

# APPENDIX

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*Appendix A*

NOTE: This disposition is nonprecedential.

United States Court of Appeals  
for the Federal Circuit

**EURICA CALIFORNIAA,**  
*Plaintiff-Appellant*

v.

**KATHERINE K. VIDAL, UNDER SECRETARY  
OF COMMERCE FOR INTELLECTUAL  
PROPERTY AND DIRECTOR OF THE UNITED  
STATES PATENT AND TRADEMARK OFFICE,**  
*Defendant-Appellee*

2022-1640

Appeal from the United States District Court for  
the Eastern District of Virginia in No. 1:20-cv-00985-  
MSN-TCB, Judge Michael S. Nachmanoff.

Decided: Nov. 7, 2022

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Before LOURIE, DYK, and HUGHES, *Circuit Judges*.

PER CURIAM.

Eurica Californiaa appeals from the decision of the United States District Court for the Eastern District of Virginia granting summary judgment in favor of the United States Patent and Trademark Office (“PTO”). *See Californiaa v. Hirshfeld*, No. 1-20-cv-00985, 2021 WL 6196996 (E.D. Va. Dec. 20, 2021). *We affirm*.

#### BACKGROUND

Californiaa alleges that the PTO incorrectly calculated the Patent Term Adjustment (“PTA”) for his patent, U.S. Patent 10,245,075 (the “075 patent”), by improperly deducting 51 days due to applicant delay.

Patent terms are generally extended by one day for each day of PTO delay, minus one day for each day during which the applicant fails to engage in reasonable efforts to conclude prosecution of the application. 35 U.S.C. § 154(b)(2)(C).<sup>1</sup> Congress

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<sup>1</sup> 35 U.S.C. § 154(b)(2)(C): Reduction of period of adjustment. —

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

delegated to the PTO the authority to define those situations that reflect a failure to engage in reasonable efforts to conclude prosecution of the patent. § 154(b)(2)(C)(iii). To avoid case-by-case determinations of what constitutes a failure to engage in reasonable efforts to conclude prosecution, it has promulgated regulations outlining examples of such efforts. See 65 Fed. Reg. 56366, 56378–79 (Sept. 18, 2000). It has defined an applicant's amendment of a patent application after it issues a notice of allowance as one such failure. 37 C.F.R. § 1.704(c)(10).<sup>2</sup> Following our January 23, 2019 decision in *Supernus*, the PTO revised its regulations governing the calculation of PTA, including §

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(ii) With respect to adjustments to patent term made under the authority of paragraph (1)(B), an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of 3 months that are taken to respond to a notice from the Office making any rejection, objection, argument, or other request, measuring such 3-month period from the date the notice was given or mailed to the applicant.

(iii) 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.

<sup>2</sup> 37 C.F.R. § 1.704(c)(10) (2019): Submission of an amendment under § 1.312 or other paper, other than a request for continued examination in compliance with § 1.114, after a notice of allowance has been given or mailed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the lesser of:

(i) The number of days, if any, beginning on the date the amendment under § 1.312 or other paper was filed and ending on the mailing date of the Office action or notice in response to the amendment under § 1.312 or such other paper; or

(ii) Four months.

1.704(c)(10). *Supernus Pharms., Inc. v. Iancu*, 913 F.3d 1351 (Fed. Cir. 2019); 85 Fed. Reg. 36335, 36335 (June 16, 2020). This subsection was amended in June 2020 to (1) distinguish between after-allowance amendments expressly requested by the PTO, and those not, and (2) change the relevant timeframe for the calculation of a reduction in PTA. 37 C.F.R. § 1.704(c)(10) (2020)<sup>3</sup>; 85 Fed. Reg. at 36335.

After an extensive prosecution involving numerous amendments, the examiner found that Californiaa's patent could issue if minor additional changes were made to the claim language. C.A. 101–03.<sup>4</sup> The examiner made the amendment on his own authority and mailed the Notice of Allowance on December 11, 2018. C.A. 100. On January 7, 2019, Californiaa requested an additional interview, attaching a new proposed amendment to the interview request. C.A. 112–16. The interview was held the following day and included discussion of the potential amendment. *Id.* On January 10, 2019, Californiaa accordingly submitted a new amendment making minor changes (*e.g.*, the addition of a comma) to some of the examiner-amended claim

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<sup>3</sup> 37 C.F.R. § 1.704(c)(10) (2020): Submission of an amendment under § 1.312 or other paper, other than an amendment under § 1.312 or other paper expressly requested by the Office or a request for continued examination in compliance with § 1.114, after a notice of allowance has been given or mailed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date of mailing of the notice of allowance under 35 U.S.C. 151 and ending on the date the amendment under § 1.312 or other paper was filed.

<sup>4</sup> “C.A.” refers to Appellee’s Corrected Appendix.

limitations, and several substantive changes (*e.g.*, the deletion of limitations) unrelated to the examiner amendment. C.A. 117–36. On February 26, 2019, the examiner responded and accepted the amendment. C.A. 140–161. The patent issued on April 2, 2019. C.A. 162.

The PTO, in calculating PTA, subtracted 51 days for the time that the plaintiff's after-allowance amendment was pending pursuant to 37 C.F.R. § 1.704(c)(10) (2019). At the time of calculation, § 1.704(c)(10) required a reduction of PTA for “[s]ubmission of an amendment under § 1.312 . . . after a notice of allowance has been given or mailed” by “the lesser of: (i) The number of days, if any, beginning on the date the amendment under § 1.312 or other paper was filed and ending on the mailing date of the Office action or notice in response to the amendment under § 1.312 or such other paper; or (ii) Four months.”

Pursuant to 35 U.S.C. § 154(3)(B)(ii), Californiaa timely filed a request for redetermination of PTA. C.A. 163–165. Californiaa argued that his only possible course of action to address the examiner's amendment was to file his own after-allowance amendment, and therefore his actions did not constitute a failure to engage in reasonable efforts to conclude prosecution. The PTO found that the situation still fell within the rule, and that Californiaa would not benefit from an exception anyway because he sought changes unrelated to the examiner's amendment and that it could have been made earlier. C.A. 6–7.

Californiaa then sought review in the U.S. District Court for the Eastern District of Virginia under 35 U.S.C. § 145. Californiaa argued again

that the PTA should not be reduced because the PTO's rule that all after-allowance amendments constitute applicant delay was contrary to § 154(b)(2)(C). Californiaa also argued that (1) he had not approved the examiner's amendment; and (2) that his PTA should be recalculated using the method outlined in the June 16, 2020 amendment to § 1.704(c)(10) because the prior version of the regulation was invalid in light of our ruling in *Supernus*, 913 F.3d at 1358–61. The court, applying *Chevron* deference, concluded that the applicant's filing of an after-allowance amendment met the criteria for a reduction of PTA, and that Californiaa's other arguments were forfeited because they were not made before the PTO. C.A. 18 n.3. The court then granted summary judgment in favor of the PTO. C.A. 15–19. Californiaa timely filed a request for rehearing, which was denied. C.A. 21–24.

Californiaa then appealed the district court's grant of the PTO's motion for summary judgment to this court. C.A. 28. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(C).

#### DISCUSSION

We review a grant of summary judgment according to the law of the regional circuit. *Intra-Cellular Therapies, Inc. v. Iancu*, 938 F.3d 1371, 1379 (Fed. Cir. 2019). The Fourth Circuit reviews grants of summary judgment *de novo*. *Norfolk S. Ry. Co. v. City of Alexandria*, 608 F.3d 150, 156 (4th Cir. 2010).

