# United States Court of Appeals for the Federal Circuit

# MAYO FOUNDATION FOR MEDICAL EDUCATION AND RESEARCH,

Plaintiff-Appellant

 $\mathbf{v}.$ 

## ANDREI IANCU, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendant-Appellee \_\_\_\_\_

2018-2031

Appeal from the United States District Court for the Eastern District of Virginia in No. 1:17-cv-01153-TSE-JFA, Judge T. S. Ellis, III.

Decided: September 16, 2019

AHMED JAMAL DAVIS, Fish & Richardson PC, Washington, DC, argued for plaintiff-appellant. Also represented by CRAIG E. COUNTRYMAN, JARED ALEXANDER SMITH, San Diego, CA.

R. TRENT MCCOTTER, Office of the United States Attorney, Alexandria, VA, argued for defendant-appellee. Also represented by G. ZACHARY TERWILLIGER; THOMAS W.

KRAUSE, KAKOLI CAPRIHAN, BRIAN RACILLA, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA.

Before NEWMAN, LOURIE, and DYK, Circuit Judges.

Opinion for the court filed by Circuit Judge LOURIE.

Dissenting opinion filed by Circuit Judge NEWMAN.

LOURIE, Circuit Judge.

The Mayo Foundation for Medical Education and Research ("Mayo") appeals from a decision of the United States District Court for the Eastern District of Virginia, Mayo Found. v. Iancu, 309 F. Supp. 3d 425 (E.D. Va. 2018) ("Decision"), which affirmed the United States Patent and Trademark Office's (the "PTO's") calculation of patent term adjustment ("PTA") for U.S. Patent 8,981,063 (the "063 patent") under 35 U.S.C. § 154. Because we conclude that the PTO's interpretation of "any time consumed by continued examination of the application requested by the applicant under section 132(b)" in 35 U.S.C. § 154(b)(1)(B)(i), see 37 C.F.R. § 1.703(b)(1), was correct, we affirm.

#### BACKGROUND

In 1994, Congress implemented the trade agreements reached during the Uruguay Round of multilateral trade negotiations by enacting the Uruguay Round Agreements Act (the "URAA"). Pub. L. No. 103-465, 108 Stat. 4809 (1994). Pursuant to the URAA, Congress changed the patent term length from seventeen years from the date of issuance of the patent to twenty years from the effective filing date of the application. See id. § 532 (codified as amended at 35 U.S.C. § 154) (defining the effective filing date as the filing date of the instant application or that of the application from which it can claim priority under §§ 120, 121 or 365). Congress envisioned in the URAA that this change could disadvantage patent owners whose

applications underwent lengthy prosecution, and it provided for PTA compensating for delays attributable to interference proceedings under 35 U.S.C. § 135(a) and certain appeals to the Board or federal courts under 35 U.S.C. §§ 134, 141, 145. See URAA, § 532.

In an effort to streamline patent prosecution, Congress expanded PTA in 1999. American Inventors Protection Act of 1999, Pub. L. No. 106-113, App. I, tit. IV, 113 Stat. 1501, 1501A-552–1501A-591 (1999) (codified as amended, in relevant portion, at 35 U.S.C. § 154(b)) (the "AIPA"). The statute compensates applicants for three broad classes of delay: § 154(b)(1)(A) ("A Delay") provides PTA when the PTO does not meet certain deadlines in the processing of patent applications; § 154(b)(1)(B) ("B Delay") generally entitles the applicant to PTA for each day the application is pending beyond three years; and § 154(b)(1)(C) ("C Delay") provides PTA for each day the application is pending in an interference proceeding, a secrecy order, or a successful appeal to the Patent Trial and Appeal Board (the "Board") or a federal court. Each of these entitlements is subject to the "[llimitations" set forth in § 154(b)(2), which, inter alia, reduce PTA "by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution." Id. § 154(b)(2)(C); see Supernus Pharm., Inc. v. Iancu, 913 F.3d 1351, 1353–54 (Fed. Cir. 2019).

