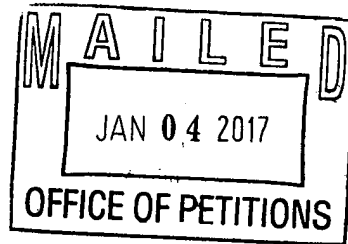




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DECHERT LLP
1095 AVENUE OF THE AMERICAS
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In re Patent No. 8,889,135 :
Fischkoff, et al. : REDETERMINATION OF
Application No. 10/163,657 : PATENT TERM ADJUSTMENT
Issue Date: November 18, 2014 : and
Filed: June 5, 2002 : NOTICE OF INTENT TO ISSUE
Attorney Docket No. 391817-093US : CERTIFICATE OF CORRECTION

This is a redetermination of the patent term adjustment, in response to the “APPLICATION FOR PATENT TERM ADJUSTMENT”, filed January 20, 2015, and the “SUPPLEMENTAL AND SUPERSEDING APPLICATION FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT”, filed June 16, 2015, requesting that the patent term adjustment indicated on the above-identified patent be corrected from nine hundred forty four (944) days to two thousand one hundred seven (2107) days.

This redetermination of patent term adjustment is not the Director's decision on the applicant's request for reconsideration for purposes of seeking judicial review under 35 U.S.C. §154(b)(4).

On November 18, 2014, the above-identified application matured into U.S. Patent No. 8,889,135. The patent issued with a PTA of 944 days. The PTA of 944 days was determined based on 1353 days of “A” delay, plus 1176 days of “B” delay, reduced by 109 days of overlap between “A” and “B” delay, and by 1476 days of Applicant delay. The 1476 days of Applicant delay was based on various instances of Applicant delay of 249, 90, 57, 78, 89, 28, 92, 49, 239, 92, 132, 150, 31, and 100 days. The Office’s calculation of “A” delay is not in dispute, nor are the Applicant delay instances of 90, 57, 28, and 49 days.

The present petition

Patentees aver that the Office improperly calculated “B” delay by one day. According to Patentees, “B” delay should be 1177 days, not 1176 days, due to the filing of an RCE. In addition, Patentees assert that the Office improperly assessed Applicant delay for the instances of Applicant delay of 249, 78, 89, 92, 239, 92, 132, 150, 31, and 100 days.

OPINION – “B” Delay

Patentees’ arguments have been carefully considered. Upon review, the USPTO finds that patentee is entitled to 1176 days of “B” delay. The Office has revisited the amount of “B” delay under 35 U.S.C. § 154(b)(1)(B) and the amount of overlapping days under 35 U.S.C. § 154(b)(2)(A) pursuant to the Federal Circuit’s decision in *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014).

As for the amount of “B” delay, the Federal Circuit reviewed the statutory interpretation of 35 U.S.C. § 154(b)(1)(B)(i) and issued a decision regarding the effects of a Request for Continued Examination (“RCE”) on “B” delay in *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014). In *Novartis*, the Federal Circuit agreed with the Office that “no [“B” delay] adjustment time is available for any time in continued examination, even if the continued examination was initiated more than three calendar years after the application’s filing.” *Novartis*, 740 F.3d at 601. However, the *Novartis* court found that if the Office issues a notice of allowance after an RCE is filed, the period after the notice of allowance should not be excluded from the “B” delay period but should be counted as “B” delay. *Id.* at 602. The Federal Circuit issued its mandate in the *Novartis* appeal on March 10, 2014.