Applying a *de novo* standard, we review the PTO's PTA decision in accordance with the Administrative



Procedure Act (“APA”). See 35 U.S.C. § 154(b)(4)(A); *Chudik v. Hirshfeld*, 987 F.3d 1033, 1039 (Fed. Cir. 2021). The APA requires that courts only “set aside agency action, findings, and conclusions” if they are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A). When reviewing an agency’s statutory interpretation, we apply the two-step framework established in *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984). The parties disagree as to whether *Chevron* applies, but, consistent with our prior decisions concerning PTA calculation, we find that it does. See *Supernus*, 913 F.3d at 1356–57; *Intra-Cellular Therapies Inc. v. Iancu*, 938 F.3d 1371, at 1379, 1383 (Fed. Cir. 2019); *Gilead Scis., Inc. v. Lee*, 778 F.3d 1341, 1346 (Fed. Cir. 2015).

Californniaa challenges the validity of § 1.704(c)(10) under two different statutory subsections: 35 U.S.C. §§ 154(b)(2)(C)(i) and 154(b)(2)(C)(iii). We address each in turn.

## I

Californniaa argues that § 1.704(c)(10) (2019), and the PTO’s calculation of applicant delay in accordance with that rule, violate § 154(b)(2)(C)(i) and our holding in *Supernus*. The PTO responds that this argument was forfeited and that its determination of PTA was consistent with § 154(b)(2)(C)(i) because all the time consumed by the PTO’s consideration of the amendment was attributable to Californniaa’s decision to file it. The district court declined to consider this issue, finding it had been forfeited by not being argued before the

PTO. We agree with the PTO on the merits, and we therefore do not reach the issue of forfeiture.

Subsection 154(b)(2)(C)(i) mandates that “[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.” § 154(b)(2)(C)(i) (emphasis added). In *Supernus*, we found the language of § 154(b)(2)(C)(i) to be “plain, clear, and conclusive.” 913 F.3d at 135. We found that, pursuant to the plain language of the statute, “PTA cannot be reduced by a period of time during which there is no identifiable effort in which the applicant could have engaged to conclude prosecution because such time would not be ‘equal to’ and would instead exceed the time during which an applicant failed to engage in reasonable efforts.” 913 F.3d at 1359. Applying that logic, we found that the PTO’s assessment of applicant delay in that case exceeded its statutory authority under step one of *Chevron*. *Id.* at 1360–61. Step one of *Chevron* asks whether Congress “directly addressed the precise question at issue.” *Chevron*, 467 U.S. at 842. As the statute is unambiguous, there was no need to proceed to *Chevron* step two, and deference was not in play.

Where the facts of *Supernus* and the present case differ, however, is that the applicant in *Supernus* had no feasible actions it could have taken to conclude prosecution between the filing of its Request for Continued Examination and the European Patent Office’s Notice of Opposition. Here, Californiaa could have, at any time in the 51 days between the filing of his after-allowance amendment and the examiner’s acceptance of the proposal,

withdrawn his after-allowance amendment, concluding prosecution. Therefore, unlike in *Supernus*, there was an “identifiable effort” in which Californiaa could have engaged to conclude prosecution.

That the PTO later amended § 1.704(c)(10) to change the period of pendency does not affect our decision. Nor can the later-amended version somehow apply to calculation of PTA for the '075 patent. The effective date of the amendment to the regulation was July 16, 2020, after the issuance of the '075 patent and calculation of its PTA. 85 Fed. Reg. at 36,335. Because we resolve this issue on the merits, we do not reach the issue of forfeiture.

## II

Californiaa further argues that § 1.704(c)(10) (2019), and the PTO’s calculation of applicant delay in accordance with that rule, violate § 154(b)(2)(C)(iii) because his actions did not constitute a failure to engage in reasonable efforts to conclude prosecution since he was responding to an examiner-made amendment. The PTO responds that its interpretation of the statute to include all after-allowance amendments as applicant delay should be sustained, particularly given *Chevron* deference, and, regardless, Californiaa’s after-allowance amendment could have been made earlier. We agree with the PTO.

Unlike the statutory terms at issue in *Supernus*, the meaning of “reasonable efforts” in subsection 154(b)(2)(C)(iii) is ambiguous here. *See Gilead*, 778 F.3d at 1346–49 (finding what constituted “failure to engage in reasonable efforts” not clearly addressed

by Congress). Although subsection 154(b)(2)(C)(ii) provides one instance where Congress provided an example of applicant delay, the third subsection of the statute directs the PTO to prescribe other instances in which applicant behavior “constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.” 35 U.S.C. § 154(b)(2)(C)(iii). Therefore, Congress did not clearly answer whether after-allowance amendments constitute a failure to engage in reasonable efforts to conclude prosecution and we must proceed to *Chevron* step two to decide this issue.

In step two, *Chevron* requires determining “whether the [PTO’s] answer is based on a permissible construction of the statute.” *Chevron*, 467 U.S. at 842–43. At this stage of the *Chevron* analysis, an agency’s construction of a statutory scheme is afforded considerable weight. *Id.* at 844. *Chevron* teaches that, when Congress explicitly leaves a gap for an agency to fill, “[s]uch legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute.” *Id.* Therefore, we accept an agency’s construction of the statute even if the agency’s reading differs from what a court believes is the best statutory interpretation. *Id.*

Here, Congress expressly delegated authority to “[t]he Director [to] prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.” 35 U.S.C. § 154(b)(2)(C)(iii). As permitted by statute, the PTO promulgated § 1.704(c)(10), which encompasses the precise situation in this case—when

the applicant files an after-allowance amendment. “Such broad language demonstrates 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 (citing § 154(b)(2)(C)(iii)). After-allowance amendments predictably delay the close of prosecution, and we cannot say that it was arbitrary for the PTO to conclude that applicants that elect to file amendments after having their claims allowed generally should be charged with delay. We therefore find that the PTO’s interpretation of the statute was permissible here.

Californiaa asserts that an exception should be made for after-allowance amendments made in response to examiner-made amendments in the Notice of Allowance, as they could not have been raised earlier. But this is not the situation at hand. Californiaa filed a substantive after-allowance amendment unrelated to the minor amendment made by the examiner and he has not provided any reason that the amendment could not have been made earlier. C.A. 101–136. We decline to consider a situation not before us.

#### CONCLUSION

We have considered Californiaa’s remaining arguments but find them unpersuasive. For the foregoing reasons, we *affirm* the judgment of the district court.

**AFFIRMED**

*Appendix B*

UNITED STATES DISTRICT COURT FOR THE  
EASTERN DISTRICT OF VIRGINIA  
Alexandria Division

EURICA CALIFORNIAA,  
Plaintiff,

v.

ANDREW HIRSHFELD,<sup>1</sup>  
Performing the Duties of Under Secretary of  
Commerce for Intellectual Property and Deputy  
Director of the United States Patent and  
Trademark Office,  
Defendant.

Civil No. 1-20-cv-00985-MSN-TCB

**MEMORANDUM OPINION**

This matter comes before the Court on plaintiff Eurica Californiaa's Motion for Summary Judgment (Dkt. No. 11) and defendant Andrew Hirshfeld's Cross Motion for Summary Judgment (Dkt. No. 13). This action arises from plaintiff's challenge to the United States Patent and Trademark Office's ("USPTO") patent term adjustment ("PTA") determination for United States Patent No. 10,245,075 (the "075 patent"). The parties'

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<sup>1</sup> Andrew Hirschfeld is performing the functions and duties of the Under Secretary of Commerce for the Intellectual Property and Deputy Director of the United States Patent and Trademark Office and is automatically substituted as a party pursuant to Fed. R. Civ. P. 25(d).

competing positions on the merits of the USPTO's PTA determination have been fully briefed, making their motions ripe for disposition. For the reasons that follow, the Court will DENY plaintiff's motion and GRANT defendant's cross motion.