This appeal concerns the calculation of B Delay. While § 154(b)(1)(B) generally "guarantee[s] . . . no more than 3-year application pendency," that 3-year period is subject to several exclusions:

- (i) any time consumed by continued examination of the application requested by the applicant under section 132(b);
- (ii) any time consumed by a proceeding under section 135(a), any time consumed by the imposition of an order under section 181, or any time

consumed by appellate review by the Patent Trial and Appeal Board or by a Federal court; or

(iii) any delay in the processing of the application by the United States Patent and Trademark Office requested by the applicant except as permitted by paragraph (3)(C)....

Id. § 154(b)(1)(B)(i)–(iii). The time consumed during one of the proceedings referred to in § 154(b)(1)(B)(ii)—interferences, secrecy orders, and appeals, respectively—is excluded because it is already counted as C Delay. See § 154(b)(2)(A) ("[PTA] shall not exceed the actual number of days the issuance of the patent was delayed.").

On several occasions since 2000, the PTO has promulgated regulations setting forth its interpretation of "time consumed by continued examination of the application requested by the applicant under section 132(b)." *Id.* § 154(b)(1)(B)(i) ("RCE time"). Section 132(b) was also enacted as part of the AIPA, *id.* § 4403, 113 Stat. at 1501A-560, and it requires the PTO to "prescribe regulations to provide for . . . continued examination . . . at the request of the applicant," commonly referred to as an "RCE." As set forth by the PTO in 37 C.F.R. § 1.114, filing an RCE "withdraw[s] the finality of any Office action" and allows prosecution to proceed.

In *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014), we held that the PTO's previous interpretation of RCE time—as extending from the filing date of the RCE to issuance, *see* 37 C.F.R. § 1.703(b)(1) (2013)—was incorrect because, absent resumption of examination after the date of mailing of the Notice of Allowance, which is an exceptional circumstance, "allowance-to-issuance time" is "plainly attributable to the PTO," regardless "whether there is a continued examination in a prosecution." *Novartis*, 740 F.3d at 602. Thereafter, the PTO promulgated and finalized a new regulation, interpreting RCE time as "[t]he number of days . . . in the period beginning on [the RCE filing date]

and ending on the date of mailing of the notice of allowance . . . . " 37 C.F.R. § 1.703(b)(1) (2019).

The '063 patent claims certain antibodies purportedly useful for treating "disease conditions characterized by immunosuppression: e.g., cancer, AIDS or AIDS-related comother virally orenvironmentally-induced conditions, and certain congenital immune deficiencies." Id. col. 14 ll. 20–23. The '063 patent issued from Application 12/421,310 (the "310 application"), filed on April 9, 2009, with an effective filing date of November 30, 1999. The PTO issued a final rejection of the pending claims on October 14, 2010, as anticipated by U.S. Patent 7,635,757 (the "757 patent"), and, for some of the claims, as lacking written description. J.A. 419–25. The PTO also noted in its rejection that Mayo had suggested an interference with the '757 patent in its previous response, and it invited Mayo to make the requisite priority showing under 37 C.F.R. § 41.202(d)(1) (2010). On September 14, 2011, Mayo filed an RCE along with remarks arguing that Mayo had priority of invention over the '757 patent and suggesting an interference.

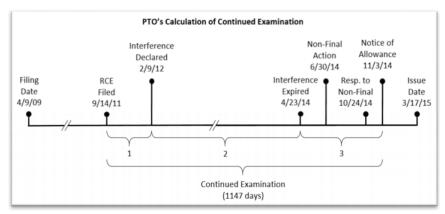
Mayo filed a supplemental amendment shortly afterward cancelling certain claims that the examiner had indicated, in an apparently off-the-record discussion, would not correspond to the count in the impending interference. Some of these claims had previously been withdrawn in response to a restriction requirement, and the examiner advised Mayo that, for the purposes of eventual PTA calculation, claims not relevant to the impending interference should be removed. Mayo accordingly cancelled those claims and pursued them in a separate continuation application, which later issued as U.S. Patent 8,460,927 (the "927 patent").

On February 9, 2012, an interference was declared between all the remaining claims of the '310 application and all the claims of the '757 patent. The interference

proceeded for two years. On February 19, 2014, the Board awarded priority to Mayo's '310 application claims and cancelled all the claims of the '757 patent. See Chen v. Freeman, Int. No. 105,872, 2014 WL 664019 (P.T.A.B. Feb. 19, 2014); J.A. 764–787. The interference decision became final on April 23, 2014, when the sixty-day period for appeal expired. See 35 U.S.C. § 142; 37 C.F.R. § 90.3.