Pursuant to the *Novartis* decision, the USPTO has determined that the patentee is entitled to 1176 days of “B” delay. In this case, the application was filed on June 5, 2002, and the patent issued on November 18, 2014; thus, the application was pending for 4550 days. During this time, Applicants filed an RCE on April 14, 2008, and the Office mailed a Notice of Allowance on July 8, 2014. Under 35 U.S.C. § 154(b)(1)(B)(i), there was one time period consumed by continued examination (“RCE period”) – from April 14, 2008 until the Notice of Allowance was issued on July 8, 2014 – *i.e.* 2277 days. Subtracting the RCE period from the total number of days the application was pending results in $4550 - 2277 = 2273$ days. Thus, for purposes of “B” delay, the application was pending for $2273 - 1097$ [*i.e.*, the 3 year delay period] = 1176 days beyond the 3-year anniversary of the filing date. Counting the period of time excluded from the “B delay” for the filing of a request for continued examination under 35 U.S.C. 132(b), from the date on which the request for continued examination is filed to the date the Office mails a Notice of Allowance, is proper.

Patentee is directed to *Changes to the Patent Term Adjustment in view of the Federal Circuit Decision in Novartis v. Lee*, 80 Fed. Reg. 1346, 1347-1348 (January 9, 2015)¹ which has been reproduced below:

The Federal Circuit confirmed in *Novartis* that any time consumed by continued examination under 35 U.S.C. 132(b) is subtracted in determining the extent to which the period defined in 35 U.S.C. 154(b)(1)(B) exceeds three years, regardless of when the continued examination under 35 U.S.C. 132(b) was initiated. *See* 740 F.3d at 601 (“[t]he better reading of the language is that the patent term adjustment time should be calculated

¹ The notice is viewable here: <http://www.gpo.gov/fdsys/pkg/FR-2015-01-09/pdf/2015-00061.pdf>.

by determining the length of the time between application and patent issuance, then subtracting any continued examination time (emphasis added) (and other time identified in (i), (ii), and (iii) of [35 U.S.C. 154](b)(1)(B)), and determining the extent to which the result exceeds three years”). The Federal Circuit, however, decided that the time consumed by continued examination under 35 U.S.C. 132(b) does not include the time after a notice of allowance unless the Office actually resumes examination of the application after allowance. *See* 740 F.3d at 602 (“[t]he common-sense understanding of ‘time consumed by continued examination,’ 35 U.S.C. 154(b)(1)(B)(i), is time up to allowance, but not later, unless examination on the merits resumes”). Therefore, the Office is revising the rules of practice to provide that the time consumed by continued examination under 35 U.S.C. 132(b) does not include the time after the mailing date of a notice of allowance, unless the applicant files a request for continued examination after such allowance.

OPINION – APPLICANT DELAY

Next the decision turns to the various instances of Applicant delay that are in dispute.

First, and throughout the instant application for patent term adjustment, Patentees argue that Applicant delay can only accrue on the same calendar days that “B” delay is also accruing. In other words, according to Patentees, no Applicant delay for filing a reply beyond 3 months can occur within the first 3 years of the application filing date, or at any time after an RCE is filed (but prior to the mailing of a Notice of Allowance). Patentees’s argument has been considered, but is not persuasive.

Adjustment of the patent term is provided in 35 U.S.C. 154(b). Specifically, “A” delay is set forth in 35 U.S.C. 154(b)(1)(A), “B” delay is set forth in 35 U.S.C. 154(b)(1)(B), and Applicant delay is set forth in 35 U.S.C. 154(b)(2)(C). 35 U.S.C. 154(b)(2)(C) states:

- (i) The period of adjustment 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 to 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 for 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.

Patentees argue that 35 U.S.C. 154(b)(2)(C)(ii) above limits Applicant delay for delay beyond 3 months exclusively to adjustments made during the “B” delay period. However, this ignores 35 U.S.C. 154(b)(2)(C)(i), which states that the period of adjustment set forth in paragraph (1)² shall be reduced by the time period in which applicant failed to engage in reasonable efforts to conclude prosecution of the application. Reasonable efforts to conclude prosecution of the application is set forth in 37 CFR 1.704.

249 days of assessed Applicant delay:

With respect to the 249 days of Applicant delay assessed under 37 CFR 1.704(b), for filing a reply to a July 3, 2002 Notice to File Missing Parts on June 9, 2003. A review of the file reveals that a reply was filed on December 9, 2002.³ The reply that was filed on June 9, 2003 was actually filed in response to an April 8, 2003 Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures. As the June 9, 2003 was timely filed within three months of the Notice, no Applicant delay should have been assessed. Rather, Applicants should have been assessed delay under 37 CFR 1.704(b) of 67 days for the December 9, 2002 reply.