## BACKGROUND

When an applicant files a patent application with the USPTO, a USPTO patent examiner reviews the application—a process known as “examination”—to determine whether to issue a patent. *See* 35 U.S.C. § 131. Examiner and applicant go through a series of back and forth edits until the examiner determines the claims should be rejected or accepted. *Pfizer, Inc. v. Lee*, 811 F.3d 466, 475–76 (Fed. Cir. 2016). If the examiner determines a patent is warranted, the examiner issues a “Notice of Allowability” that sets out the terms of the patent that will subsequently be issued. Def. Mem. (Dkt. No. 14) at 5 (citing *Manual of Patent Examining Procedure* at ¶ 1302.03). The USPTO also provides the applicant with a more formal “Notice of Allowance” that identifies additional fees owed before a patent can issue. *Id.* (citing *Manual of Patent Examining Procedure* at ¶ 1303). At this point, examination and prosecution of the patent are complete, unless the examination is reopened on the merits. *See Novartis AG v. Lee*, 740 F. 3d 593, 602 (Fed. Cir. 2014). If an applicant is dissatisfied with the patent claims laid out in the Notice of Allowance, the applicant may file a request to amend the claims under 37 C.F.R. § 1.312. *See* Def. Mem. at 5–6. This “after allowance” amendment effectively reopens the patent examination process. In simplified terms, once the amendment is

addressed and there are no additional changes to the patent application, the patent is issued.

A patent term, *i.e.* the length of time the patent is enforceable, is calculated starting from the day the application is submitted to the USPTO. When determining the patent term, the USPTO accounts for delays caused by either the examiner or applicant that may have occurred during examination. For example, there are three types of statutorily-required adjustments to the patent term when the USPTO fails to meet benchmarks in the examination process or an applicant successfully challenges a negative patent eligibility determination. *See generally* 35 U.S.C. § 154(b)(1).<sup>2</sup> The USPTO is also statutorily required to account for delays in the patent examination “during which the applicant failed to engage in reasonable efforts to conclude [prosecution, processing, or examination] of the application.” 35 U.S.C. § 154(b)(2)(C).

The PTA is the sum of the delays caused by the USPTO and the applicant. *See Intra-Cellular Therapies, Inc. v. Iancu*, 938 F.3d 1371, 1374 (Fed. Cir. 2019) (discussing PTA adjustments). The patent term is increased if delays were due to the USPTO or

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<sup>2</sup> An “A delay” occurs when the examiner fails to send a Notice of Allowance within fourteen (14) months after an application is filed. *See* 35 U.S.C. § 154(b)(1)(A)(i)(I). A “B delay” occurs when the USPTO fails to issue a patent within “three years after the actual filing of the application in the United States.” *Id.* § 154(b)(1)(B). Lastly, a “C delay” is caused when the patent applicant is successful in challenging an administrative or judicial decision. *See id.* § 154(b)(1)(C). Any days that overlap between an A, B, and C delay are deducted from the PTA determination. *See id.* § 154(b)(2)(A).



decreased if due to the applicant. If an applicant is dissatisfied with the PTA determination, the applicant may file a request for reconsideration. *See* 35 U.S.C. § 154(b)(3)(B)(ii). If the applicant is still dissatisfied with the PTA determination after reconsideration, the applicant may seek Article III review in this Court. *See id.* § 154(b)(4)(A).

### PROCEDURAL HISTORY

Plaintiff owns the '075 patent issued on April 2, 2019. In calculating the PTA for '075, the USPTO released an Issue Notification on March 13, 2019, which included a PTA of 1,018 days. Admin. Record (Dkt. No. 7-3) at 130. That PTA calculation was based in part on a finding that the applicant was responsible for 51 days of delay during the patent's prosecution under 37 C.F.R. § 1.704(c)(10). The USPTO tied these 51 days of delay to an amendment plaintiff filed pursuant to 37 C.F.R. § 1.312 after he received the '075 patent's Notice of Allowance. *Id.* at 142.

Plaintiff filed a request for reconsideration on April 3, 2019, asking that the USPTO recalculate the '075 patent's PTA at 1,069 days. *Id.* at 139. In support, plaintiff argued that he was required to file the Section 1.312 amendment in response to an "Examiner's Amendment" that appeared for the first time in the '075 patent's Notice of Allowance. *Id.* at 142. Plaintiff further asserted that because he had no other way to address that "Examiner's Amendment," he should not be penalized for filing a *responsive* Section 1.312 amendment. *Id.* The USPTO disagreed and denied plaintiff's request on March 30, 2020. *See id.* at 138–145. This action followed

pursuant to 35 U.S.C. § 154(b)(4). *See id.* at 139; Compl. (Dkt. No. 1) at ¶¶ 17–19.

### LEGAL STANDARD

Summary judgment is proper where, viewing the facts in a light most favorable to the non-moving party, there remains no genuine issue of material fact and the evidence demonstrates the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986); *Evans v. Techs. Applications & Serv. Co.*, 80 F.3d 954, 958-59 (4th Cir. 1996). A party opposing a motion for summary judgment must respond with specific facts, supported by proper documentary evidence, showing that a genuine dispute of material fact exists, and that summary judgment should not be granted in favor of the moving party. *Anderson*, 477 U.S. at 250.

Under 35 U.S.C. § 154 this Court applies its Rule 56 standard in consideration of the APA's judicial review provisions. *See* 35 U.S.C. § 154(b)(4)(A) ("Chapter 7 of title 5 shall apply to" an action brought by an applicant dissatisfied with the USPTO's decision on a request for reconsideration; chapter 7 of title 5, in turn, refers to the judicial review provision of the Administrative Procedure Act ("APA")). When reviewing under the APA, this Court shall uphold the USPTO's actions, findings, and conclusions under the regulation unless they are found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *See Pfizer, Inc.*, 811 F.3d at 471. This standard "is the most deferential of the APA standards of review, and is only met where a reviewing court can conclude

with definite and firm conviction that a clear error of judgment or a mistake has been committed.” *President & Fellows of Harvard Coll. v. Lee*, 589 F. App’x. 982, 986 (Fed. Cir. 2014) (internal citations and quotations omitted). Under the APA, “the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did.” *Buckingham v. Mabus*, 772 F. Supp. 2d 295, 300 (D.D.C. 2011).

## DISCUSSION

Plaintiff challenges the USPTO’s decision to include 51 days of applicant’s delay in its PTA for the ‘075 patent. *See* Compl. at ¶ 22. Plaintiff primarily requests a full reduction of that applicant’s delay and alternatively seeks a partial reduction of the same. *Id.* at ¶¶ 23–24. Plaintiff pursues both theories at summary judgment by arguing there is no dispute of material fact as to the dates or content of the relevant office actions and responses thereto, and therefore the only issues to be resolved are issues of law. *See* Pl. Br. (Dkt. No. 12) at 12.

Defendant agrees that the case is appropriate for resolution at summary judgment but disputes plaintiff’s application of the law. *See* Def. Mem. at 2, 12–13 (quoting *R.R. Donnelley & Sons Co. v. Dickinson*, 123 F. Supp. 2d 456, 458 (N.D. Ill. 2000)).

To resolve both motions, the Court must determine whether the USPTO acted arbitrarily and capriciously in determining plaintiff’s filing of an after allowance amendment did not constitute a “reasonable effort to conclude processing or examination” of his patent application under 35

U.S.C. § 154(b)(2)(C).

**A. 37 C.F.R. § 1.704(c)(10) and the Prior Proceedings**

Congress delegated authority to the USPTO to promulgate regulations that would establish circumstances in which an applicant fails to engage in “reasonable efforts to conclude processing or examination of [his patent] application.” 35 U.S.C. § 154(b)(2)(C). So as not to engage in a case-by-case determination of each application, the USPTO promulgated regulations outlining actions that are “strict examples” of unreasonable efforts. *See* 65 Fed. Reg. at 56378–79. Specifically at issue here, 37 C.F.R. § 1.704(c)(10) states,

Circumstances that constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application . . . include . . . . [s]ubmission of an amendment under § 1.312 or other paper, other than an amendment under § 1.312 or other paper expressly requested by the Office or a request for continued examination in compliance with § 1.114, after a notice of allowance has been given or mailed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date of mailing of the notice of allowance under 35 U.S.C. § 151 and ending on the date the amendment under § 1.312 or other paper was filed.