Following termination of the interference, the Board returned the '310 application to the examiner. The examiner conducted a further prior art search, and on June 30, 2014, issued an Office Action rejecting the claims of the '310 application on the ground of non-statutory obviousness-type double patenting in view of the '927 patent, which contained the claims that had been cancelled in the '310 application. Mayo filed a reply on October 24, 2014, arguing on the merits that the claims of the '310 application were patentably distinct. The examiner then withdrew the rejection and mailed a Notice of Allowance on November 3, 2014. The '310 application issued as the '063 patent on March 17, 2015.

Mayo provides the following timeline to summarize the prosecution events:



Mayo Br. 7. The first bracketed time period is 148 days; the second, 805 days; and the third, 194 days. The parties

agree that the first period is RCE time and the second period is not. This appeal concerns the third period.

Upon issuance of the '063 patent, the PTO calculated a PTA of 621 days, with no B Delay. Mayo filed a request for redetermination, claiming that it was due 685 days, because "[t]he examiner's sua sponte reopening of prosecution after termination of the interference was not [RCE time under 35 U.S.C. § 154(b)(1)(B)(i)]." J.A. 877–79. Mayo calculated the RCE time as 148 days, the time between the filing of the RCE and the declaration of the interference.

The PTO disagreed, asserting that RCE time did not end when the interference was declared, but instead when the Notice of Allowance was mailed. 37 C.F.R. § 1.703(b)(1). Accordingly, the PTO calculated 342 days of RCE time: the 148 days identified by Mayo and the 194 days between the termination of the interference and mailing of the Notice of Allowance. Because RCE time is deducted from the B Delay calculation under § 154(b)(1)(B)(i), and the PTO's calculation of RCE time is greater than Mayo's, the PTO concluded that there was no B Delay and, as a result, that Mayo is entitled to less PTA than it sought. Mayo requested reconsideration, but the PTO denied its request. 1

Mayo then appealed to the United States District Court for the Eastern District of Virginia. See 35 U.S.C. § 154(b)(4)(A). Mayo argued that a declaration of an interference terminates RCE time for the purposes of calculating B Delay for two reasons. First, it asserted that the holding of *Novartis* is that continued examination ends once the claims are "deemed allowable," not necessarily on

<sup>&</sup>lt;sup>1</sup> Both Mayo and the PTO have since changed their PTA calculations for reasons not relevant to the issue in this appeal. Mayo now claims 723 days, while the PTO has finally determined that Mayo is due 604 days.

the date of mailing of the Notice of Allowance, and since the PTO's regulations require an application "otherwise be in condition for allowance" before an interference is declared, the declaration is tantamount to a Notice of Allowance. In the alternative, Mayo also contended that the examiner's reopening of examination after remand from the Board is time attributable to the PTO, not the applicant, because Mayo never requested examination after remand.

The district court carefully evaluated, but rejected, Mayo's interpretations of both § 154(b)(1)(B)(i) and Novartis. In its view, Novartis established that RCE time "presumptively ends" upon mailing of the Notice of Allowance, Decision, 309 F. Supp. 3d at 433. The court also found that, because "the applicant's requested continued examination does not presumptively end at the time the interference is declared," id. at 434, the declaration of an interference is not analogous to resumption of examination after the Notice of Allowance—the only "exceptional" circumstance identified by this court in *Novartis*, 740 F.3d at 602, as possibly giving rise to a departure from the "general rule" that examination ends upon mailing of the Notice of Allowance, Decision, 309 F. Supp. 3d at 433. It also concluded that the examination after remand was RCE time "attributable to Mayo, and not to the PTO," because "[h]ad Mayo not requested a continued examination, the PTO would not have conducted the interference proceedings . . . [or] examined the issue of double patenting." Decision, 309 F. Supp. 3d at 432–33.

