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

MAYO CLINIC FOUNDATION,)	
Plaintiffs,)	
)	
v.) Case No. 1:17	'-cv-1153
)	
ANDREI IANCU,¹)	
Defendant.)	
)	
)	
N/I	AND ANDIM ODINION	

MEMORANDUM OPINION

This is an appeal from a decision by the United States Patent & Trademark Office ("PTO"), calculating the patent term adjustment for United States Patent No. 8,981,063, owned by plaintiff, the Mayo Foundation for Medical Education and Research ("Mayo"). Specifically, the PTO determined that the six-month period extending from the conclusion of the interference proceeding until the PTO's mailing of the notice of allowance constituted "time consumed by continued examination requested by the applicant" pursuant to 35 U.S.C. § 154(b)(1)(B). Accordingly, the PTO excluded this period from the patent term adjustment calculation. Mayo argues that the PTO erred in excluding this time period from its adjustment calculation because the applicant's requested "continued examination" ended when the interference was declared. This dispute has been fully briefed and argued and is now ripe for disposition.

¹ Plaintiff originally named the former Acting Director of the United States Patent and Trademark Office ("PTO"), Joseph Matal, as the defendant in this case. Since this case was filed, Andrei Iancu has become the Director of the PTO, and as such, is the proper defendant here.

I.

Because Congress has relatively recently altered the patent law landscape in a manner particularly pertinent to this appeal, a brief description of this new landscape provides necessary context for resolution of the issues here.

The patent process begins when an applicant seeking a United States patent files an application with the PTO. See 35 U.S.C. § 111. The PTO then conducts an examination of that application, reviewing the application first for procedural requirements and then referring the application to an examiner to determine whether the claimed invention meets substantive patentability requirements. Id. §§ 101, 112, 103, 131. If the examiner determines that an applicant is entitled to a patent, a written notice of allowance is given or mailed to the applicant. Id. § 151. If, on the other hand, the examiner determines that the application does not meet patentability requirements, the examiner sends the applicant a notice rejecting the application and explaining the reasons for the rejection. See id. § 132(a). The applicant may then appeal the determination to the Patent Trial and Appeal Board ("PTAB") or file a request for continued examination ("RCE") of the application pursuant to 35 U.S.C. § 132(b). See 37 C.F.R. § 1.114. When an applicant files an RCE, the PTO withdraws the finality of the rejection, and an examiner continues examination of the application. See id. § 1.114(d).

Throughout this process, the examiner or the applicant can also recommend an application for an "interference" proceeding. *See* 35 U.S.C. § 135(a); *see also* 37 C.F.R. § 41.202(a).² Where two parties claim the same patentable invention, an interference proceeding serves to determine which party is entitled to priority of invention. *See Rolls Royce, PLC v. United Techs. Corp.*, 603 F.3d 1325, 1330 (Fed. Cir. 2010). Because interference proceedings

² The 2013 America Invents Act ("AIA") replaced "interferences" with "derivation proceedings." *See* 35 U.S.C. § 135(a). The interference here was declared before 2013, and the parties do not dispute that the inference was properly conducted as an interference pursuant to pre-AIA statutory provisions of the Patent Act.

are costly and time-consuming, examiners generally must complete examination or reexamination of the application before an interference is declared, and there must be at least one claim that "(1) [i]s patentable but for judgment in the contested case, and (2) [w]ould be involved in the contested case." 37 C.F.R. § 41.102.³

Once an interference is declared, the PTAB takes evidence and "enters final judgment on questions of priority and patentability arising in an interference." Manual of Patent Examining Procedure ("MPEP") § 2301.⁴ Generally, the examiner will not examine the application again until after the interference concludes.⁵ At that point, the application returns to the examiner, who then takes action, depending on the judgment in the interference proceeding. *See id.* If the PTAB's judgment contains a recommendation for further action, the examiner must reopen prosecution to consider the recommendation. *See id.* § 2308. Specifically, the PTAB may recommend rejection of a claim in which case the examiner generally must issue the recommended rejection. *See* 37 C.F.R. § 41.127(c). If, on the other hand, the PTAB determines that the applicant has priority with respect to a claim, the examiner "should update the search and may, but is not required to, reopen prosecution for any claim not disposed of in the judgment." *See* MPEP § 2308; *see id.* § 2301.