In denying plaintiff's request for redetermination of the '075 patent's PTA, the USPTO explicitly relied on this language—finding (a) the 51-day delay plaintiff challenged was due to his filing of an amendment under 37 C.F.R. § 1.312, and (b) that “an amendment under 37 C.F.R. §

1.312 after allowance, is a paper that *is* considered a failure to engage in reasonable efforts to conclude processing or examination of an application.” Admin. Record at 144 (emphasis in original).

### **B. This Court's Review**

Plaintiff challenges the USPTO's application of 37 C.F.R. § 1.704(c)(10) by arguing the USPTO exceeded its regulatory authority to the extent it adopted and then interpreted a regulation that prevented the USPTO from considering exceptional circumstances when determining the '075 patent's PTA. Pl. Br. at 22–23. Plaintiff supports this position by arguing that he faced extraordinary circumstances when the examiner presented changes to plaintiff's claims for the first time in the Notice of Allowance. *Id.* at 17–20; Admin. Record at 144 (“[t]he filing of the amendment under 37 C.F.R. 1.312 is not a basis for a reduction . . . because it is the ‘only procedure available for an applicant to suggest changes to an Examiner's amendment . . . presented for the first time in a notice of allowance’”). Therefore, plaintiff concludes that he is entitled to an exception under 37 C.F.R. § 1.704(c)(10) and challenges the USPTO's failure to recognize as much. *Id.*

Defendant responds that the USPTO's regulations are entitled to *Chevron* deference

because 37 C.F.R. § 1.704(c)(10) is properly promulgated under the authority delegated to it by Congress in 35 U.S.C. § 154. *See* Def. Mem. at 24–27. Defendant further argues that plaintiff's after allowance amendment is a failure to engage in reasonable efforts to conclude processing or examination because it firmly falls within the language of the regulation. *See id.* (citing 37 C.F.R. § 1.704(c)(10)). Therefore, defendant claims the USPTO did not err in assessing applicant delay to the '075 patent, nor commit a "clear error in judgment." Def. Reply (Dkt. No. 26) at 2.

"When reviewing an agency's statutory interpretation, this court applies the two-step framework established in *Chevron*." *See Gilead Scis., Inc. v. Lee*, 778 F.3d 1341, 1345 (Fed. Cir. 2015). However, the *Chevron* framework applies only when "it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001). The statute at issue provides, "[t]he Director shall prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application." 35 U.S.C. § 154(b)(2)(C)(iii). Thus, it is clear from the face of the statute that Congress has provided the USPTO with express authority to promulgate 37 C.F.R. § 1.704(c)(10). *See Gilead Scis., Inc.*, 778 F.3d at 1346-49 (engaging in a *Chevron* analysis of 35 U.S.C. § 154). As such, the *Chevron* framework applies, and the Court must apply it.

*Chevron* step one asks whether Congress "directly

addressed the precise question at issue.” *Gilead Scis., Inc.*, 778 F.3d at 1346. If not, the Court then determines in *Chevron* step two whether the agency’s interpretation is based on a permissible construction of the statute. *Nuclear Energy Inst., Inc. v. Env’t Prot. Agency*, 373 F.3d 1251, 1269 (D.C. Cir. 2004).

The precise question at issue here is whether an amendment, filed after prosecution has concluded, that responds to an examiner’s amendment filed with the Notice of Allowance, constitutes a “failure to engage in reasonable efforts to conclude processing or examination of an application” such that applicant delay would accrue under the PTA statute. *See* 35 U.S.C. § 154(b)(2)(C)(iii). Plaintiff argues that the term “reasonable” is unambiguous. Pl. Resp. (Dkt. No. 23) at 37. Defendant, however, argues it *is* ambiguous and that the statute does not identify whether the USPTO should consider applicants’ efforts generally, or whether it must engage in an *ad hoc* determination for every application. Def. Reply at 5. Because nothing in the language of the PTA statute addresses what constitutes “reasonable efforts” when an applicant files an amendment post-Notice of Allowance, the Court finds the statute ambiguous and does not answer the question at issue here. Accordingly, the Court’s analysis must proceed to *Chevron* step two.

*Chevron* step two requires the Court to determine “whether the [USPTO’s] answer is based on a permissible construction of the statute.” *Gilead Scis., Inc.*, 778 F.3d at 1349. When Congress expressly directs an agency to promulgate regulations, “judicial deference to an agency’s construction of a statutory scheme is afforded considerable weight,” *id.*, and will be upheld unless it is found to be “arbitrary,

capricious, an abuse of discretion, or otherwise not in accordance with law.” *See Pfizer, Inc.*, 811 F.3d at 471.

Here, Congress explicitly delegated the authority to the USPTO to “prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.” 35 U.S.C. § 154(b)(C)(iii). The USPTO exercised its congressionally delegated authority by promulgating 37 C.F.R. § 1.704(c)(10). While plaintiff’s interpretation—that filing an after allowance amendment in response to an examiner’s amendment in the Notice of Allowance constitutes a “reasonable effort” to conclude prosecution of the patent application—is arguably a plausible one, nothing in the plain language of the statute commands that understanding of what conduct constitutes “reasonable efforts” by an applicant following a Notice of Allowance. *Intra-Cellular Therapies, Inc.*, 938 F.3d at 1380. Courts that have examined the issue have held that the term “reasonable efforts” “focuses on applicant conduct as opposed to the results of such conduct,” *Gilead Scis., Inc.*, 778 F.3d at 1347, and the USPTO has determined that an after allowance amendment filed under 37 C.F.R. § 1.312 is unreasonable conduct. Thus, the Court will defer to the USPTO’s regulations regarding the assessment of PTA reduction for applicant delay under 37 C.F.R. § 1.704(c)(10).

Having concluded the regulation is entitled to *Chevron* deference, the Court now applies APA standards of review and will only overturn the USPTO’s PTA determination if the Court finds the



USPTO's decision was arbitrary and capricious. According to the administrative record, the applicant filed an amendment under 37 C.F.R. § 1.312 after the mailing of the Notice of Allowance. Admin. Record at 143. The USPTO determined that under 37 C.F.R. § 1.704(c)(10), the filing of the amendment under 37 C.F.R. § 1.312 in this instance constituted a failure to engage in reasonable efforts. Admin. Record at 144. Further, the USPTO found 37 C.F.R. § 1.704(c)(10) "does not provide for an exception to reduction of PTA for the filing of an amendment under 37 C.F.R. § 1.312 where an applicant finds the changes and/or additions made by an examiner's amendment unacceptable." Admin. Record at 144 (the USPTO previously considered and rejected the possibility of an exception during the rulemaking process for 37 C.F.R. § 1.704(c)(10)).

Because the applicant's filing of an after allowance amendment was clearly considered a failure to engage in reasonable efforts under 37 C.F.R. § 1.704(c)(10), and the regulation did not provide for an exception for responding to an examiner's amendment filed with the Notice of Allowance, the Court finds 51 days of applicant delay was not arbitrary and capricious.<sup>3</sup>

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<sup>3</sup> Plaintiff's alternative request for a partial reduction of the 51-day calculation similarly fails because Plaintiff did not raise the issue of reducing the PTA determination by a lesser amount in his PTA petition and the USPTO could not have anticipated that plaintiff would make this argument. Plaintiff only made two arguments in his petition: (1) 37 C.F.R. 1.704(c)(10) does not apply and (2) justice requires an exception to the regulation. Admin. Record at 132. At no point did plaintiff assert that the *amount* of applicant delay was too high, only that there should be no applicant delay at all. The USPTO was not on notice of plaintiff's argument and could not have surmised it based on

## CONCLUSION

This Court finds that the Patent Office's determination of applicant delay is supported by a permissible reading of the PTA statute and that the determination was not arbitrary and capricious. This Court has considered plaintiff's remaining arguments and finds them unpersuasive. Accordingly, this Court finds that summary judgment should be granted in favor of defendant. Plaintiff's motion for summary judgment is denied.

An appropriate order shall issue.