This appeal followed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

#### DISCUSSION

We review a district court's grant of summary judgment according to the law of the regional circuit. *Kaneka Corp. v. Xiamen Kingdomway Grp. Co.*, 790 F.3d 1298, 1303 (Fed. Cir. 2015) (citing *Halo Elecs.*, *Inc. v. Pulse El-*

ecs., Inc., 769 F.3d 1371, 1377 (Fed. Cir. 2014)). In the Fourth Circuit, summary judgment is reviewed de novo, viewing the evidence and drawing all inferences in favor of the nonmovant. Halpern v. Wake Forest Univ. Health Scis., 669 F.3d 454, 460 (4th Cir. 2012); Fed. R. Civ. P. 56(a) ("The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.").

Patent term adjustments are reviewed in accordance with the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701–06. See 35 U.S.C. § 154(b)(4)(A). We must set aside an action of the PTO if it is, inter alia, "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706. The only question in this appeal is one of statutory interpretation, and neither party has identified a material, disputed issue of fact. Statutory interpretation is a question of law, which we review de novo. See Power Integrations, Inc. v. Semiconductor Components Indus., LLC, 926 F.3d 1306, 1313–14 (Fed. Cir. 2019) (citing Unwired Planet, LLC v. Google Inc., 841 F.3d 1376, 1379 (Fed. Cir. 2016)).

Mayo contends that 37 C.F.R. § 1.703(b)(1) reflects a misinterpretation of RCE time as defined in 35 U.S.C. § 154(b)(1)(B)(i). It argues that it never "requested" any examination after the Board's remand and that, under PTO regulations, an interference cannot be declared unless at least some claims, and in this case all of the claims, are deemed allowable but for the outcome of the interference. In addition, Mayo reprises its argument to the district court that, under *Novartis*, RCE time ends "once the [PTO] takes an official action indicating that all the pending claims are allowable and closes prosecution," Mayo Br. 14, or the claims are "deemed allowable," Mayo Br. 8. While this date is "presumptively" upon the mailing of the Notice of Allowance, *Novartis*, 740 F.3d at 602, Mayo argues that

under PTO regulations a declaration of an interference comprises such an indication of allowability.

The PTO responds that a declaration of an interference does not close prosecution on the merits, and the PTO's operating procedures, as well as the previous version of 35 U.S.C. § 135(a) (governing interferences), contemplate that examination may continue afterward. See id. (the Board "may determine questions of patentability" in an interference and the Director "may issue a patent to [a victorious] applicant"); see also M.P.E.P. § 2308. The PTO also points out, as a practical matter, that Mayo's rule requiring a determination of when the PTO deems the claims allowable would turn PTA calculation into a "wildly impractical" and "hotly contested factual inquiry in nearly every PTA case." PTO Br. 4.

We agree with the PTO. While the PTO's regulations do indicate that at least one claim in an application should be in condition for allowance before an interference is declared, see 37 C.F.R. § 41.102, the regulations also explicitly contemplate that the Board may recommend further action by the examiner, including issuing a rejection. *Id.* § 41.127(c); see also M.P.E.P. § 2308 (instructing examiners to update their prior art search after remand and advising that "[an interference] judgment does not prevent the examiner from making a rejection in further examination in the same application or a different application"). Thus, the PTO's regulations as a whole do not indicate that a declaration of an interference is tantamount to a Notice of Allowance.

Neither does *Novartis*. We find Mayo's interpretation of *Novartis*—that examination ends once the claims are "deemed allowable"—strained, given that we said there that "[t]he common-sense understanding of 'time consumed by continued examination' . . . is time up to allowance, but not later, unless examination on the merits resumes." 740 F.3d at 602 (citation omitted). We held in *Novartis* that the

time between the date of mailing of the Notice of Allowance and issuance is not RCE time, absent special circumstances where examination is reopened after allowance, because examination on the merits closes upon allowance in the great majority of cases. *Id.* 

This case is no exception. Upon remand, the examiner updated her search in accordance with M.P.E.P. § 2308, and, finding Mayo's continuation application had issued as the '927 patent, issued a rejection for obviousness-type double patenting. Mayo, for its part, argued against that rejection on the merits, succeeded in persuading the examiner that the claims were patentably distinct, and secured an allowance. But examination clearly did not end until the date the Notice of Allowance was mailed. Thus, Mayo's interpretation of *Novartis* is incorrect.

