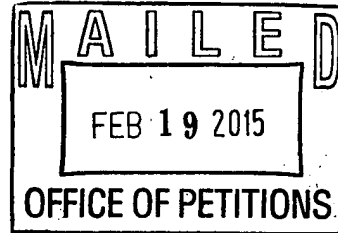




UNITED STATES PATENT AND TRADEMARK OFFICE

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE CA 92614



In re Patent No. 8,277,500 :
Schmid et al. : DECISION ON REQUEST
Issue Date: 10/02/2012 : FOR RECONSIDERATION OF
Application No. 11/455,986 : PATENT TERM ADJUSTMENT
Filed: 06/20/2006 :
Attorney Docket No: REVAMD.027CP1 :

This is a decision on the “REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT FOR PATENT UNDER 37 C.F.R. § 1.705(b),” filed on August 20, 2014. The request is treated as one in which patentees request that the patent term adjustment indicated on the face of the Letters of Patent be corrected from one thousand three hundred eighty (1380) days to one thousand six hundred fifty-four (1654) days. This is also a decision on the concurrently-filed petition under 37 CFR 1.182 requesting that the redetermination of the patent term adjustment be stayed until the completion of *Gilead Sciences, Inc. v. Lee*, Case No. 2014-1159 (Fed. Cir. 2014).

The request for reconsideration is granted to the extent that the determination has been reconsidered; however, the request for reconsideration of patent term adjustment is **DENIED** with respect to making any change in the patent adjustment determination under 35 U.S.C. 154(b) of 1380 days. This decision may be viewed as a final agency action within the meaning of 5 U.S.C. 704 and for purposes of seeking judicial review. See MPEP 1002.02.

The petition under 37 CFR 1.182 is **DISMISSED**.

BACKGROUND

On October 2, 2012, the above-identified application matured into U.S. Patent No. 8,277,500, with a revised patent term adjustment of 1580 days. On November 29, 2012, an application for patent term adjustment was filed. On May 20, 2014, a decision on Redetermination of Patent Term Adjustment was mailed, stating that the Office had re-determined the PTA to be 1380

days. This redetermination included entry of a period of reduction of 251 days pursuant to 37 CFR 1.704(c)(8) for the filing of a supplemental reply or other paper on 251 days after the day after the date a reply was filed and entry of a period of reduction of 23 days pursuant to 37 CFR 1.704(c)(8) for the filing of a supplemental reply or other paper 23 days after the day after the date a reply was filed.

On August 20, 2014, the subject request for reconsideration was filed. Patentee asserts that the reductions of 251 days and 23 days should be withdrawn. Specifically, patentee states that the 251-day delay involved a series of supplemental IDSs filed after an RCE had been filed. Patentee asserts that because nearly 7 months passed between the filing of the supplemental IDSs and the review of the prior art by the Examiner, the filing of the IDSs should not be considered undue delay by the applicant, and that the reduction of 251 days is not warranted.

Likewise, patentee asserts that the 23 day reduction for the filing of an IDS after a non-final Office action should not be considered undue delay because the supplemental IDS filed 23 days after the reply was filed contained only a single reference, and the Examiner reviewed the single reference on that same day, along with the references filed with the reply to the Office action.

STATUTE AND REGULATION

35 U.S.C. 154(b)(2)(C) as amended by the Leahy-Smith America Invents Act (AIA)¹ provides:

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.

¹ Public Law 112-29, 125 Stat. 284 (Sept. 16, 2011).

37 CFR 1.182 states:

All situations not specifically provided for in the regulations of this part will be decided in accordance with the merits of each situation by or under the authority of the Director, subject to such other requirements as may be imposed, and such decision will be communicated to the interested parties in writing. Any petition seeking a decision under this section must be accompanied by the petition fee set forth in § 1.17(f).