/s/

Hon. Michael S. Nachmanoff  
United States District Judge

Alexandria, Virginia  
December 30, 2021

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the arguments before it in his petition. Therefore, plaintiff waived his ability to raise in district court any argument for a lesser applicant delay amount. *See Nuclear Energy Inst., Inc. v. Env't Prot. Agency*, 373 F.3d 1251, 1297 (D.C. Cir. 2004) ("Issues not raised before an agency are waived and will not be considered by a court on review."); *Rocky Mountain Health Maint. Org., Inc. v. Price*, 297 F. Supp. 3d 152, 158 (D.D.C. 2018) ("argument is preserved if the agency reasonably should have understood the full extent of the plaintiff's argument." (internal quotations omitted)); *Buckingham v. Mabus*, 772 F. Supp. 2d 295, 300 (D.D.C. 2011) (review of PTA determination is limited to the administrative record and the arguments presented before the agency).

*Appendix C*

UNITED STATES PATENT AND  
TRADEMARK OFFICE

In re Patent No. 10,245,075  
EURICA CALIFORRNIAA  
Issue Date: April 2, 2019  
Application No. 14/214,897  
Filing or 371(c) Date: March 15, 2014  
Title: NONDESTRUCTIVE MEANS  
OF ECTOPIC PREGNANCY  
MANAGEMENT

DECISION DENYING REQUEST FOR  
REDETERMINATION OF PATENT TERM  
ADJUSTMENT

This is a decision on the “REQUEST FOR REDETERMINATION OF PATENT TERM ADJUSTMENT” filed April 3, 2019, requesting the Office adjust the patent term adjustment determination (“PTA”) from one thousand eighteen (1018) days to one thousand sixty-nine (1069) days.

The request for the Office to adjust the PTA to 1069 days is **DENIED**.

**This decision is the Director’s decision on the patentee’s request for reconsideration for purposes of seeking judicial review under 35 U.S.C. 154(b)(4).**

Relevant Procedural History

The patent issued with a PTA determination of 1018 days on April 2, 2019. On April 3, 2019, patentee timely filed the present Request under 37 CFR 1.705(b), seeking an adjustment of 1069 days, accompanied by a \$200 petition fee.

### **Decision**

The PTA is on the following determination previously made by the Office:

- (1) The period of delay under 35 U.S.C. 154(b)(1)(A) ("A Delay") is 401 days;
- (2) The period of delay under 35 U.S.C. 154(b)(1)(B) ("B Delay") is 748 days;
- (3) The period of delay under 35 U.S.C. 154(b)(1)(C) ("C Delay") is 0 days;
- (4) The number of days of overlapping delay ("Overlap") between the periods of A Delay, B Delay, and C Delay is 80 days; and
- (5) The period of delay under 35 U.S.C. 154(b)(2)(C) ("Applicant Delay") is 51 days.

The PTA is the sum of the days of A Delay, B Delay, and C Delay reduced by the number of days of Overlap and Applicant Delay. In other words, the following formula is be used to calculate the PTA:

$$\text{PTA} = \text{A Delay} + \text{B Delay} + \text{C Delay} - \text{Overlap} - \text{Applicant Delay}$$

The patent set forth a PTA of 1018 days (401 days of A Delay + 748 days of B Delay + 0 days of C Delay -

80 days of Overlap - 51 days of Applicant Delay).

In the present Request, patentee asserts that the period of reduction under 37 CFR 1.704(c)(10) of 51 days for the submission of an amendment under 37 CFR 1.312 on January 7, 2019, after the mailing of a Notice of Allowance on December 11, 2018, is improper and should be removed. This change would result in a total period of Applicant Delay of 0 days. Patentee avers the correct PTA is 1069 days (401 days of A Delay + 748 days of B Delay + 0 days of C Delay - 80 day of Overlap - 0 days of Applicant Delay).

As further discussed below, the Office finds the total period of applicant delay is 51 days. Therefore, correct PTA is 1018 days (401 days of A Delay + 748 days of B Delay + 0 days of C Delay - 80 days of Overlap - 51 days of Applicant Delay).

#### **A Delay**

Patentee does not dispute the Office's prior determination that the period of A Delay is 401 days. The Office has recalculated the period of A Delay as part of the Office's redetermination of the PTA and confirmed the period of A Delay is 401 days.

The "A" delay periods include the following:

- (1) 321 days under 37 CFR 1.703(a)(1) for the period beginning on May 16, 2015 (day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. 111(a)) and ending on

March 31, 2016 (date of mailing of an action under 35 U.S.C. 132);

- (2) 49 days under 37 CFR 1.703(a)(2) for the period beginning on September 13, 2017 (day after the date that is four months after the date a reply under § 1.111 was filed) and ending October 31, 2017 (date of mailing of an action under 35 U.S.C. 132); and
- (3) 31 days under 37 CFR 1.703(a)(3) for the period beginning on May 1, 2018 (day after the date that is four months after the date a reply in compliance with § 1.113(c) was filed) and ending May 31, 2018 (date of mailing of an action under 35 U.S.C. 132).

### **B Delay**

Patentee does not dispute the Office's prior determination that the period of B Delay is 748 days. The Office has recalculated the period of B Delay as part of the Office's redetermination of the PTA and confirmed the period of B Delay is 748 days.

The *Novartis* decision includes "instructions" for calculating the period of "B" delay. Specifically, the decision states,

The better reading of the language is that the patent term adjustment time [for "B" delay] should be calculated by determining the length of the time between application and patent issuance, then subtracting any continued

examination time (and other time identified in (i), (ii), and (iii) of (b)(1)(B)) and determining the extent to which the result exceeds three years.<sup>1</sup>

The length of time between application and issuance is 1845 days, which is the number of days beginning on March 15, 2014 (date on which the application was filed under 35 U.S.C. 111(a)) and ending on April 2, 2019 (date the patent issued).

The time consumed by continued examination is 0 days.

The number of days beginning on the date on which the application was filed under 35 U.S.C. 111 (a) (March 15, 2014) and ending on the date three years after the date the application was filed (March 15, 2017) is 1097 days.

The result of subtracting the time consumed by continued examination (0 days) from the length of time between the filing date and issuance (1845 days) is 1845 days, which exceeds three years (1097 days) by 748 days. Therefore, the period of B delay is 748 days.

### C Delay

Patentee does not dispute the Office's prior determination that the period of C Delay is 0 days. The Office has recalculated the period of C Delay as

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<sup>1</sup> *Novartis AG v. Lee*, 740 F.3d 593, 601 (Fed. Cir. 2014).

part of the Office's redetermination of the PTA and confirmed the period of C Delay is 0 days.

### **Overlap**

Patentee does not dispute the Office's prior determination that the number of days of Overlap is 80 days. The Office has recalculated the number of days of Overlap as part of the Office's redetermination of the PTA and confirmed the number of days of Overlap is 80 days.

The overlapping periods between A delay and B delay include the following:

- (1) 49 days for the period beginning on September 13, 2017, and ending October 31, 2017; and
- (2) 31 days for the period beginning on May 1, 2018, and ending May 31, 2018.

### **Applicant Delay**

Patentee disputes the Office's prior determination that the number of days of Applicant Delay is 51 days. The Office has recalculated the number of days of Applicant Delay as part of the Office's redetermination of the PTA and confirmed the number of days of Applicant Delay is 51 days.

The Applicant Delay includes the following periods:

- (1) 51 days under 37 CFR 1.704(c)(10) beginning on January 7, 2019 (beginning on the date the amendment under § 1.312



or other paper was filed) and ending on February 26, 2019 (mailing date of the Office action or notice in response to the amendment under § 1.312 or such other paper).