If, at the end of this process, a patent issues, the patent term will last for twenty years from the date the initial patent application was filed. Prior to 1994, patent terms were seventeen years from the date the patent issued. In 1994, Congress changed the patent term to twenty years

³ See also Capon v. Eshar, 418 F.3d 1349, 1351 (Fed. Cir. 2005) ("An interference is instituted after the separate patent applications have been examined and found to contain patentable subject matter.").

⁴ The Federal Circuit has made clear that the "MPEP does not have the force and effect of law; however, it is entitled to judicial notice as the agency's official interpretation of statutes or regulations, provided that it is not in conflict with the statutes or regulations." *Refac Intn'l, Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576, 1584 n.2 (Fed. Cir. 1996).

⁵ But in certain circumstances, the PTAB "may refer a matter to the examiner or may consult with the examiner on an issue." MPEP § 2301.

from the date the application was first filed. In changing the start date of the patent term to the date when the application was first filed, Congress acknowledged that PTO delays in the processing of applications would now consume some portion of the patent term. Accordingly, to account for certain of these delays, Congress passed the American Inventors Protection ("AIPA") of 1999, requiring the PTO to grant several patent term adjustments based on delays in the application processing attributable to the PTO. See 35 U.S.C. § 154(b). Specifically, there are three types of delays for which patentees are entitled to term adjustments: A Delay; B Delay; and C Delay. A Delay extends the patent term one day for each day the PTO fails to meet prescribed deadlines for certain events during the processing and prosecution of the patent application, including deadlines for mailing notices of allowance, responding to replies under § 132, and issuing the patent after payment of the required fees. See id. § 154(b)(1)(A). B Delay extends the patent term one day for each day beyond three years that the application remains pending. Id. § 154(b)(1)(B). C Delay extends the patent term one day for each day of the pendency of an interference proceeding, a secrecy order, or successful appellate review by the Board, or a Federal court. *Id.* § 154(b)(1)(C).

Most relevant to this case is the PTO's calculation of B Delay. As described above, B Delay accounts for delays "due to the failure of the [PTO] to issue a patent within [three] years after the actual filing date of the application" *Id.* § 154(b)(1)(B). The statute excludes certain time periods from the calculation of this three-year period of time, including "any time consumed by continued examination of the application requested by the applicant under section 132(b)" and "any time consumed by a proceeding under section 135(a)," which includes an interference proceeding. *Id.* § 154(b)(1)(B)(i)-(ii). In essence, the patent term adjustment

provisions limit the time the PTO may take in considering patent applications, but provide for exceptions where the delay is attributable to the applicant or outside the PTO's control.

In addition to establishing these categories of delay, the statute delegates to the PTO Director the authority to "prescribe regulations establishing procedures for the application for and determination of patent term adjustments" *Id.* § 154(b)(3)(A). Pursuant to this authority, the PTO promulgated a rule calculating the "time consumed by continued examination of the application requested by the applicant" in 35 U.S.C. § 154(b)(1)(B)(i) to include:

(1) The number of days, if any, in the period beginning on the date on which any request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date of mailing of the notice of allowance under 35 U.S.C. 151

37 C.F.R. § 1.703(b)(1).

Given this description of the patent application examination process and given the changes Congress implemented, it is appropriate to consider the parties' dispute.

II.6

Plaintiff, Mayo, a Minnesota non-profit corporation, is the owner of United States Patent No. 8,981,063 ("the '063 Patent"), relating to antibodies that bind to polypeptides. On April 9, 2009, Mayo filed Application No. 12/421,310 ("the '310 Application"), the application that culminated in the issuance of the '063 Patent. On October 14, 2010, the PTO issued a final office action rejecting the claims in the '310 Application. Specifically, the PTO determined that all of the claims in the '310 Application were unpatentable as anticipated by existing United States Patent No. 7,635,757 ("the '757 Patent") and that a subset of the claims were also unpatentable due to the lack of a written description. *See* AR 327-33. Approximately one year later, on September 14, 2011, Mayo filed an RCE pursuant to 35 U.S.C. § 132(b), amending

⁶ The facts recited here are derived from the Administrative Record ("AR"). The parties do not identify any disputed material facts, nor does the record reflect that any exist.

some of the claims to provide written descriptions, arguing that its claims had priority over the '757 patent, and suggesting an interference proceeding to resolve any remaining questions of priority. *See* AR 390-411. On October 20, 2011, an examiner contacted Mayo and informed Mayo that although the claims in the application were allowable, some of the claims were not relevant to the anticipated interference proceeding. AR 615. Accordingly, Mayo filed an amendment to its RCE on December 1, 2011, cancelling the unrelated claims and filing those claims in a separate application, which is not at issue here.