Mayo's novel reading of the term "requested" also does not show that 37 C.F.R. § 1.703(b)(1) reflects an erroneous interpretation of the statute. Mayo only gets to its conclusion by placing more weight on the term "requested"—a word having little more than clerical significance on a fair reading of the statute—than it can reasonably bear. Continued examination, like regular examination, is not limited to the issues the applicant would like to see resolved. Nothing in § 132(b) implies that an RCE entitles the applicant to a special form of examination, where the claims must be allowed once the grounds of rejection presented in the Final Rejection are resolved; nor does the statute imply that continued examination is no longer requested by the applicant once the PTO issues a new ground of rejection. Mayo has not asserted any authority contrary to our understanding. See, e.g., In re Brandt, 886 F.3d 1171, 1175-76 (Fed. Cir. 2018) (examination involves a process of initial and final rejections and "if the applicant timely requests continued examination, [that] process is repeated").

At the heart of Mayo's appeal is the misapprehension that the examiner could not have issued a rejection that "had nothing to do with any issue raised in the [RCE]," Mayo Br. 24, or, at the very least, that such time should not be deducted from B Delay. But continued examination, both on its own terms and as interpreted by the PTO, see 37 C.F.R. § 1.114 (2019), simply entitles an applicant to continue examination. It is not just an opportunity to seek rehearing of a final rejection, and, as in regular examination, the PTO's regulations allow the examiner to issue a new ground of rejection, as was the case here. See J.A. 790 (explaining that, upon rejoinder of the non-elected claims, the double-patenting rejection was newly permissible under M.P.E.P. § 804.01). Mayo requested continued examination, and that is what it received, both before and after the interference proceeding.

We are also persuaded by the PTO's point that Mayo's rule could require an unduly burdensome, fact-intensive inquiry into when the PTO actually conceded the allowability of the claims. This is a case in point. Mayo claims that, after it filed its RCE, the examiner "indicated" on a phone call that its claims were in condition for allowance but for the interference, J.A. 707, or, in Mayo's words, were "deemed allowable." Mayo Br. 24. The PTO understandably wishes to avoid such disputes over what "indicated" means and when claims are "deemed allowable." See, e.g., Mayo Found, for Med. Educ. & Research v. United States, 562 U.S. 44, 59 (2011) (an "administrab[le]" interpretation is often preferred over a "purely case-by-case approach" that precipitates "wasteful litigation and continuing uncertainty" (quoting U.S. v. Correll, 389 U.S. 229, 302–03 (1967))).

### CONCLUSION

We have considered the parties' other arguments but find them unpersuasive. For the foregoing reasons, we hold that, where an RCE has previously been filed, the time between termination of an interference and the date of mailing of the Notice of Allowance is "time consumed by continued examination of the application requested by the applicant under section 132(b)" pursuant to 35 U.S.C. § 154(b)(1)(B)(i). Accordingly, we conclude that the PTO correctly determined that there was no B Delay, and we affirm the decision of the district court.

### **AFFIRMED**

# United States Court of Appeals for the Federal Circuit

# MAYO FOUNDATION FOR MEDICAL EDUCATION AND RESEARCH,

Plaintiff-Appellant

 $\mathbf{v}$ .

## ANDREI IANCU, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendant-Appellee

2018-2031

Appeal from the United States District Court for the Eastern District of Virginia in No. 1:17-cv-01153-TSE-JFA, Judge T. S. Ellis, III.

NEWMAN, Circuit Judge, dissenting.

This appeal concerns calculation of the patent term adjustment ("PTA") that is established by statute to compensate for the patent life consumed by prolonged (over three years) examination of the patent application. The aspect on appeal relates to the period of *ex parte* examination conducted after termination of an interference and ending with mailing of the notice of allowance. The district court, affirming the United States Patent and Trademark Office ("PTO"), held that this additional period of examination is

not subject to any term adjustment,<sup>1</sup> and my colleagues agree. This holding does not comport with the statutory provisions and precedent, and is contrary to the purpose of term adjustment. Mayo is correct that the calculation of PTA includes the period of examination after termination of the interference.

