final Office action, Intra-Cellular argues that this submission was a bona fide attempt to advance prosecution, thus constituting “reasonable efforts to conclude prosecution” under a plain reading of the PTA statute. While, in a vacuum, this reading may be one plausible interpretation of “reasonable efforts,” nothing in the plain language of the statute or its overall structure commands that outcome for understanding what constitutes “reasonable efforts” by an applicant when responding to a *final* Office action. Moreover, Intra-Cellular’s reading appears to be in tension with the fact that it no longer had the right to continue debating

the merits of the rejection once the final Office action issued in this case.

When read in the context of the overall statutory scheme, we conclude that the language of the PTA statute does not answer the question of what type of action by an applicant constitutes “reasonable efforts to conclude prosecution” for purposes of responding to a *final* Office action. The PTA statute does not shed any additional light as to the meaning of this phrase in addressing this question. The PTA statute was passed against a backdrop of existing regulations that regulate applicant responses to *final* Office actions much more restrictively than responses to *non-final* Office actions. To properly respond to a non-final Office action, regulations require a “bona fide attempt to advance prosecution,” which entails addressing each and every outstanding objection and rejection. § 1.135; § 1.111. But the requirements for responding to a final Office action are stricter. If the applicant wishes to keep arguing against the examiner’s rejections, it must take those arguments to the Patent Board on appeal or file an RCE to reopen prosecution in front of the examiner. § 1.113(a); § 1.114. If the applicant wishes to make an amendment to a claim, only certain types of amendments are allowed to be admitted under § 1.116. *See* § 1.116(b)(1)–(3). Moreover, the regulation indicates that not all after-final amendments constitute proper replies. As § 1.116(b) provides, “[t]he admission of, or refusal to admit, any amendment after a final rejection . . . will not operate to relieve the application . . . from its condition as subject to appeal or to save the application from abandonment” Thus, none of these regulations suggests that attempts to *address* all rejections and objections by continuing to argue the merits are sufficient after-final replies. Against this pre-existing regulatory backdrop, what may be “reasonable efforts” in the context of responding to a non-final Office action can be quite different from “reasonable efforts” for responding to a final Office action. Because nothing in the language or

structure of the PTA statute addresses what may be regarded as “reasonable efforts” on the part of an applicant in responding to a final Office action, we proceed to an analysis under *Chevron* Step 2.

II. *Chevron* Step 2: The Patent Office’s PTA Determination Is Supported By a Permissible Construction of the PTA Statute.

At Step 2, *Chevron* requires determination of whether the Patent Office’s answer to the precise question at issue is based on a “permissible construction of the statute.” *Chevron*, 467 U.S. at 843. We have “long recognized that considerable weight should be accorded to an [agency’s] construction of a statutory scheme it is entrusted to administer, and the principle of deference to administrative interpretations.” *Id.* at 844.

In attributing the 21-day period at issue to applicant delay, the Patent Office determined that Intra-Cellular’s first after-final submission constituted a “fail[ure] to engage in reasonable efforts to conclude prosecution” under the PTA statute because its after-final submission was not a compliant “reply” under § 1.704(b), which is the Patent Office’s implementing regulation for defining what constitutes applicant delay. This determination is supported by a permissible construction of the PTA statute. That is, we hold that it is permissible to interpret an after-final submission that merely continues to argue the merits of an examiner’s final rejection as a “fai[lure] to engage in reasonable efforts to conclude prosecution” such that such an applicant submission would not stop the accrual of applicant delay under the PTA statute.

Section 1.704(b) provides that “*an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of three months that are taken to reply to any notice or action by the [Patent] Office making any rejection, objection,*

argument, or other request . . .” § 1.704(b) (emphases added). While § 1.704(b) does not explicitly define “reply,” that does not mean that *any* type of submission by the applicant, no matter how flimsy or superficial, necessarily qualifies as a “reply” for purposes of stopping accrual of applicant delay. Intra-Cellular does not dispute this. Oral Arg. at 11:35–12:17. Thus, some standard of compliance must be used, and the Patent Office already had longstanding regulatory standards in place for a complete and proper reply—one for replies to *non-final* Office actions (§ 1.111) and one for replies to *final* Office actions (§ 1.113). Given that the submission at issue was filed in response to a final Office action, the Patent Office appropriately turned to pre-existing regulatory requirements set forth in § 1.113 for responding to a final Office action, unchallenged here, in interpreting whether Intra-Cellular’s after-final submission qualified as a “reply” under § 1.704(b). See *Roberto v. Dep’t of Navy*, 440 F.3d 1341, 1350 (Fed. Cir. 2006) (finding that “[t]he rules of statutory construction apply when interpreting an agency regulation,” and “[w]hen construing a regulation or statute,” the court may “consider the language of related regulations”); *Strategic Housing Fin. Corp. v. United States*, 608 F.3d 1317, 1330 (Fed. Cir. 2010) (“[C]ourts should interpret statutes with similar language that generally address the same subject matter together, ‘as if they were one law’” (quoting *Erlenbaugh v. United States*, 409 U.S. 239, 243 (1972))).