Thereafter, on February 9, 2012, the assigned Administrative Patent Judge issued a declaration of interference between the remaining 26 claims in the '310 Application and 13 claims in the '757 Patent. Two years later, on February 19, 2014, the PTAB issued a judgment, granting Mayo's motion for judgment on the basis of priority and canceling 13 of the claims in the '757 Patent. The interference terminated as of April 23, 2014, when the losing party's time for filing an appeal expired. *See* 35 U.S.C. § 142 (providing that an appeal from a PTAB decision in an interference proceeding must be submitted no less than 60 days after the date of the PTAB decision). Following the termination of the interference, the '310 Application was returned to the examiner, who then conducted additional prior art searches. On June 30, 2014, the examiner issued a non-final office action, rejecting some of the claims on grounds of double patenting. Mayo filed a response to this non-final agency action on October 24, 2014. On November 3, 2014, the PTO withdrew the rejection and mailed a notice of allowance for all of the claims in the '310 Application.

Four months later, on March 17, 2015, the PTO issued the '063 Patent and awarded a 604-day patent term adjustment. Specifically, the PTO calculated 898 days of A Delay, 0 days of B Delay, and 805 days of C Delay—a total of 1703 days of delay. Because 294 days of this

delay was attributable to the applicant and the 805 days of C Delay overlapped entirely with the A Delay days, the PTO then subtracted the 294 days of applicant delay and 805 days of the overlapping delay to reach a patent term adjustment of 604 days.

The parties agree that the PTO correctly calculated the A Delay, C Delay, applicant delay, and overlap; the only issue on which the parties part company here concerns the calculation of B Delay. The PTO calculated 0 days of B Delay by determining that the "time consumed by continued examination of the application requested by the applicant" lasted 1147 days from the day Mayo filed the RCE on September 14, 2011 until the day the PTO mailed the notice of allowance on November 3, 2014. The PTO then subtracted that 1147 days consumed by continued examination from the 2169 days of total time from the date of the application's filing to the date of the patent's issuance. *See* AR 834. Because the remaining time (1022 days) did not exceed three years (1095 days), the PTO determined that the B Delay was 0 days.

The PTO also provided an alternative calculation that reached the same result. Specifically, in its alternative calculation, the PTO interpreted the interference proceeding as "pausing" the continued examination requested by the applicant. AR 834. Accordingly, the PTO calculated that the 148 days between the RCE and the declaration of interference were consumed by continued examination requested by the applicant, after which the continued examination was paused for the 805 days devoted to the interference. Finally, according to the PTO, the applicant's requested continued examination then resumed for the 194 days between the termination of the interference and the allowance of the claims. The PTO then subtracted the period of continued examination (342 days) and the period of interference (805 days)⁷ from the application's total pendency (2169 days) and reached the same result of 1022 days, which does

⁷ Mayo correctly concedes that the 805 days consumed by the interference proceedings are properly excluded from the B Delay calculation pursuant to 35 U.S.C. § 154(b)(1)(B)(ii).

not exceed three years and therefore does not warrant any B Delay (2169 minus 342 days of continued examination and 805 days of interference is 1022 days, which is less than three years, or 1095 days).

Following the PTO's decision denying any B Delay, Mayo filed a request for reconsideration, contending that the B Delay was 119, and not 0 days, and as such, Mayo was entitled to a 723-day patent term adjustment. Specifically, Mayo argued that the "time consumed by continued examination of the application requested by the applicant" lasted from the date that Mayo filed the RCE to the date the interference was declared, not, as the PTO contended, from the date of the RCE until the mailing of the notice of allowance. In essence, Mayo argued that the applicant's requested continued examination permanently ended when the interference was declared, and as such, the time between the termination of interference on April 23, 2014 and the issuance of the notice of allowance on November 3, 2014 should not have been excluded from the B Delay calculation.

On July 12, 2017, the PTO issued a final decision denying the request for reconsideration and confirming that Mayo was entitled to a patent term adjustment of only 604 days. *See* AR 832-33. Mayo timely filed the instant action on October 13, 2017, pursuant to 35 U.S.C. § 154(b)(4)(A) and the Administrative Procedure Act ("APA").