37 CFR 1.704(c) states, in pertinent part:

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:

(8) Submission of a supplemental reply or other paper, other than a supplemental reply or other paper expressly requested by the examiner, after a reply has been filed, 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 the initial reply was filed and ending on the date that the supplemental reply or other such paper was filed;

37 CFR 1.704(d) states:

(1) A paper containing only an information disclosure statement in compliance with §§ 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under paragraphs (c)(6), (c)(8), (c)(9), or (c)(10) of this section if it is accompanied by a statement that each item of information contained in the information disclosure statement:

(i) Was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement; or

(ii) Is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

(2) The thirty-day period set forth in paragraph (d)(1) of this section is not extendable.

OPINION

Patentee's argument has been considered, but is not persuasive. It is undisputed that on December 14, 2010, a reply (an RCE and submission) were filed, and that on August 22, 2011, 251 days after the day after the date the reply was filed, a supplemental reply or other paper (an IDS) was filed. The IDS was neither expressly requested by the examiner nor accompanied by a statement under 37 CFR 1.704(d). As such, the filing of the IDS constitutes a failure to engage in reasonable efforts to conclude processing or examination. Whether or not applicant believes the filing of the IDSs constituted "undue delay" is not relevant.

Furthermore, it is undisputed that on July 12, 2012, a supplemental reply or other paper (an IDS) was filed, 23 days after the day after the date a reply was filed, and that IDS was also neither expressly requested by the examiner nor accompanied by a statement under 37 CFR 1.704(d). In this regard, the number of references contained in the IDS is not at issue. 37 CFR 1.704(c)(8) states that an IDS filed as a supplemental reply will be considered a failure to engage in reasonable efforts to conclude processing or examination if the IDS is not accompanied by a statement under 37 CFR 1.704(d).

With regard to the petition under 37 CFR 1.182, the petition is dismissed. Under the circumstances of this case, patentee may file a renewed petition (no fee required) within two months of the issuance of an opinion by the Federal Circuit on the matter referenced in the petition under 37 CFR 1.182. No extensions of the two (2)-month time period are permitted.

Overall PTA Calculation

Formula:

"A" delay + "B" delay + "C" delay - Overlap - applicant delay = X

USPTO's Calculation:

$1324 + 615 + 0 - 283 - 276 = 1380$

Patentee's Calculation

$1324 + 615 + 0 - 283 - 2 = 1654$

In view of the redetermination, the petition is granted to the extent that the PTA calculation has been revised, but is denied with respect to any change in redetermination of the PTA.

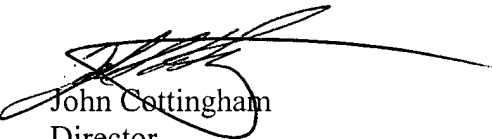
CONCLUSION

The request for reconsideration of the revised patent term adjustment is denied.

The petition under 37 CFR 1.182 is dismissed.

The Office acknowledges the submission of the \$200.00 fee set forth in 37 CFR 1.18(e) and the \$400.00 fee set forth in 37 CFR 1.17(f).

Telephone inquiries specific to this matter should be directed to Attorney Advisor Douglas I. Wood at 571-272-3211.



John Cottingham
Director
Office of Petitions

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 8,277,500 B2
APPLICATION NO. : 11/455986
DATED : October 2, 2012
INVENTOR(S) : Schmid et al.

Page 1 of 1

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

On the Title Page:

The first or sole Notice should read --

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b)
by 1380 days.

Signed and Sealed this
Twenty-eighth Day of October, 2014



Michelle K. Lee
Deputy Director of the United States Patent and Trademark Office

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patentees	:	Schmid <i>et al.</i>
Patent No.	:	8,277,500
App. No	:	11/455,986
Filed	:	June 20, 2006
Title	:	SLIDE-AND-LOCK STENT
Examiner	:	Kathleen C. Sonnett
Art Unit	:	3731

PETITION UNDER 37 C.F.R. § 1.182

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In accordance with 37 C.F.R. § 1.182, Applicant requests that the Petition Decision mailed on May 20, 2014 regarding the redetermination of the patent term adjustment be stayed until the completion of *Gilead Sciences, Inc. v. Lee*, Case No. 2014-1159 (Fed. Cir. 2014). Applicant believes a request for such a stay is not specifically provided for elsewhere in the regulations.