Section 1.113(a) sets forth limited ways for an applicant to properly respond to a final Office action. It provides that an applicant’s “reply is limited to appeal in the case of rejection of any claim . . . or to amendment as specified in § 1.114 or § 1.116.” § 1.113(a). It also states that a “[r]eply to a final rejection or action must comply with § 1.114 or paragraph (c) of this section.” *Id.* Thus, § 1.113(a) at minimum sets forth two ways to file a proper reply to a final Office action—by either complying with § 1.114 (filing an RCE) or § 1.113(c) (cancellation or appeal of rejected

claims). While § 1.113(a) also indicates that a § 1.116 amendment can be filed, § 1.116 itself indicates that a § 1.116 amendment filed by an applicant, without more, does not necessarily relieve the applicant's responsibility to timely reply to a final Office action. As § 1.116(c) provides, the "admission of, or refusal to admit, any amendment after a final rejection, a final action, an action closing prosecution, or any related proceedings, *will not operate to relieve the application . . . from its condition as subject to appeal or save the application from abandonment.*" § 1.116(c) (emphasis added); *see also* § 1.135(b) ("The admission of, or refusal to admit, any amendment after final rejection . . . will not operate to save the application from abandonment."). Thus, the regulatory framework makes clear that for purposes of responding to a final Office action rejecting at least some of the claims, a proper "reply" must either comply with § 1.113(c) or § 1.114. The Patent Office properly read the term "reply" in § 1.704(b) in harmony with those regulatory requirements for determining whether an applicant's response to a final Office action cuts off accrual of applicant delay.

It is undisputed that Intra-Cellular's first after-final submission did not comply with § 1.113(c) or § 1.114. Intra-Cellular, in its initial response, could have pursued either path for filing a proper reply to the final Office action, but it chose not to. In that first after-final submission, Intra-Cellular continued to dispute the § 103 rejection with the same arguments the examiner had previously found unpersuasive in overcoming the same § 103 rejection in the non-final Office action. Because prosecution was closed and the examiner at that point was under no obligation to reconsider arguments that had already been rejected in the final Office action, such applicant conduct does not amount to "reasonable efforts to conclude" prosecution under § 1.704(b). Until a compliant reply was filed, Intra-Cellular began accruing "applicant delay" once the three-month deadline passed for responding to the final Office action.

In filing the *second* after-final submission, Intra-Cellular ceased resisting the examiner's objections and rejections and accepted the examiner's positions, adopting all of the examiner's suggestions for canceling or amending claims to overcome all rejections and objections of record. This complete capitulation to the examiner's final Office action placed the application in condition for allowance and directly led to a Notice of Allowance, concluding prosecution of the application. Because Intra-Cellular's second after-final submission amended the application to conform with all the requirements the examiner had set forth in the Advisory Action, the Patent Office effectively determined that this response constituted "reasonable efforts to conclude prosecution," cutting off any further accrual of applicant delay.

Intra-Cellular's proposed interpretation of "reply" under § 1.704(b) as any bona fide attempt to address all rejections and objections in an Office action is impermissible because it incorrectly applies the standard for a compliant "reply" to a *non-final* Office action as set forth in § 1.111 to the reply to a *final* Office action at issue here. See § 1.111(b) (stating that a reply to a non-final Office action "must reply to every ground of objection and rejection"). As explained above, a separate regulation, § 1.113, defines a proper "reply" to a final Office action, which is the relevant standard for this case. Moreover, under Intra-Cellular's interpretation, an applicant would be allowed to continue to liberally argue and make amendments without accruing applicant delay as long as it addressed all outstanding issues in the final Office action. But treating this type of submission as a proper "reply" would give the applicant the benefits of an RCE (which re-opens prosecution) without the concomitant PTA reduction that comes with an RCE. This clearly contravenes the structure of the existing PTA statute, which prevents extension of PTA through B Delay accrual for time consumed by an RCE. § 154(b)(1)(B)(i); *Novartis*, 740 F.3d at 601 ("[A]ny time consumed by

continued examination” under § 154(b)(1)(B)(i), “no matter when initiated, does not count toward depleting the allotment of three years the PTO has before any adjustment time begins to accrue.”).