The PTO contends that "time consumed by continued examination of the application requested by the applicant" includes any time after the filing of an RCE, which occurred in September 2011, up until the mailing of the notice of allowance, which occurred in November 2014. As such, the time from April 2014 when the interference proceeding ended until November 2014 was properly excluded. Mayo counters by arguing that continued examination permanently

ended when the interference proceedings began, and as such, the time from the termination of the interference proceeding until the notice of allowance should not be excluded and instead should be credited to Mayo as B Delay.

III.

The standard of review on motions for summary judgment is too well-settled to warrant extensive discussion. Under Rule 56, Fed. R. Civ. P., summary judgment is appropriate only where there is "no genuine dispute as to any material fact" such that the moving party "is entitled to judgment as a matter of law." *Celotex v. Catrett*, 477 U.S. 317, 322 (1986). A genuine dispute exists if "there is sufficient evidence on which a reasonable jury could return a verdict in favor of the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Where, as here, judicial review is limited to the Administrative Record, and the parties, having filed crossmotions for summary judgment, agree that no genuine issues of material fact exist, the parties' dispute is appropriately resolved by way of summary judgment. *See Wyeth v. Kappos*, 591 F.3d 1364, 1369 (Fed. Cir. 2010).

IV.

The dispute here is whether the time from the close of the interference proceedings until the notice of allowance was mailed in this matter constitutes "time consumed by continued examination of the application requested by the applicant" pursuant to § 154(b)(1)(B), or whether the applicant's requested continued examination ended when the interference was declared. In *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014), the Federal Circuit addressed the question of when "time consumed by continued examination of the application requested by the applicant" ends for purposes of § 154(b)(1)(B). Specifically, the Federal Circuit held that "examination" as used in § 154(b)(1)(B) "presumptively ends at allowance, when prosecution is

closed and there is no further examination on the merits in the absence of a special reopening." *Id.* at 602. In this regard, the Federal Circuit determined that "continued examination . . . requested by the applicant" pursuant to § 154(b)(1)(B) occurred until the notice of allowance was mailed and the application moved from the examiner to the office of publication. *Id*.

Although *Novartis* involved a somewhat different factual scenario, the decision nonetheless announces a principle that points persuasively to the conclusion that the time prior to the mailing of the notice of allowance for the '310 Application constituted "time consumed by continued examination of the application requested by the applicant" pursuant to § 154(b)(1)(B). Until November 3, 2014, when the examiner mailed the notice of allowance, prosecution of the '310 Application remained open. Examination of merits of the application continued on the question of priority during the interference proceedings, and thereafter examination continued on the question of patentability as the examiner updated prior art searches and considered the question of double patenting. AR 698-703. Because prosecution was not closed and examination on the merits continued until November 3, 2014, the time from the end of the interference until November 3 is clearly "time consumed by continued examination of the application requested by the applicant" as defined by *Novartis*.

The result reached here is consistent with Congress's purpose in enacting the patent term adjustments. As the Federal Circuit in *Novartis* made clear, "154(b)(1)(B) is best understood as making distinctions based on whether certain delays are attributable to the PTO." *Novartis*, 740 F.3d at 602. Here, the time from the termination of the interference proceedings to the mailing of the notice of allowance is attributable to Mayo, and not to the PTO. Had Mayo not requested a continued examination, the PTO would not have conducted the interference proceedings nor would the PTO have updated the prior art search and examined the issue of double patenting

following the interference proceedings. And importantly, Mayo's RCE remained pending throughout this entire time period. The patent statute makes clear that an application remains pending until the PTO determines either (i) that the application has been abandoned after a final rejection, or (ii) that the applicant is entitled to a patent under the law, and the PTO mails a notice of allowance. *See* 35 U.S.C. §§ 133, 151. Here, the PTO neither issued a final rejection nor determined that Mayo was entitled to a patent under the law until November 3, 2014. As such, the RCE remained pending until that time and any continued examination of the application was attributable to Mayo's RCE and not to examination independently initiated by the PTO. As such, the exclusion of this time is consistent with the purposes of patent term adjustments.