Remarks begin on page 2.

Application No.: 11/455,986
Filing Date: June 20, 2006

REMARKS

Statement of Facts

On October 2, 2012, the above-identified application issued as U.S. Patent No. 8,277,500. The patent issued with 1580 days of Patent Term Adjustment (“PTA”).

On November 29, 2012, less than two months from the issuance of the ’500 Patent, Applicant filed a Request for Reconsideration of Patent Term Adjustment under 37 C.F.R. §1.705(d) in light of the decision made in *Exelixis, Inc. v. Kappos*, Case No. 1:12cv96 (E.D. Va. Nov. 1, 2012). Applicant requested a recalculation to increase the PTA from 1580 days to 1868 days or, in the alternative, to 1655 days.

On May 20, 2014, Applicant received a response from the United States Patent and Trademark Office in the form of a Petition Decision (“the Decision”), indicating that the request was granted to the extent indicated in the Decision based on *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014). The Decision indicates that 251 days should be removed from the original PTA due to “applicant delay.” Namely, the filing of information disclosure statements (IDS) after the filing of a Request for Continued Examination, but prior to the receipt of the Notice of Allowance, and without the statement set forth in §1.704(d). Thus, the ’500 Patent’s original PTA was **reduced by 200 days**, from a total of 1580 to 1380 days.

Gilead’s Pending Appeal Regarding PTA

The issue of whether an IDS filed prior to the receipt of a first Office Action on the merits constitutes applicant delay is the subject of current litigation before the Federal Circuit Court of Appeals. See *Gilead Sciences, Inc. v. Lee*, Case No. 2014-1159 (Fed. Cir. 2014). In *Gilead*, Gilead filed a supplemental IDS prior to receiving a first Office Action on the merits and was penalized PTA days due to alleged Applicant delay. Gilead’s Opening Br., pp. 6-7 (copy attached as Appendix A). Gilead disagreed that such a situation should incur a PTA penalty and brought suit in the U.S. District Court for the Eastern District of Virginia seeking a judgment that the USPTO improperly calculated the patent term adjustment of Gilead’s patent. The District Court found that the USPTO interpretation of PTA was permissible, and therefore ruled for the USPTO on Summary Judgment. Gilead appealed to the Federal Circuit.

Application No.: 11/455,986
Filing Date: June 20, 2006

At the Federal Circuit, Gilead has argued the filing of the supplemental IDS did not in fact cause undue delay to the Examiner, and thus PTA should not have been reduced. *See id.* at pp. 16 and 23. For example, Gilead argued that because the Examiner had not reviewed the case until after filing the supplemental IDS, there was no undue delay by Gilead. *Id.* It “appears that the examiner started work on Gilead’s application only after the [filing of the Supplemental IDS], and never had to restart or duplicate efforts. The PTO therefore erred in reducing Gilead’s term adjustment at all because there was no evidence of actual delay.” *Id.* at p. 23-24.

Additionally, Gilead argued that the reduction of PTA is against Congressional intent. For example, Gilead argued that Congress only intended to punish applicants who engage in “intentional or unjustifiable delay,” meaning that “only the most egregious and obvious delay tactics will go unrewarded.” *Id.* at p. 13.