The sole issue in dispute is the calculation of the period of applicant delay under 37 CFR 1.704(c)(10) of 51 days for the submission of the amendment under § 1.312 on January 7, 2019, after the mailing of the Notice of Allowance on December 11, 2018. Patentee acknowledges that the filing of an amendment under § 1.312 after a Notice of Allowance has been given or mailed constitutes a failure to engage in reasonable efforts to conclude prosecution and results in a reduction of patent term adjustment under 37 CFR 1.704(c)(10). However, patentee states that due to special circumstances in this case, a reduction of the patent term under 37 CFR 1.704(c)(10) does not apply or that justice requires an exception to the rule pursuant to 35 U.S.C. 154, the 5<sup>th</sup> Amendment to the U.S. Constitution, and the Administrative Procedure Act. In particular, patentee asserts;

The Notice of Allowance contained an Examiner's Amendment not previously discussed with the applicant, which states in part (p. 2, ¶ 2): 'An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312.'

From this it is evident that an amendment

under Rule 312 is the only procedure available for an applicant to suggest changes to an Examiner's amendment drafted under MPEP 707.07(j) and presented for the first time in a notice of allowance.

Accordingly, a pro se applicant does not fail to engage in reasonable efforts to conclude prosecution of an application under 35 USC § 154(b)(2)(C)(i) by filing a Rule 312 amendment in response to such an amendment.

Where there is a conflict between the United States Code and the Code of Federal Regulations, the United States Code should be controlling.

35 USC § 154(b)(2)(C)(iii) provides that '[t]he Director shall prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.'

In light of the foregoing, it would be contrary to justice for the Director to deem the present circumstances to constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of the application.

*Request, 04/03/19, p. 3.*

The Office has considered patentee's arguments, but does not find them persuasive.

37 CFR 1.704 Reduction of period of adjustment of patent term provides:

(c) Circumstances that constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application also include the following circumstances, which will result in the following reduction of the period of adjustment set forth in § 1.703 to the extent that the periods are not overlapping:

...

(10) Submission of an amendment under § 1.312 or other paper, other than a request for continued examination in compliance with § 1.114, after a notice of allowance has been given or mailed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the lesser of:

(i) The number of days, if any, beginning on the date the amendment under § 1.312 or other paper was filed and ending on the mailing date of the Office action or notice in response to the amendment under § 1.312 or such other paper; or

(ii) Four months;

37 CFR 1.704(c)(10) establishes that the submission of an amendment under 37 CFR 1.312 or other paper, other than a request for continued

examination in compliance with 37 CFR 1.114, after a notice of allowance has been given or mailed, as a circumstance that constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. *See* MPEP § 2732.

The record shows applicant filed an amendment under 37 CFR 1.312 on January 7, 2019, after the mailing of the Notice of Allowance on December 11, 2018, and was assessed 51 days of applicant delay under 37 CFR 1.704(c)(10). This amendment sought to make changes that were unrelated to the examiner's amendment of December 11, 2018. For example, in claim 37 seeking to change "the presenting face having a diameter and curvature which" to "the presenting face, having a diameter and curvature that" were unrelated to the examiner's amendment.

The Office is not persuaded by patentee's argument that the submission of the amendment on January 7, 2019, does not constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of the application. Under 37 CFR 1.704(c)(10), an amendment under 37 CFR 1.312 after allowance, is a paper that is considered a failure to engage in reasonable efforts to conclude processing or examination of an application. *See* MPEP § 2732. The amendment filed January 7, 2019, after allowance, is not the type of paper for which the Office will not consider its submission a failure to engage in reasonable efforts to conclude processing or examination of the application. *See id.*

Furthermore, the Office finds patentee's assertion that the filing of the amendment under 37 CFR 1.312 is not a basis for reduction under 37 CFR 1.704(c)(10) because it is the "only procedure available for an applicant to suggest changes to an Examiner's amendment drafted under MPEP 707.07(j) and presented for the first time in a notice of allowance" equally unavailing. The Office previously addressed this argument in response to comments objecting to the reference to "or other paper" in § 1.704(c)(10) (as adopted) because a paper filed to correct an examiner's amendment should not be construed as a failure to engage in reasonable efforts to conclude prosecution. *See Changes to Implement Patent Term Adjustment under Twenty-Year Patent Term*, 65 Fed. Reg. 56366, 56387 (Sept. 18, 2000) (comment 41 and response). Moreover, the January 7, 2019 paper sought changes unrelated to the Examiner's amendment.

The Office has maintained that the submission of amendment (or other papers) after allowance of an application may substantially interfere with the patent issue process, and therefore, constitutes a circumstance resulting in reduction of PTA under 37 CFR 1.704(c)(10). *Id.* The Office finds no reason to depart from its long-held position that submission of an amendment under § 1.312 or other papers after allowance impacts the ability of the Office to process the application for issuance as a patent. Regardless of whether the filing of the amendment was in response to an examiner's amendment, such a submission after allowance is treated as a failure to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR 1.704(c)(10). 37 CFR 1.704(c)(10)

does not provide for an exception to reduction of PTA for the filing of an amendment under 37 CFR 1.312 where an applicant finds the changes and/or additions made by an examiner's amendment unacceptable.

In the present case, the submission of the amendment on January 7, 2019, after the mailing of the Notice of Allowance on December 11, 2018, is a ground for reduction under 37 CFR 1.704(c)(10). Therefore, the Office properly assessed a period of 51 days of applicant delay beginning on the January 7, 2019, the date the applicant filed the amendment under §1.312, and ending on February 26, 2019, the mailing date of the Office communication in response to the amendment.

The period of Applicant Delay is 51 days.

### **Conclusion**

Patentee argues the correct PTA is 1069 days (401 days of A Delay + 748 days of B Delay + 0 days of C Delay - 80 days of Overlap - 0 days of Applicant Delay).

For the above-stated reasons, a review of the Request and Image File Wrapper of the above-identified application reveals a correction of the determination of patent term adjustment under 35 U.S.C. 154(b) to 1069 days is not merited. Therefore, the request for reconsideration of the patent term adjustment to adjust the patent term adjustment determination under 35 U.S.C. 154(b) from 1018 days to 1069 days is **denied**.

As previously discussed, the period of Applicant Delay remains 51 days. Therefore, the correct PTA is 1018 days (401 days of A Delay + 748 days of B Delay + 0 days of C Delay - 80 days of Overlap - 51 days of Applicant Delay).

Telephone inquiries specific to this matter should be directed to Christina Tartera Donnell, Attorney Advisor, at (571) 272-3211.

/ROBERT CLARKE/

Robert A. Clarke

Patent Attorney

Office of the Deputy Commissioner

for Patent Examination Policy - USPTO

*Appendix D*

NOTE: This order is nonprecedential.

United States Court of Appeals  
for the Federal Circuit

**EURICA CALIFORNIAA,**  
Plaintiff-Appellant

v.

**KATHERINE K. VIDAL, UNDER  
SECRETARY OF COMMERCE FOR  
INTELLECTUAL PROPERTY AND DIRECTOR  
OF THE UNITED STATES PATENT AND  
TRADEMARK OFFICE,**  
Defendant-Appellee

2022-1640

Appeal from the United States District Court for  
the Eastern District of Virginia in No. 1:20-cv-00985-  
MSN-TCB, Judge Michael S. Nachmanoff.

**ON PETITION FOR PANEL REHEARING AND  
REHEARING EN BANC**

Before MOORE, Chief Judge, NEWMAN, LOURIE, DYK,  
PROST, REYNA, TARANTO, CHEN, HUGHES, STOLL,  
CUNNINGHAM, and STARK, Circuit Judges.

PER CURIAM.

**ORDER**



Erica California filed a combined petition for panel rehearing and rehearing en banc. The petition was referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc was referred to the circuit judges who are in regular active service.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

The petition for rehearing en banc is denied.

FOR THE COURT

December 21, 2022

Date

/s/ Peter R. Marksteiner

Peter R. Marksteiner

Clerk of Court

*Appendix E*

UNITED STATES DISTRICT COURT FOR THE  
EASTERN DISTRICT OF VIRGINIA  
Alexandria Division

EURICA CALIFORNIAA,  
*Plaintiff,*

v.