Mayo, in attempting to avoid this conclusion compelled by *Novartis*, argues that a declaration of interference is analogous to allowance for the purposes of § 154(b)(1)(B) because the claims in the patent are otherwise "deemed allowable" by the patent examiner before an interference is declared. But this argument is unpersuasive because allowance and interference are distinct in several respects that the Federal Circuit considered important in *Novartis*. Significantly, in *Novartis*, the Federal Circuit made clear that "continued examination of the application requested by the applicant" presumptively ends at allowance because at that point, "prosecution is closed and there is no further examination on the merits in the absence of a special reopening." *Novartis*, 740 F.3d at 602. In this regard, the Federal Circuit recognized that the notice of allowance itself provides that prosecution is closed when it is mailed. Specifically, notices of allowances state that "THE APPLICATION . . . HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED." *Id.* And importantly, as the *Novartis* court noted, when the notice of allowance is

mailed, jurisdiction transfers from the examiner to the office of publication. *Id.* (citing MPEP § 1305). Once jurisdiction transfers to the office of publication, "[t]o regain jurisdiction over the application, the examiner must write a letter to the Director requesting it." MPEP § 1305. The Federal Circuit further noted that only in "exceptional" circumstances does the PTO take affirmative action to resume examination after a notice of allowance is mailed and jurisdiction transfers to the office of publication. *Novartis*, 740 F.3d at 602.

These factors, considered significant by the *Novartis* court in defining the end point of continued examination requested by the applicant, do not apply where, as here, an interference is declared. To begin with, the examiner here never indicated that the prosecution on the merits was closed by mailing a written notice stating as much. Indeed, the examiner specifically told Mayo that an interference proceeding was likely to occur and that the claims would continue through that process. See AR 615. And importantly, examination on the merits both during and after interference proceedings is routine, not exceptional. During the interference proceedings themselves, the PTAB "may refer a matter to the examiner or may consult with the examiner on an issue." MPEP § 2301. And, once interference terminates, the MPEP indicates that "[j]urisdiction over an application returns to the examiner." Id. § 2308. At that point, the examiner takes any further required action, which may include sending the claims to the office of publication for issuance, entering a recommended rejection of the claims, or updating the prior art search. Id. §§ 2301, 2308. Put simply, the examiner's continued engagement with the application is the norm following an interference, and not an exceptional circumstance as in the context of post-allowance proceedings. As such, the applicant's requested continued examination does not presumptively end at the time the interference is declared in the same way

that the applicant's requested continued examination ends at allowance, because prosecution is not closed by the declaration of interference and further examination is expected.

Moreover, to adopt Mayo's argument that the applicant's requested continued examination ends when the claims are "deemed allowable" would lead to absurd results not envisioned by the Federal Circuit in *Novartis*. For example, if an examiner were to indicate in a conversation with the applicant that he or she believed the claims in the RCE were allowable, Mayo's interpretation of the statute would then attribute any additional examination of the application to the PTO, not to the applicant. This result, in addition to discouraging patent examiners from communicating with applicants about the status of their applications, would require the PTO to delve into each day of the continued examination process and to assess whether the examiner had effectively finished its prosecution of the application at any point in time before the examiner mailed the notice of allowance. The Federal Circuit plainly sought to avoid these intensive day-by-day factual inquiries when it established in *Novartis* that "time consumed by continued examination of the application requested by the applicant" ends at allowance, when prosecution is formally closed, and further examination on the merits does not occur absent truly exceptional circumstances. *Novartis*, 740 F.3d at 602.

In sum, Mayo's efforts to draw an analogy between a declaration of interference and an allowance fail because the Federal Circuit held that allowance marks the end of the applicant's requested continued examination precisely because after allowance, as notices of allowance make clear, prosecution is closed and does not continue absent a special reopening. Interference, by contrast, does not signal the end to prosecution; instead, prosecution continues throughout the interference proceedings and jurisdiction automatically returns to the examiner to take any remaining action following interference.

Even assuming, arguendo, that a declaration of interference is analogous to allowance as Mayo contends, the Federal Circuit in Novartis noted that "time consumed by continued examination of the application requested by the applicant" pursuant to § 154(b)(1)(B) is "time up to allowance, but not later, unless examination on the merits resumes." Novartis, 740 F.3d at 602. In doing so, the Federal Circuit recognized that although "time consumed by continued examination of the application requested by the applicant" ordinarily ends when the allowance is mailed, it can, in certain circumstances, include time after allowance where "examination on the merits resumes." Id. And Mayo concedes that here "[t]here is no dispute that 'examination' occurred after the interference." Mayo Reply Br. (Doc. 25) at 11. Thus, even assuming, as Mayo argues, that "time consumed by continued examination" is time up to the declaration of interference, Novartis makes clear that "time consumed by continued examination" includes time after a declaration of interference where, as here, "examination on the merits resumes" after the interference proceeding concludes.