Here, Applicant believes that aspects of the prosecution of the ’500 patent are analogous to the question at issue in *Gilead*. In the ’500 Patent, like in *Gilead*, Applicant filed a supplemental IDS prior to receiving a first Office Action on the merits and was penalized PTA days due to alleged Applicant delay. Specifically, Applicant filed a Request for Continued Examination (RCE) on December 14, 2010 and the last of a series of IDSs on August 22, 2011, which was well before the Examiner issued an Office Action on April 19, 2012. Moreover, the PAIR file history of this case (an excerpt of the Image File History attached as Appendix B, and a copy of the Examiner’s search strategy and results dated April 19, 2012, which is circled in Appendix B, attached as Appendix C) indicates that the Examiner had done no prior art searching related to this case from the December 14, 2010 filing of the RCE up until April 12, 2012—about **7 months after the filing of the last supplemental IDS**. Accordingly, like in *Gilead*, Applicant’s submission of the August 22, 2011 IDS does not appear to have actually caused any undue delay to the Examiner.

Accordingly, the prosecution history of the ’500 patent is similar to the situation in *Gilead*. Both relate to whether an IDS filed before a first Office Action on the merits, but without the statement set forth in §1.704(d), can be the basis for reducing the Applicant’s PTA. Indeed, in the present application, the time period between the filing of the Supplemental IDS and the Office Action was significantly greater than that in *Gilead*. This suggests that there would be even less of

Application No.: 11/455,986
Filing Date: June 20, 2006

a burden on the Examiner than any burden that existed in *Gilead*, and even less of a reason to penalize the Applicant by reducing the PTA.

Applicant Requests the Office Stay a Decision on the Concurrently Filed Request for Reconsideration

Because the outcome of *Gilead* could significantly affect the PTA for the '500 Patent, Applicant respectfully submits that the PTA for the '500 Patent should be determined only after the Federal Circuit has issued a decision in *Gilead*. Thus, *Applicant respectfully requests a stay of the Office's consideration of Applicant's concurrently-filed Request for Reconsideration under 35 C.F.R. §1.705(b) (regarding redetermining the PTA for the '500 Patent) pending the outcome of the Gilead case.* This will allow the Office to consider, in accordance with what the Federal Circuit decides in *Gilead*, the PTA redetermination for the '500 Patent.

This Petition and the concurrently filed Request for Reconsideration are being filed by the final deadline set by the Decision, i.e., December 20, 2014.

CONCLUSION

In view of at least the foregoing, Applicant requests that the PTA redetermination of the '500 Patent be stayed until a decision is issued in *Gilead Sciences, Inc. v. Lee*, Case No. 2014-1159 (Fed. Cir. 2014), as that decision could significantly affect the amount of patent term adjustment of the '500 Patent.

The petition fee set forth in § 1.17(f) is submitted herewith. However, the Office is authorized to deduct any deficiency, or credit any overpayment, to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 20, 2014_____

By: /Daniel J. Fischer/
Dan Fischer
Registration No. 68,043
Attorney of Record
Customer No. 20995
(949) 760-0404

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patentees	: Schmid <i>et al.</i>
Patent No.	: 8,277,500
App. No	: 11/455,986
Filed	: June 20, 2006
Title	: SLIDE-AND-LOCK STENT
Examiner	: Kathleen C. Sonnett
Art Unit	: 3731

**REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37
C.F.R. §1.705(b)**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

With regard to the above-referenced patent (the “’500 Patent”), Patentees hereby submit this request for reconsideration of Patent Term Adjustment (PTA) to correct the Office’s PTA calculation of 1380 days made in the Petition Decision mailed on May 20, 2014.

A petition under 37 C.F.R. §1.182 to stay the redetermination of patent term adjustment is being filed concurrently, which includes a discussion of the case that would affect the PTA of the ’500 Patent, *Gilead Sciences, Inc. v. Lee*, Case No. 2014-1159 (Fed. Cir. 2014).

Application No.: 11/455,986
Filing Date: June 20, 2006

REMARKS

On October 2, 2012, the above-identified application issued as U.S. Patent No. 8,277,500. The patent issued with 1580 days of Patent Term Adjustment (“PTA”).