ANDREW HIRSHFELD,<sup>1</sup>  
*Performing the Duties of Under  
Secretary of Commerce for Intellectual  
Property and Deputy Director of the  
United States Patent and Trademark  
Office,*  
*Defendant.*

Civil No. 1-20-cv-00985-MSN-TCB

**MEMORANDUM OPINION**

This matter comes before the court on plaintiff Eurica Californiaa's Motion to Alter or Amend a Judgment (Dkt. No. 31), pursuant to Rule 59(e) of the Federal Rules of Civil Procedure. Having reviewed the motion and defendant's opposition, the Court finds that oral argument on the motion is unnecessary and that the matter is ripe for

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<sup>1</sup> Andrew Hirschfeld is performing the functions and duties of the Under Secretary of Commerce for the Intellectual Property and Deputy Director of the United States Patent and Trademark Office and is automatically substituted as a party pursuant to Fed. R. Civ. P. 25(d).

disposition. For the foregoing reasons, plaintiff's motion will be DENIED.

### I. Background

On December 30, 2021, this Court entered an Order dismissing plaintiff's complaint for failure to state a claim. *See* Mem. Op. (Dkt. No. 27); Order (Dkt. No. 28). Plaintiff requested the Court reconsider its Order and Memorandum Opinion on January 14, 2022—seeming to argue that the Court committed clear error of law on six grounds. *See* Pl. Mtn. (Dkt. No. 31) at 1. Defendant responded on January 27, 2022, arguing that plaintiff “simply rehashe[d] the same arguments” presented in his summary judgment papers. *See* Def. Opp. (Dkt. No. 32) at 1–2. Plaintiff failed to file a reply.

### II. Legal Standard

The Court's power to alter or amend a prior judgment pursuant to Rule 59 “is an extraordinary remedy which should be used sparingly.” *Pac. Ins. Co. v. Am. Nat'l Fire Ins. Co.*, 148 F.3d 396, 403 (4th Cir. 1998) (internal quotation marks and citation omitted). The United States Court of Appeals for the Fourth Circuit has recognized three limited grounds for granting relief under Rule 59: “(1) an intervening change in the controlling law, (2) new evidence that was not available at trial, or (3) that there has been a clear error of law or a manifest injustice,” *Robinson v. Wix Filtration Corp., LLC*, 599 F.3d 403, 407 (4th Cir. 2010). A clear error in the law “does not [occur] by being just maybe or probably wrong; it must strike [the Court] as wrong with the force of a five-

week-old, unrefrigerated dead fish . . . . It must be dead wrong,” *TFWS, Inc. v. Franchot*, 572 F.3d 186, 194 (4th Cir. 2009) (internal quotations omitted). Furthermore, a party may not raise arguments in his Rule 59 motion which could have been raised in summary judgment papers, nor may he argue a novel legal theory that could have been addressed prior to dismissal. *Pac. Ins. Co.*, 148 F.3d at 403.

### III. Analysis

Plaintiff contends the Court committed clear error on six points: (1) by deferring to the USPTO’s statutory interpretation of 35 U.S.C. § 154(b)(2)(C)(i) under the standard for judicial deference announced in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984) instead of the less deferential standard propounded in *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), and by relying on *Gilead Sciences, Inc. v. Lee*, 778 F.3d 1341 (4th Cir. 2015) when doing so, Pl. Mtn. at 2;<sup>2</sup> (2) in failing to recognize that the Federal Circuit’s opinion in *Supernus Pharmaceuticals, Inc. v. Iancu*, 913 F.3d 1351 (Fed. Cir. 2019) put the USPTO on notice “of plaintiff’s argument” for a partial reduction of the 51-day PTA calculation even if plaintiff had not done so

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<sup>2</sup> As noted by plaintiff on summary judgment, the United States Court of Appeals for the Federal Circuit has reached inconsistent conclusions on this very point. *See* Pl. Opp. (Dkt. No. 23) at 21 (The “Federal Circuit has consistently reviewed the USPTO’s decision about patent term adjustments using the *Chevron* framework,” and “The Federal Circuit has decided that the PTO’s regulations are not entitled to *Chevron* deference.”). Accordingly, the Court cannot find that it committed clear legal error by analyzing plaintiff’s challenge to the USPTO’s statutory authority under *Chevron* deference.

himself, *id.* at 2–4;<sup>3</sup> (3) by finding plaintiff waived his ability to seek a reduction of application delay for the first time in district court despite the Supreme Court’s ruling in *Kappos v. Hyatt*, 566 U.S. 431 (2012), *id.* at 4–7;<sup>4</sup> (4) in not examining Congress’

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<sup>3</sup> It was not “[clear] error to refuse to apply a rule of federal law retroactively after the case announcing the rule has already done so” when plaintiff’s case was not in active litigation on January 23, 2019—the date the *Supernus* decision was issued. 913 F.3d 1351 (Fed. Cir. 2019); *Novartis AG v. Kappos*, 904 F. Supp. 2d 58, 73–74 (D.D.C. 2012) (finding USPTO violated its own policy in refusing to recalculate PTA in accordance with judicial decision when plaintiff was in litigation challenging the USPTO’s PTA); see *Harper v. Virginia Dep’t of Tax’n*, 509 U.S. 86, 97 (1993) (finding new federal rule applied retroactively only to cases “still open on direct review”). Furthermore, the USPTO did not violate its rule in failing to apply *Supernus* to plaintiff’s claims. Instead, the USPTO deliberately chose to limit application of *Supernus* to requests for reconsideration made after a certain date. See *Patent Term Adjustment Reductions in View of the Federal Circuit Decision in Supernus Pharm., Inc. v. Iancu*, 85 Fed. Reg. 36335-01, 36333 (June 16, 2020) (the “Rule”) (“[T]he USPTO is not adopting an ad hoc procedure for requesting a patent term adjustment recalculation directed to the changes in this final rule. The USPTO will decide any timely request for reconsideration . . . in which a notice of allowance was mailed before July 16, 2020 . . . if requested by the patentee.”).

<sup>4</sup> This was also not clear error. Plaintiff did not qualify for a reduction under the USPTO’s rule applying *Supernus*. The Rule provides: “The USPTO will decide any timely request for reconsideration in compliance with § 1.705(b) of a patent term adjustment determination in applications and patents eligible for patent term adjustment in which a notice of allowance was mailed on or after July 16, 2020 . . . . The USPTO will decide any timely request for reconsideration in compliance with § 1.705(b) of a patent term adjustment determination in applications and patents eligible for patent term adjustment in which a notice of allowance was mailed before July 16, 2020, consistent with the changes in this final rule, *if requested by the*

intent in deciding whether “reasonable efforts” in the PTA statute was ambiguous, *id.* at 7–8; (5) by finding the “rulemaking [in which the USPTO rejected an exception to PTA reduction when an applicant files an amendment on the basis that the changes or additions made by an examiner’s amendment are unacceptable] only contemplated an ‘examiner’s amendment’ in the ordinary sense of the term, rather than in an exceptional sense,” *id.* at 9;<sup>5</sup> and, (6) by “overlook[ing] plaintiff’s statement of the precise question at issue in favor of a statement of its own.” *Id.* at 10.

The Court finds plaintiff has not identified a clear error in the law, nor identified an issue that could not have been addressed prior to dismissal, nor asserted an argument not already in his summary judgment papers.<sup>6</sup> *See Pac. Ins. Co.*, 148 F.3d at 403

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*patentee.*” *See* 85 Fed. Reg. 36335-01, 36338 (emphasis added). Plaintiff’s notice of allowance was mailed on December 11, 2018. A.R. (Dkt. No. 7-3) at A64. Plaintiff’s Patent Term Adjustment Petition was filed on April 3, 2019, *id.* at A131–A133; thus, the Rule required a timely notice of allowance *and* request for reconsideration based on the *Supernus* ruling—*i.e.*, express notice to the USPTO.

<sup>5</sup> Plaintiff failed to raise this argument in his summary judgment papers despite defendant mentioning the rulemaking comment in their brief. *Pac. Ins. Co.*, 148 F.3d at 403; Def. Br. (Dkt. No. 14) at 11 (USPTO received and rejected a comment that suggested each application should be reviewed on a case-by-case basis “to determine [whether] a reduction of PTA is warranted”).

