

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 8,598,149 B2
APPLICATION NO. : 12/199114
DATED : December 3, 2013
INVENTOR(S) : Belanoff 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 990 days.

Signed and Sealed this
Thirtieth Day of December, 2014



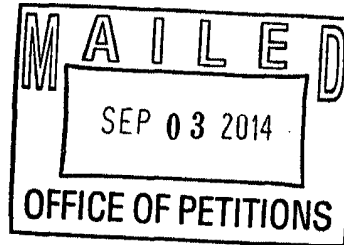
Michelle K. Lee
Deputy Director of the United States Patent and Trademark Office



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In re Patent No. 8,598,149
Joseph K. Belanoff
Issue Date: 12/03/2013
Application No. 12/199114
Filing or 371(c) Date: 08/27/2008
Atty. Docket No.:
85178-756824(004110US)

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: ON REDETERMINATION OF
: PATENT TERM ADJUSTMENT
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This is a response to applicants "REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 CFR 1.705(d)", requesting that the Office adjust the PTA in view of *Exelixis v. Kappos*. The Office has re-determined the PTA to be 990 days.

This redetermination of patent term adjustment is not the Director's decision on the applicant's request for reconsideration within the meaning of 35 U.S.C. 154(b)(4) that triggers a 180-day period for applicant disagreeing with the Office redetermination to commence a civil action in the District Court for the Eastern District of Virginia.

Relevant Procedural History

On December 3, 2013, the above-identified application matured into U.S. Patent No. 8,598,149. The patent issued with a PTA of 866 days. The present request for redetermination of the patent term adjustment was timely filed within two months of the issue date of the patent. Patentee requests recalculation of the Patent Term Adjustment in view of *Exelixis v. Kappos*.

Decision

Patents' arguments have been carefully considered. Upon review, the USPTO finds that patentee is entitled to **990** 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 as to the amount of "applicant delay" under 35 U.S.C. § 154(b)(2)(C) and 1.704(b); however, patentee and the Office continue to disagree regarding the amount of "A" delay under 35 U.S.C. § 154(b)(1)(A) and 37 CFR 1.702(a).

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 519 days of “B” delay. In this case, it was previously determined that the application filing date is August 27, 2008, and the issue date of the patent is December 3, 2013. Accordingly, the total pendency of the application was 1925 days. Thus, the application was pending for $1925 - 1096 = 829$ days beyond the three-year anniversary of the application’s filing date. This three-year pendency period began on August 28, 2011, and ended on December 3, 2013. During this time, the applicant filed one RCE on September 27, 2012, and the Office mailed a Notice of Allowance on August 2, 2013, for a total of 310 days, which is excluded from the amount of “B” delay. Accordingly, in light of the RCE, the amount of “B” delay amounted to 519 days ($1925 - 1096 - 310 = 519$).

Regarding patentee delay, Office records confirm that the due date for the reply to the final Office action mailed April 4, 2012, was July 4, 2012, a Federal Holiday, and the due date for the reply was therefore July 5, 2012. Applicant filed a reply to the Office action on September 27, 2012. Accordingly, a period of reduction of 84 days, not 85 days, is properly entered for the reply. *Id.*

The Office finds that there are no overlapping 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” delays. Under this interpretation, the Office finds that no days of “A” delay overlap with the B periods iterated above.

Overall PTA Calculation

Formula:

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

USPTO’s Calculation:

$637 + 519 + 0 - 0 - 166 = 990$

Patentee’s Calculation

$637 + 519 + 0 - 0 - 167 = 989$

Conclusion

Patentee is entitled to a PTA of nine hundred ninety (990) days. Using the formula “A” delay + “B” delay + “C” delay - overlap - applicant delay = X, the amount of PTA is calculated as following: $637 + 519 + 0 - 0 - 166 = 990$ 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 **nine hundred ninety (990) days**.

Telephone inquiries specific to this matter should be directed to the undersigned at (571) 272-3232.