On November 29, 2012, less than two months from the issuance of the ’500 Patent, Applicant filed a Request for Reconsideration of Patent Term Adjustment under 37 C.F.R. §1.705(d) in light of the decision made in *Exelixis, Inc. v. Kappos*, Case No. 1:12cv96 (E.D. Va. Nov. 1, 2012). Applicant requested a recalculation to increase the PTA from 1580 days to 1868 days, or in the alternative, to 1655 days in light of the ruling.

On May 20, 2014, Applicant received a response from the United States Patent and Trademark Office in the form of a Petition Decision (“the Decision”), indicating that the request was granted to the extent indicated in the Decision based on *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014). The Decision indicates that 251 days should be removed from the original PTA due to “applicant delay.” Namely, the filing of information disclosure statements after the filing of a Request for Continued Examination, but prior to the receipt of the Notice of Allowance, and without the statement set forth at §1.704(d). The Decision thus reduced Applicant’s original PTA by **200 days**, from a total of 1580 to 1380. This is over half a year in lost PTA.

Reduction of 251 Days

Page 3 of the Decision indicates:

On December 14, 2010, an RCE and submission under 37 CFR 1.114 were filed. On May 11, 2011, a supplemental reply or other paper (an IDS) was filed, 148 days after the day after the date the RCE was filed. The IDS did not contain the statement set forth at § 1.704(d). On July 15, 2011, a supplemental reply or other paper (an IDS) was filed, 213 days after the day after the date the RCE was filed. The IDS did not contain the statement set forth at § 1.704(d). On August 22, 2011, a supplemental reply or other paper (an IDS) was filed, 251 days after the day after the date the RCE was filed. The IDS did not contain the statement set forth at § 1.704(d). Thus, the total period from the day after the date the reply was filed until the date the supplemental reply or other paper was filed was 251 days. Accordingly, a reduction of 251 days for applicant delay pursuant to 37 CFR 1.704(c)(8) is warranted and will be entered.

As discussed above, Applicant filed a series of supplemental IDSs after the filing of a Request for Continued Examination (RCE), but prior to receipt of a first Office Action. The last IDS was filed 251 days after the filing of the RCE. As discussed in detail in the concurrently filed § 1.182 petition, the PAIR file history of this case shows that Examiner had conducted no prior art searching related to this case in the time from the December 14, 2010 filing of the RCE up

Application No.: 11/455,986
Filing Date: June 20, 2006

until April 12, 2012. Thus, nearly 7 months passed between the filing of the supplemental IDSs and the review of the prior art by the Examiner. Therefore, the filing of the IDSs should not be considered undue delay by Applicant, and Applicant should not be penalized by a reduction of PTA of 251 days.

Accordingly, Applicant requests that the Decision's reduction of 251 days of PTA be withdrawn.

Reduction of 23 Days

Page 3 of the Decision indicates:

On June 19, 2012, a reply to a non-final Office action was filed. On July 12, 2012, a supplemental reply or other paper (an IDS) was filed, 23 days after the day after the date the reply was filed. The IDS did not contain the statement set forth at § 1.704(d). Accordingly, a reduction of 23 days for applicant delay pursuant to 37 CFR 1.704(c)(8) is warranted and will be entered.

As described above, Applicant filed an IDS on July 12, 2012, which was 23 days after the date of filing a response to a non-final Office Action. This supplemental IDS included a single reference. On that same day, the Examiner reviewed the single reference cited, along with the references cited in the IDS filed with the Office Action Response. Accordingly, rather than causing examination delay, Applicant expedited the review of the application by allowing the Examiner to consider multiple IDSs during the same day. Accordingly, it appears that Applicant did not cause any undue delay with the filing of the July 12, 2012 IDS. The lack of delay is further underscored by the small size of the IDS (a single reference).

Accordingly, Applicant requests that the Decision's reduction of 23 days of PTA be withdrawn.