The panel majority holds that this post-interference examination period is not included in the patent term adjustment, although it plainly is examination delay due to PTO procedures. I respectfully dissent.

### The PTA Statute and Regulations

Until 1994, the United States patent term was seventeen years from the date of patent issuance, irrespective of the length of examination in the PTO. After the term was re-set as twenty years from the earliest priority date, 35 U.S.C. § 154(a)(2), it was recognized that unduly prolonged examination reduces the effective life of the issued patent. Thus legislation was enacted to provide that when the examination consumes more than three years, or the PTO fails to meet certain schedules, or special proceedings occur such as interferences or appeals, the expiration of the patent is extended in compensatory amount. See American Inventors Protection Act of 1999, Pub. L. No. 106–113, § 1000(a)(9) (codified at 35 U.S.C. § 154).

The statute describes the three general sources of delay. First, § 154(b)(1)(A) ("A Delay") implements the "[g]uarantee of prompt patent and trademark office responses," whereby "the term of the patent shall be extended 1 day for each day" that the PTO does not meet certain deadlines in processing the application.

Mayo Clinic Found. v. Iancu, 309 F. Supp. 3d 425
(E.D. Va. 2018) ("Dist. Ct. Op.").

Second, § 154(b)(1)(B) ("B Delay") provides a "[g]uarantee of no more than 3-year application pendency," and entitles the applicant to PTA for each day the application is pending beyond three years.

Third, § 154(b)(1)(C) ("C Delay") provides PTA for each day the application is pending in an interference proceeding,<sup>2</sup> a secrecy order, or a successful appeal to the Patent Trial and Appeal Board or a federal court.

At issue is the post-interference examination of the '063 patent application, after the decision awarding priority to Mayo and ending with mailing of the notice of allowance. The PTO held that this period is excluded from adjustment, based on PTO interpretation of a statutory exception to B Delay, shown in boldface:

§ 154(b)(1)(B). Guarantee of no more than 3-year application pendency.—Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application under section 111(a) in the United States or, in the case of an international application, the date of commencement of the national stage under section 371 in the international application, not including—

(i) any time consumed by continued examination of the application requested by the applicant under section 132(b)....

<sup>&</sup>lt;sup>2</sup> Interferences were abolished on March 26, 2013, but the interference involving Mayo's U.S. Patent No. 8,981,063 ("the '063 patent") was declared before this abolition. See Manual of Patent Examining Procedure ("MPEP") § 2301.04.

(emphasis added).

The PTO cites 37 C.F.R. § 1.703(b)(1) as limiting the term adjustment when the applicant requested continued examination:

37 C.F.R. § 1.703(b)(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 . . . .

In turn, 37 C.F.R. § 1.114 states that a "[r]equest for continued examination" may occur "[i]f prosecution in an application is closed." *Id.* Mayo argues that these regulations do not negate term adjustment for the period of examination after an interference is resolved. Mayo correctly states that Section 1.703(b)(1) was adopted to establish that the period of examination ends with mailing of the notice of allowance; it has no relation to post-interference examination.

### The Examination Proceedings

Mayo's patent application was initially rejected on grounds that included anticipation by a recently issued patent. The examiner duly advised that some of the claims in U.S. Patent Application No. 12/421,310 ("the '310 application") were allowable but for the conflicting patent. Mayo then amended some claims, and moved other claims into a separate application. The examiner then declared the interference, which proceeded for over two years.

Priority was awarded to Mayo. The application was then returned to the examiner, who conducted a prior art search and rejected the claims on the ground of "double patenting." The rejection was based on Mayo's separate patent containing the claims that had been removed from Mayo's application. Mayo explained this background, and the examiner withdrew the double patenting rejection. On

November 3, 2014, a notice of allowance was mailed, and the application issued as the '063 patent on March 17, 2015.

With issuance of the patent, the PTO calculated the term adjustment. The PTO held that the period starting with Mayo's request for declaration of interference, until mailing of the notice of allowance, was "time consumed by continued examination of the application requested by the applicant" and that § 154(b)(1)(B)(ii) excludes this period from B Delay term adjustment. On this reasoning, the PTO held that the period of examination after termination of the interference is not eligible for term adjustment. The district court, and now my colleagues, agree.