<sup>6</sup> Plaintiff raised or had the opportunity to raise each of the six grounds upon which he moves for reconsideration in his summary judgment papers. *See* Pl. Opp. at 19–23 (“[I]n at least two of these cases, [including *Gilead Sciences, Inc.*,] it appears both parties agreed to the *Chevron* framework at the district court.”); *id.* at 17–19 (“The dispute revolves around whether the decision in *Supernus* should apply to the PTA calculation.”);

("The Rule 59(e) motion may not be used to relitigate old matters."); *Above the Belt, Inc. v. Mel Bohannan Roofing, Inc.*, 99 F.R.D. 99, 101 (E.D. Va. 1983) (a motion to reconsider cannot appropriately be granted where the moving party simply seeks to have the Court "rethink what the Court has already thought through—rightly or wrongly"). As such, the Court will deny plaintiff's motion.

\* \* \*

Accordingly, it is hereby

**ORDERED** that plaintiff's Motion to Alter or Amend a Judgment (Dkt. No. 31) is **DENIED**.

It is **SO ORDERED**.

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*id.* at 17 ("Plaintiff contends on the authority of *Kappos v. Hyatt* . . . that the doctrine of administrative exhaustion . . . does not apply to this appeal."); *id.* at 41 ("It would therefore be inconsistent with Congress' own interpretation . . . for the Director to promulgate regulations . . . without regard for making appropriate adjustment in exceptional circumstances."); see Pl. Mem. at 9–10 (conceding plaintiff identified his view of the precise question at issue in his summary judgment papers); see also Pl. Opp. at 36–38 (identifying precise question at issue for *Chevron* analysis). The Court considered and rejected each argument raised. See generally, Mem. Op. "Mere disagreement with a court's ruling does not support a Rule 59(e) motion." *Ervin v. Corizon Health*, No. CV ELH-19-1666, 2020 WL 6161696, at \*2 (D. Md. Oct. 21, 2020). Because a motion to amend the court's findings "may not be used to relitigate old matters," plaintiff's assertions do not meet the exacting requirements for relief under Rule 59.

/s/

Hon. Michael S. Nachmanoff  
United States District Judge

February 16, 2022  
Alexandria, Virginia



*Appendix F*

**RELEVANT PROVISIONS**

MANUAL OF PATENT EXAMINING PROCEDURE

**MPEP § 707.07(j) State When Claims Are Allowable [R-11.2013]**

**I. INVENTOR FILED APPLICATIONS**

When, during the examination of a *pro se* application it becomes apparent to the examiner that there is patentable subject matter disclosed in the application, the examiner should draft one or more claims for the applicant and indicate in his or her action that such claims would be allowed if incorporated in the application by amendment.

This practice will expedite prosecution and offer a service to individual inventors not represented by a registered patent attorney or agent. Although this practice may be desirable and is permissible in any case deemed appropriate by the examiner, it is especially useful in all cases where it is apparent that the applicant is unfamiliar with the proper preparation and prosecution of patent applications.

\* \* \* \* \*

**¶ 7.43.04 Suggestion of Allowable Drafted Claim(s), Pro Se**

The following claim [1] drafted by the examiner and considered to distinguish patentably over the art of

record in this application, [2] presented to applicant for consideration:

[3].

**Examiner Note:**

1. In bracket 2, insert --is-- or --are--.
2. In bracket 3, insert complete text of suggested claim(s).

\* \* \* \* \*

**MPEP § 1302.04 Examiner's Amendments and Changes [R-07.2015]**

With the exception of the following no corrections or interlineations may be made by the examiner in the body of written portions of the specification or any other paper filed in the application for patent, except by examiner's amendment approved by applicant and as described hereinafter. (See 37 CFR 1.121.):

(A) Renumber the claims in accordance with 37CFR 1.126;

(B) Correct erroneous citations on an Information Disclosure Statement (see MPEP §707.05(g));

(C) Correct an amendment filed under 37 CFR 1.312 that is non-compliant under 37 CFR 1.121 whose entry would otherwise be recommended (see MPEP § 714.16);

(D) Cancel claims directed to a non-elected invention, where the election was made without traverse and the claims are not eligible for rejoinder (see MPEP § 821.02); and

(E) Amendment and/or cancellation of claims following a decision by the Patent Trial and Appeal Board as described in MPEP §§ 1214, 1214.05, and 1214.06.

\* \* \* \* \*

An examiner's amendment should include form paragraph 13.02 and form paragraph 13.02.01.

\* \* \* \* \*

**¶ 13.02 Examiner's Amendment**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

\* \* \* \* \*

**¶ 13.02.01 Examiner's Amendment Authorized**

Authorization for this examiner's amendment was given in an interview with [1] on [2].

\* \* \* \* \*

No examiner's amendment may make substantive changes to the written portions of the specification, including the abstract, without first obtaining applicant's approval.

\* \* \* \* \*

CODE OF FEDERAL REGULATIONS

37 C.F.R. § 1.704(c)(10) Revised as of March, 10  
2015:

**§ 1.704 Reduction of Period of Adjustment of  
Patent Term.**

\* \* \* \* \*

(c) Circumstances that constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application also include the following circumstances, which will result in the following reduction of the period of adjustment set forth in § 1.703 to the extent that the periods are not overlapping:

\* \* \* \* \*

(10) Submission of an amendment under § 1.312 or other paper, other than a request for continued examination in compliance with § 1.114, after a notice of allowance has been given or mailed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the lesser of:

(i) The number of days, if any, beginning on the date the amendment under § 1.312 or other paper was filed and ending on the mailing date of the Office action or notice in response to the amendment under § 1.312 or such other paper; or

(ii) Four months;

\* \* \* \* \*

UNITED STATES CODE

35 U.S.C. § 154 (2011):

**§ 154. Contents and term of patent; provisional rights**

\* \* \* \* \*

(b) ADJUSTMENT OF PATENT TERM.—

\* \* \* \* \*

(2) LIMITATIONS.—

\* \* \* \* \*

(C) REDUCTION OF PERIOD OF ADJUSTMENT.—

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

reasonable efforts to conclude prosecution of the application.

(ii) With respect to adjustments to patent term made under the authority of paragraph (1)(B), an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of 3 months that are taken to respond to a notice from the Office making any rejection, objection, argument, or other request, measuring such 3-month period from the date the notice was given or mailed to the applicant.

(iii) 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.

(3) PROCEDURES FOR PATENT TERM ADJUSTMENT DETERMINATION.—

\* \* \* \* \*

(B) Under the procedures established under subparagraph (A), the Director shall—

\* \* \* \* \*

(ii) provide the applicant one opportunity to request reconsideration of any patent term

adjustment determination made by the Director.

(C) The Director shall reinstate all or part of the cumulative period of time of an adjustment under paragraph (2)(C) if the applicant, prior to the issuance of the patent, makes a showing that, in spite of all due care, the applicant was unable to respond within the 3-month period, but in no case shall more than three additional months for each such response beyond the original 3-month period be reinstated.

\* \* \* \* \*

(4) APPEAL OF PATENT TERM ADJUSTMENT DETERMINATION.—

(A) An applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the United States District Court for the Eastern District of Virginia within 180 days after the grant of the patent. Chapter 7 of title 5 shall apply to such action. Any final judgment resulting in a change to the period of adjustment of the patent term shall be served on the Director, and the Director shall thereafter alter the term of the patent to reflect such change.

\* \* \* \* \*

CONSTITUTION OF THE UNITED STATES

**Fifth Amendment, Due Process Clause**

No person shall . . . be deprived of life, liberty, or property, without due process of law.

**Fourteenth Amendment, Due Process Clause**

[N]or shall any State deprive any person of life, liberty, or property, without due process of law;

**Fourteenth Amendment, Equal Protection Clause**

[N]or shall any State . . . deny to any person within its jurisdiction the equal protection of the laws.