CONCLUSION

For at least the foregoing, reconsideration of the PTA of the '500 Patent is requested. Consistent with the above, *Applicant hereby respectfully requests that the Office correct the calculation of PTA to reflect an additional 274 days (251 days + 23 days), for a total PTA of 1654 days.*

As a first alternative, Applicant requests that the Office correct the calculation of PTA to reflect an additional 251 days, for a total PTA of 1631 days. As a second alternative, Applicant

Application No.: 11/455,986
Filing Date: June 20, 2006

requests that the Office correct the calculation of PTA to reflect at least an additional 23 days, for a total PTA of at least 1403 days.

The fee prescribed by 37 C.F.R. § 1.18(e) is enclosed. However, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 20, 2014

By: /Daniel J. Fischer/_____
Dan Fischer
Registration No. 68,043
Attorney of Record
Customer No. 20995
(949) 760-0404

Electronic Patent Application Fee Transmittal

Application Number:	11455986
Filing Date:	20-Jun-2006
Title of Invention:	SLIDE-AND-LOCK STENT
First Named Inventor/Applicant Name:	Eric Schmid
Filer:	Daniel J. Fischer
Attorney Docket Number:	REVAMD.027CP1

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Petition fee- 37 CFR 1.17(f) (Group I)	1462	1	400	400
Application for patent term adjustment	1455	1	200	200

Patent-Appeals-and-Interference:

Post-Allowance-and-Post-Issuance:

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				600

Electronic Acknowledgement Receipt

EFS ID:	19920516
Application Number:	11455986
International Application Number:	
Confirmation Number:	2239
Title of Invention:	SLIDE-AND-LOCK STENT
First Named Inventor/Applicant Name:	Eric Schmid
Customer Number:	20995
Filer:	Daniel J. Fischer/Christina Graul
Filer Authorized By:	Daniel J. Fischer
Attorney Docket Number:	REVAMD.027CP1
Receipt Date:	20-AUG-2014
Filing Date:	20-JUN-2006
Time Stamp:	20:12:06
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$600
RAM confirmation Number	8204
Deposit Account	111410
Authorized User	KNOBBE MARTENS OLSON AND BEAR

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Abstract	Exhibits.pdf	4536231 c2846148b2befc6aea055d5bb7fd0a4dce55c167	no	59
Warnings:					
Information:					
2	Petition for review by the Office of Petitions.	Petition_under_37.pdf	170499 faafa6bc092e03834ab6d7eec4dda2db289546fc	no	4
Warnings:					
Information:					
3	Patent Term Adjustment Petition	PTA_Petition.pdf	145226 5bcbb768050b3cae95154176979fbc730447096c	no	4
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	31895 7d1f1700882b249f7e0232d71d45fc9dd964c49d	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			4883851		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

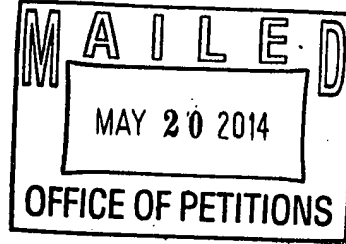
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

KNOBBE MARTENS OLSON & BEAR
LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE CA 92614



In re Patent No. 8,277,500 :
Schmid et al. : ON REQUEST FOR
Issue Date: 10/02/2012 : REDETERMINATION OF
Application No. 11/455,986 : PATENT TERM ADJUSTMENT
Filing or 371(c) Date: 06/20/2006 :
Atty. Docket No.:REVAMD.027CP1 :

This is a redetermination of the patent term adjustment in response to the “REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)”, filed on November 29, 2012, requesting that the patent term adjustment determination for the above-identified patent be changed from 1580 days to 1868 days, or in the alternative, 1655 days.