78 days of assessed Applicant delay:

Applicants filed an RCE on April 14, 2008, and subsequently filed a supplemental amendment on July 1, 2008. As a result, Applicants were assessed Applicant delay of 78 days under 37 CFR 1.704(c)(8). Patentees argue that they should not have been assessed any delay for this filing, because 37 CFR 1.704(c)(8) does not apply to papers filed after an RCE. Patentees’ argument has been considered, but is not persuasive.

The Office notes that the Federal Circuit determined that submission of an IDS after the filing of a response to an election or restriction requirement is a reduction under 37 CFR 1.704(c)(8). See *Gilead Sciences, Inc. v. Lee* cv 14-1159 (Fed. Cir. 2015). In *Gilead*, the court noted that conduct of filing an IDS after the submission of a response to an election or restriction requirement interferes with the PTO’s ability to conclude the application process because of significant time constraints faced by the PTO. See *Gilead* at page 15. Because the “A” Delay provision of the statute penalizes the PTO if the examiner fails to respond within four months of the applicant’s response to the restriction requirement, any relevant information received after an initial response to a restriction requirement “interferes with the [PTO’s] ability to process an application. *Id.* A supplemental IDS may force an examiner to go back and review the application again, while still trying to meet his or her timeliness obligations under § 154. *Id.*

The same analysis applies to submission of an IDS document after the filing of an RCE. The Office must respond to the submission of an RCE within four months of the filing of the RCE or

² 35 U.S.C. 154(b)(1) covers both “A” and “B” delay.

³ Patentees state that the reply was filed on December 3, 2002, because it included a Certificate of Mailing dated December 3, 2002. However, under 37 CFR 1.703(f), the date indicated on any certificate of mailing or transmission is not taken into account in the PTA calculation.

provide additional “A” delay. Any IDS submission by patentee after the filing of a RCE “interferes” with the [PTO’s ability] to process an application because the examiner may be forced to go back and review the application again. Accordingly, the Office maintains the reduction of applicant delay for the IDS submission after the filing of an RCE.

89 days of assessed Applicant delay:

On March 25, 2009, Applicants filed a response to a non-final Office action mailed September 25, 2008, and were assessed Applicant delay of 89 days under 37 CFR 1.704(b). Patentees argue that they should have only been assessed Applicant delay of 86 days pursuant to 37 CFR 1.7(a), because the due date fell on a federal holiday, the following day also fell on a federal holiday, and the following two days fell on Saturday and Sunday. Patentees’ argument has been considered, and found to be persuasive. Accordingly, only 86 days of Applicant delay should have been assessed for this filing.

92 days of assessed Applicant delay:

Applicants filed a reply to a December 1, 2009 non-final Office action on June 1, 2010, and were assessed Applicant delay of 92 days under 37 CFR 1.704(b). Patentees argue that no Applicant delay should have been assessed, because Applicant delay for a reply filed after 3 months can only be assessed when “B” delay is accruing. For the reasons previously set forth above, this argument is not persuasive. The assessment of 92 days of Applicant delay was proper.

239 days of assessed Applicant delay:

On June 24, 2011, Applicants filed an IDS subsequent to a reply filed October 28, 2010, and were assessed Applicant delay of 239 days pursuant to 37 CFR 1.704(c)(8). Patentees argue that the Office failed to apply 37 CFR 1.704(d). However, the assessment of Applicant delay was proper because the IDS was not accompanied by a Rule 704(d) statement. As set forth in 37 CFR 1.704(d), the “paper containing only an information disclosure statement...will not be considered a failure to engage in reasonable efforts to conclude prosecution...if the paper [is] accompanied by a statement” set forth in 37 CFR 1.704(d)(i) or 37 CFR 1.704(d)(ii). Patentees’ argument that the statement needs to accompany the IDS is arbitrary and capricious is not persuasive. The reduction for an IDS after the filing of an RCE has been addressed in the Courts and the Court has affirmed the Office position that an IDS after the filing of an RCE but prior to an additional Office action is deemed an applicant delay under 37 CFR 1.704(c)(8). See *Supernus v. Lee* 1:16-cv-342 (E.D. Va 2016).