My colleagues cite *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014) as authority. However, Novartis was not concerned with this aspect. *Novartis* held that "examination' 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. *Novartis* did not relate to ongoing or continuing prosecution or any activity before mailing of the notice of allowance. *Novartis* was concerned only with the "time from allowance to issuance." *Id.* 

Mayo argued in the district court 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." Dist. Ct. Op. at 435. Mayo does not dispute the PTO's authority to reopen examination, but argues that PTA applies to that period of examination. Mayo points out that the examiner's only rejection after the interference decision pertained to a new rejection for double patenting; the examiner wrote that "[i]n view of the [interference] [j]udgment," the claims "directed to an antibody that binds specifically to <u>human</u> B7-H1 polypeptide are deemed to be free of grounds of rejection, except for the Double Patenting rejection set forth

herein." J.A. 790 (Office Action, dated June 30, 2014, Paper No. 12-1, at 2) (underline in original).

PTO Regulations Authorize post-interference examination:

37 C.F.R. § 41.127(c). The [interference] judgment may include a recommendation for further action by the examiner or by the Director. If the Board recommends rejection of a claim of an involved application, the examiner must enter and maintain the recommended rejection unless an amendment or showing of facts not previously of record is filed which, in the opinion of the examiner, overcomes the recommended rejection.

Here the interference judgment contained no recommendation for further action. MPEP § 2308 guides further examination when there is no recommendation in the interference judgment:

MPEP § 2308. If there is no recommendation in the judgment, the examiner should update the search and may, but is not required to, reopen prosecution for any claim not disposed of in the judgment.

An interference judgment simply resolves any question of priority between the two parties to the interference. The judgment does not prevent the examiner from making a rejection in further examination in the same application or a different application.

Such "further examination" is at the initiative of the examiner. Here the double patenting rejection was based on Mayo's continuation patent as separated from the original application; Mayo provided this history, and the examiner withdrew the rejection and issued the notice of allowance. It is not disputed that Mayo did not request further examination.

My colleagues hold that Mayo's initial request that an interference be declared, applied to eliminate adjustment for the period of examination after termination of the interference. That is not an appropriate view of the statute or of patent examination procedure. The panel majority errs in holding that post-interference examination is part of the "continued examination of the application requested by the applicant" that led to the interference proceeding. Maj. Op. at 12–13.

# The Result is Contrary to Statute, Regulation, and Policy

The House Committee Report explains the legislative purpose to adjust for "administrative delays caused by the PTO that were beyond the control of the applicant." H.R. Rep. No. 106-287, pt. 1, at 49 (1999). The Report states the intent to "compensate applicants fully for PTO-caused administrative delays," and "guarantee[s] diligent applicants at least a 17-year term by extending the term of any patent not granted within three years of filing." *Id.* at 49–50.

Congress intended that "[o]nly those who purposely manipulate the system to delay the issuance of their patents will be penalized." *Id.* at 50. It is not suggested that Mayo "manipulate[d] the system to delay issuance." *Id.* 

The PTO argues that this court should defer to the PTO's calculation of term adjustment. However, "it is elementary that 'no deference is due to agency interpretations at odds with the plain language of the statute itself." Wyeth v. Kappos, 591 F.3d 1364, 1372 (Fed. Cir. 2010) (quoting Smith v. City of Jackson, 544 U.S. 228, 267 (2005)). 37 C.F.R. § 1.703(b)(1) requires that the delay in examination be requested by the applicant. "Where a statute's language carries a plain meaning, the duty of an administrative agency is to follow its commands as written, not to supplant those commands with others it may prefer." SAS Inst., Inc. v. Iancu, 138 S. Ct. 1348, 1355 (2018).

Here the post-interference examination was PTO activity, part of the examination procedure before issuance of the notice of allowance. It plainly is within the purpose of the term adjustment statute. Indeed, were this post-interference activity deemed part of interference delay, as my colleagues' ruling requires, this examination would be included in C Delay. Whether as B Delay or C Delay, the adjusted term would include this period of examination.

From the panel majority's contrary holding, I respectfully dissent.