The request for redetermination of the patent term adjustment is **GRANTED TO THE EXTENT INDICATED HEREIN.**

On October 2, 2012, the above-identified application matured into U.S. Patent No. 8,277,500. The patent issued with a PTA of 1580 days. The present request for redetermination of the patent term adjustment was timely filed within two months of the issue date of the patent.

The present petition

Patentee avers that it is entitled to 1200 additional days of PTA under 35 U.S.C. § 154(b)(1)(B) because when determining whether the “trigger” condition is met, *i.e.*, whether the Office issued a patent within 3 years, one does not count any time consumed by an RCE. Patentee further avers that in *Exelixis, Inc. v. Kappos*, Case No. 1:12cv96, 2012 U.S. Dist. LEXIS 157762 (E.D. Va. November 1, 2012), the court expressly held that “RCE’s have no impact on PTA if filed after the three year deadline [for B-delay] has passed.” Patentee asserts that as the “trigger” condition was satisfied, the “remedy” portion of the statute requires a day patent term extension of each day after the end of that 3 year period, until the patent has issued, the three 3 year period being the period from the time of filing of the application to three years later, excluding time taken consumed by RCE. Alternatively, patentee asserts that the PTA should include an

additional 75 days for B delay from the mailing of the notice of allowance until issuance of the patent.

Discussion

Patentee's arguments have been carefully considered. Upon review, the USPTO finds that patentee is entitled to **1380** days of PTA. 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). Patentee and the Office are in agreement regarding the amount of "A" delay under 35 U.S.C. § 154(b)(1)(A) and 37 CFR 1.702(a). Patentee and the Office are not in agreement regarding the amount of "applicant delay" under 35 U.S.C. § 154(b)(2)(C) and 1.704(b).

As for the amount of "B" delay, the Office and patentee agreed at the time of the filing of the civil action that there was no "B" delay. The Office notes that the interpretation of the "B" delay was based upon rule 37 CFR 1.703(b)(1) which excluded from the amount of "B" delay the period beginning on the date of filing of the continued examination and ending on the date of the issuance of the patent. However, subsequent to the filing of this lawsuit and remand to the Office, 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 the *Novartis* appeal. 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 373 days of "B" delay. In this case, the application was filed on June 20, 2006, and the patent issued on July 20, 2012; thus, the application was pending for 2297 days. During this time, the applicant filed an RCE – on December 14, 2010. Under 35 U.S.C. § 154(b)(1)(B)(i), there was one time period consumed by continued examination ("RCE period"). The period was from December 14, 2010 until the notice of allowance was issued on July 20, 2012 – *i.e.*, 585 days. Subtracting the RCE period from the total number of days the application was pending results in $2297 - 585 = 1712$ days. Thus, for purposes of "B" delay, the application was pending for $1712 - 1097$ [*i.e.*, 1×366 days¹ + 2×365 days + 1 day] = 615 days beyond the 3-year anniversary of the filing date.

The Office finds that the amount overlapping days of Office delay is 283 days. In *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010), the United States Court of Appeals for the Federal Circuit determined that overlap occurs when the calendar days overlap between the "A" and "B"

¹ 2008 was a leap year.

delays. Under this interpretation, the Office finds that the following days of “A” delay and “B” delay overlap: the 283 days of “A” delay period starting on June 21, 2009, the day after the date three years after the application was filed and ending on March 30, 2010; the date a non-final Office action was mailed.

With regard to applicant delay, § 1.704(c)(8) states that:

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: Submission of a supplemental reply or other paper, other than a supplemental reply or other paper expressly requested by the examiner, after a reply has been filed, 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 the initial reply was filed and ending on the date that the supplemental reply or other such paper was filed;

On December 14, 2010, an RCE and submission under 37 CFR 1.114 were filed. On May 11, 2011, a supplemental reply or other paper (an IDS) was filed, 148 days after the day after the date the RCE was filed. The IDS did not contain the statement set forth at § 1.704(d). On July 15, 2011, a supplemental reply or other paper (an IDS) was filed, 213 days after the day after the date the RCE was filed. The IDS did not contain the statement set forth at § 1.704(d). On August 22, 2011, a supplemental reply or other paper (an IDS) was filed, 251 days after the day after the date the RCE was filed. The IDS did not contain the statement set forth at § 1.704(d). Thus, the total period from the day after the date the reply was filed until the date the supplemental reply or other paper was filed was 251 days. Accordingly, a reduction of 251 days for applicant delay pursuant to 37 CFR 1.704(c)(8) is warranted and will be entered.