Intra-Cellular makes numerous arguments against the permissibility of the Patent Office’s PTA determination, but we find none of them to be persuasive. First, Intra-Cellular argues that by focusing on the *result* of applicant’s conduct (i.e., a failure to successfully overcome all outstanding rejections and objections in the final Office action) rather than the conduct itself (e.g., a bona fide attempt to address all issues), the Patent Office’s PTA determination violates our holding in *Gilead*. Appellant’s Br. at 24–26. We disagree. In *Gilead*, the Patent Office found that an applicant’s untimely filing of a supplemental Information Disclosure Statement (IDS) still caused applicant delay to accrue even though it did not result in *actual* prosecution delay because it was filed before the first Office action had issued. *Gilead*, 778 F.3d at 1345, 1349. Nevertheless, we upheld the Patent Office’s applicant delay finding because the “failure to engage in reasonable efforts” focused on an applicant’s “conduct,” not results. *Id.* at 1349. Here, the Patent Office’s applicant delay determination is entirely consistent with *Gilead*’s conduct-oriented focus. In continuing to dispute the merits of the § 103 rejection using arguments that were previously considered and rejected by the examiner, Intra-Cellular’s conduct not only had the potential to, but actually did, result in prosecution delay. As we stated in *Gilead*, it was reasonable to find that this type of applicant behavior was the kind Congress intended to sanction as a “failure to engage in reasonable efforts” under the PTA statute. *Id.* at 1349 (“[T]his court finds that a reasonable interpretation of the [PTA] statute is 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.”).

Second, Intra-Cellular argues that the Patent Office’s applicant delay determination is contrary to our reasoning in *Pfizer, Inc. v. Lee*, 811 F.3d 466, 470 (Fed. Cir. 2016). Appellant’s Br. at 40–43. We disagree. In *Pfizer*, we held that the time it took for an examiner to correct a defective restriction requirement did not count as delay attributed to the Patent Office, because the examiner’s actions were part of the typical “back and forth” process of prosecution. *Id.* at 476. Here, the submission at issue was filed by an applicant after a final Office action was issued. A final Office action marks the end of prosecution as of right. *See, e.g.*, § 1.114(b) (“Prosecution in an application is closed as used in this section means . . . that the last Office action is a final action . . .”). As such, any delay caused by the applicant in after-final territory is not part of the typical “back and forth” process of prosecution. Thus, the reasoning in *Pfizer* does not apply.

Third, Intra-Cellular argues that it was “unfair surprise” for the Patent Office to require the generic recitation of “reply” in § 1.704(b) to mean a “reply in compliance with § 1.113(c).” Appellant’s Br. at 11. Intra-Cellular points out that when the Patent Office wants to impose compliance with § 1.113(c), it will say so, as it did with the recitation of “reply in compliance with § 1.113(c)” under § 1.703(a), another regulation that addresses the computation of delay attributed to the agency (rather than the applicant). We disagree that the more specific recitation of “reply” in § 1.703(a) renders it impermissible to require “reply” under § 1.704(b) to be compliant with § 1.113(c) when filed in the context of responding to a final Office action. Section 1.703(a) is in fact entirely consistent with our and the Patent Office’s reading of “reply” in § 1.704(b). The specific reference to a “reply in compliance with § 1.113(c)” in § 1.703(a) reflects the Patent Office’s recognition that Office actions in response to replies to final Office actions and Office actions in response to replies to non-final Office actions represent two different situations, both of which may

separately give rise to agency delay. Indeed, § 1.703(a) specifically sets forth separate rules for computing agency delay in the context of replies to non-final Office actions and replies to final Office actions. Under § 1.703(a)(2), agency delay accrues where an Office action is filed more than four months after “a reply under § 1.111” is filed. Under § 1.703(a)(3), agency delay accrues where an Office action is filed more than four months after “a reply in compliance with § 1.113(c)” is filed. Given that the Patent Office’s context-based reading of “reply” under § 1.704(b) is consistent with the sensitivity to different types of replies in § 1.703(a) (replies to non-final versus final Office actions) and the agency’s long-standing requirements treating these replies differently (as evidenced by § 1.113 and § 1.111), we are unpersuaded that the Patent Office’s PTA determination here was based on a reading that presented an “unfair surprise.” *Cf. Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156–58 (2012) (finding that “the potential for unfair surprise [wa]s acute” where the agency announced an interpretation that was preceded by the agency’s decades-long practice signaling endorsement of a contrary interpretation).

Intra-Cellular also argues that it is impermissible for the Patent Office to rely on an interpretation that requires compliance with § 1.113(c) because such an interpretation conflicts with the Patent Office’s promotion of various after-final “pilot” programs that encourage applicants to engage in further prosecution after a final Office action. Appellant’s Reply Br. at 21–25. We need not address this argument because it is waived. However, for completeness, we note that none of these after-final pilot programs were utilized in this case, and Intra-Cellular has not argued or presented any evidence of how participation in these “pilot” programs would affect, if at all, the computation of applicant delay.

CONCLUSION

We find that the Patent Office's determination of applicant delay is supported by a permissible reading of the PTA statute. We have considered Intra-Cellular's remaining arguments and find them unpersuasive. Accordingly, we conclude that the district court did not err in granting summary judgment in favor of the Patent Office.³

AFFIRMED**COSTS**

No costs.

³ We note that our decision upholding the Patent Office's determination of PTA does not rely on deference to the agency under *Auer v. Robbins*, 519 U.S. 452 (1997) because that doctrine is not necessary to understanding the regulations and deciding this case.