Mayo next argues that the time after the interference proceedings ended was attributable to the PTO, and not to Mayo, because the examiner *sua sponte* reopened examination after interference. This argument mischaracterizes the nature of examination following an interference. An examiner's updating of prior art searches following an interference proceeding is not a *sua sponte* reopening of examination; rather, it is the resumption of the continued examination that was initially requested by the applicant. As the MPEP notes, "[j]urisdiction over an application returns to the examiner once the interference has been terminated," and at that point, if there is no recommendation in the PTAB's judgment, the examiner "*should* update the search" MPEP § 2308 (emphasis added). Notably, the word "should," the "past of

shall," is "[u]sed to express obligation or duty," THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 1623 (5th ed. 2016). Thus, unlike prosecution after allowance, which requires the examiner to write a special letter to the Director requesting that the Director reopen prosecution, prosecution after an interference proceeding continues automatically as PTO guidance requires the examiner, at the very least, to update the prior art search. The period of examination after the termination of examination is thus a "resum[ption]" of the continued examination initiated by the applicant's RCE and not a *sua sponte* reopening prompted entirely and exclusively by the PTO. *See* § MPEP 2308, ¶ 23.02

Finally, Mayo contends that when the PTO excluded the time from the termination of interference until the mailing of a notice of allowance, the PTO improperly differentiated between continued-examination cases and cases not involving continued examination. But the PTO's differentiation in this respect was not improper because the statute *mandates* that the PTO distinguish cases in which the patentee files an RCE by excluding "time consumed by continued examination of the application requested by the applicant" from its calculation of B Delay. 35 U.S.C. § 154(b)(1)(B)(i). Mayo relies on the Federal Circuit's determination in *Novartis* that there was no basis for distinguishing a continued-examination case with respect to time from allowance to issuance. This argument ignores the fact that in *Novartis*, the Federal Circuit had already determined that the period of time from allowance to issuance could not possibly be "time consumed by continued examination of the application requested by the applicant" because once the PTO mails the notice of allowance, the prosecution is closed and examination on the merits has ended. Here, as described above, examination on the merits of Mayo's RCE continued after the interference was terminated and thus the PTO properly distinguished this

⁸ WEBSTER'S THIRD NEW INT'L DICTIONARY 2104 (3d ed. 2002).

continued-examination case and excluded the "time consumed by continued examination of the application requested by the applicant" pursuant to 35 U.S.C. § 154(b)(1)(B)(i).

In the end, Mayo's arguments fail because Federal Circuit precedent makes clear that "time consumed by continued examination of the application requested by the applicant" includes time up until "allowance"—that is, when the notice of allowance is mailed, prosecution is closed, and further examination on the merits does not occur absent a special reopening. *Novartis*, 740 F.3d at 602. A declaration of interference is not allowance; after interference proceedings conclude, jurisdiction automatically returns to the examiner, and the examiner is required to conduct additional examination by updating prior art searches. As such, prosecution remains open at this point, further examination is routine, not exceptional, and this time is properly considered "time consumed by continued examination of the application requested by the applicant" pursuant to § 154(b)(1)(B).

V.

In sum, *Novartis* makes clear that "time consumed by continued examination of the application requested by the applicant" pursuant to § 154(b)(1)(B) "presumptively ends at allowance, when prosecution is closed and there is no further examination on the merits in the absence of a special reopening." *Novartis*, 740 F.3d at 602. Here, allowance occurred on November 3, 2014 when the PTO mailed the notice of allowance for the '310 Application. Until that point, prosecution of the application and examination on the merits continued both throughout the interference proceedings and after those proceedings concluded. Accordingly, the PTO correctly excluded the time from the request for continued examination until the mailing of the notice of allowance from the B Delay calculation and thus, correctly calculated a B Delay of 0 days on the '063 Patent.

An appropriate Order will issue.

Alexandria, Virginia April 23, 2018

T. S. Ellis, III

United States District Judge