On June 19, 2012, a reply to a non-final Office action was filed. On July 12, 2012, a supplemental reply or other paper (an IDS) was filed, 23 days after the day after the date the reply was filed. The IDS did not contain the statement set forth at § 1.704(d). Accordingly, a reduction of 23 days for applicant delay pursuant to 37 CFR 1.704(c)(8) is warranted and will be entered.

Overall PTA Calculation

Formula:

“A” delay + “B” delay + “C” delay - Overlap - applicant delay = X

USPTO’s Calculation:

1324 + 615 + 0 – 283 – 276 = 1380

Patentee's Calculation

A: $1324 + 1200 + 0 - 654 - 2 = 1868$

B: $1324 + 616 + 0 - 283 - 2 = 1655$

Conclusion

Patentee is entitled to PTA of one thousand three hundred eighty (1380) days. Using the formula "A" delay + "B" delay + "C" delay - overlap - applicant delay = X, the amount of PTA is calculated as following: $1324 + 615 + 0 - 283 - 276 = 1380$ days.

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

Patentee is given TWO (2) MONTHS from the mail date of this decision to respond to this redetermination. Extensions of time under 37 CFR 1.136(a) are permitted. This is not final agency action within the meaning of 5 U.S.C. § 704.

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 three hundred eighty (1380) days**.

Telephone inquiries specific to this matter should be directed to the undersigned at (571) 272-3231.



Douglas I. Wood
Attorney Advisor
Office of Petitions

Enclosure: Copy of DRAFT Certificate of Correction

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT : 8,277,500 B2

DATED : October 2, 2012

INVENTOR(S) : Schmid 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 1580 days.

Delete the phrase "by 1580 days" and insert – by 1380 days--

Please Direct All Correspondence to Customer Number 20995

REQUEST FOR CERTIFICATE OF CORRECTION

Inventor : Schmid *et al.*
App. No. : 11/455,986
Filed : June 20, 2006
Patent No. : 8,277,500
Issue Date : October 2, 2012
Title : SLIDE-AND-LOCK STENT
Conf No. : 2239

Commissioner for Patents
Office of Data Management Attention: Certificates of Correction Branch
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing is a Certificate of Correction in connection with the above-identified patent. As the errors cited in the Certificate of Correction are believed to have been incurred through the fault of the PTO, no fee is believed to be required. However, please charge any fees or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 5, 2013

By: Jason R. Swartz/

Jason R. Swartz
Registration No. 64,420
Attorney of Record
Customer No. 20995
(949) 760-0404

**UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION**

Page 1 of 1

PATENT NO. : 8,277,500
APPLICATION NO. : 11/455,986
ISSUE DATE : October 2, 2012
INVENTORS : Schmid et al.

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

In column 34 at line 33-34, change “epolyglutarunic” to --polyglutamic--.

In column 43 at line 26, in Claim 4, change “claim 2,” to --claim 3,--.

In column 43 at line 63, in Claim 11, after “first” insert --radial--.

In column 43 at line 65, in Claim 11, after “first” insert --radial--.

In column 44 at line 2, in Claim 11, change “radical” to --radial--.

In column 44 at line 5, in Claim 11, change “radical” to --radial--.

14739978

MAILING ADDRESS OF SENDER:

Jason Swartz
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Floor
Irvine, California 92614

DOCKET NO. REVAMD.027CP1