92 days of assessed Applicant delay:

Applicants filed an RCE in response to an August 3, 2011 final Office action on February 3, 2012, and were assessed Applicant delay of 92 days under 37 CFR 1.704(b). Patentees argue that no Applicant delay should have been assessed, because Applicant delay for a reply filed after 3 months can only be assessed when “B” delay is accruing. For the reasons previously set

forth above, this argument is not persuasive. The assessment of 92 days of Applicant delay was proper.

239 days of assessed Applicant delay:

On June 14, 2012 Applicants filed an IDS subsequent to a reply filed October 28, 2010, and were assessed Applicant delay of 132 days pursuant to 37 CFR 1.704(c)(8). The assessment of Applicant delay was proper because the IDS was not accompanied by a Rule 704(d) statement. As set forth in 37 CFR 1.704(d), the “paper containing only an information disclosure statement...will not be considered a failure to engage in reasonable efforts to conclude prosecution...if the paper [is] accompanied by a statement” set forth in 37 CFR 1.704(d)(i) or 37 CFR 1.704(d)(ii).

150 days of assessed Applicant delay:

Patentees argue that they were improperly assessed Applicant delay of 150 days under 37 CFR 1.704 for filing an RCE on February 7, 2014, after they had filed a Notice of Appeal on December 9, 2013, which itself was filed in response to an Office action mailed June 10, 2013. Patentees assert that they should have only been assessed 90 days of Applicant delay. Patentees' argument has been considered, and found to be persuasive. Because Applicants filed the RCE within three months of the Notice of Appeal, no Applicant delay should have been assessed for the RCE, pursuant to 37 CFR 1.704(c)(11). However, 90 days of Applicant delay should have been assessed for late filing of the Notice of Appeal, pursuant to 37 CFR 1.704(b).

31 and 100 days of assessed Applicant delay:

On July 18, 2014, Applicants filed an Amendment and drawings, after the Office had mailed a Notice of Allowance on July 8, 2014. The Office did not mail a paper in response to the July 18, 2014 filing until the Office mailed an issue notification on October 29, 2014 (the Office paper mailed on August 7, 2014 did not indicate that it was in response to the July 18, 2014 Amendment, and as such, the time period for measuring delay under 37 CFR 1.704(c)(10) should not have ended on that date). Accordingly, 104 days of Applicant delay should have been assessed pursuant to 37 CFR 1.704(c)(10), not 31 days as reflected in PAIR.

100 days of Applicant delay were also assessed for the filing of drawings on August 11, 2014, after the Notice of Allowance was mailed. However, as these 100 days overlap with the 104 days above, no Applicant delay is warranted for the August 11, 2014 drawings.

In view thereof, the correct number of days of patent term adjustment is **one thousand two hundred sixteen (1216)** days (1353 days of “A” delay plus 1176 days of “B” delay, reduced by 109 days of overlap and 1204 (67+90+57+78+86+28+92+49+239+92+132+90+104) days of Applicant delay.

The application is being forwarded to the Certificate of Corrections Branch for issuance of a certificate of correction. The Office will issue a certificate of correction indicating that the term of the above-identified patent is extended or adjusted by **one thousand two hundred sixteen (1216) days**.

Telephone inquiries specific to this matter should be directed to the undersigned at (571) 272-3207.

/Cliff Congo/

Cliff Congo
Attorney Advisor
Office of Petitions

Enc: draft Certificate of Correction (1 page)

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UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT : 8,889,135
DATED : November 18, 2014
INVENTOR(S) : Fischkoff et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the cover page,

[*] Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 USC 154(b) by 944 days.

Delete the phrase “by 944 days” and insert – by 1216 days--