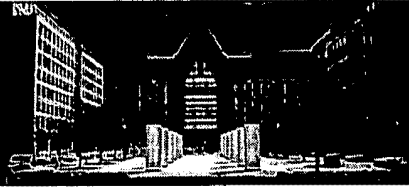
/DW/

Derek Woods
Attorney Advisor
Office of Petitions

Enclosure: Adjusted PTA calculation
Draft Certificate of Correction



Patent Term Adjustments



PTA/PTE Information

Application Number*: 12199114 [Explanation of PTA Calculation](#) [Explanation of PTE Calculation](#)

PTA Calculations for Application: 12199114

Application Filing Date	08/27/2008	Overlapping Days Between (A and B) or (A and C)	0
Issue Date of Patent	12/03/2013	Non-Overlapping USPTO Delays	1033
A Delays	637	PTO Manual Adjustment	124
B Delays	396	Applicant Delay (APPL)	167
C Delays	0	Total PTA (days)	990

* - Sorted Column

File Contents History

Action Number	Action Recorded Date	Action Due Date	Action Code	Action Description	Duration PTO	Duration APPL	Parent Action Number
83	09/02/2014		P028	Adjustment of PTA Calculation by PTO	124		0
83	09/02/2014		P028	Adjustment of PTA Calculation by PTO	124		0
77	12/03/2013		PTAC	Patent Issue Date Used in PTA Calculation			0
76	11/01/2013		EFDC	Export to Final Data Capture			0
75	10/31/2013		D1935	Dispatch to FDC			0
74	10/31/2013		PILS	Application Is Considered Ready for Issue			0
73	10/28/2013		N084	Issue Fee Payment Verified			0
72	10/28/2013		IFEE	Issue Fee Payment Received			0
71	08/31/2013		FIDC	Finished Initial Data Capture			0
67	08/02/2013		MN/=	Mail Notice of Allowance			0
66	07/29/2013		OAR	Office Action Review			0
65	07/29/2013		OAR	Office Action Review			0
61	07/29/2013		IREV	Issue Revision Completed			0
60	07/29/2013		DVER	Document Verification			0
59	07/29/2013		N/=	Notice of Allowance Data Verification Completed			0
58	07/29/2013		DOCK	Case Docketed to Examiner in GAU			0
57	07/29/2013		ACRE	Allowed Case Returned to the Examiner for Clerical Processing			0
56	07/29/2013		OAR	Office Action Review			0
55	07/29/2013		OAR	Office Action Review			0
54	07/23/2013		EX.R	Reasons for Allowance			0
53	07/23/2013		CNTA	Allowability Notice			0
52	07/19/2013		FWDX	Data Forwarded to Examiner			0
51	07/18/2013		A.QU	Response after Ex Parte Quayle Action			0
50	05/24/2013		ELC_RVW	Electronic Review			0
49	05/24/2013		EML_NTF	Email Notification			0
48	05/24/2013	01/27/2013	MCTEQ	Mail Ex Parte Quayle Action (PTOL - 326)	117		43
47	05/21/2013		OAR	Office Action Review			0
46	05/20/2013		CTEQ	Quayle action			0
45	10/01/2012		FWDX	Data Forwarded to Examiner			0
42	10/01/2012		ABN9	Disposal for a RCE / CPA / R129			0
44	09/27/2012		AMSB	Amendment Submitted/Entered with Filing of CPA/RCE			0
43	09/27/2012	07/04/2012	RCEX	Request for Continued Examination (RCE)		8.5	37
41	09/27/2012		XT/G	Request for Extension of Time - Granted			0
40	09/27/2012		BRCE	Workflow - Request for RCE - Begin			0
77.5	09/26/2012	08/27/2011	PTA36M	PTA 36 Months	396		0.5
39	04/04/2012		ELC_RVW	Electronic Review			0
38	04/04/2012		EML_NTF	Email Notification			0
37	04/04/2012		MCTFR	Mail Final Rejection (PTOL - 326)			0
36	03/28/2012		OAR	Office Action Review			0
35	03/27/2012		CTFR	Final Rejection			0
33	01/26/2012		FWDX	Data Forwarded to Examiner			0
32	01/24/2012	11/03/2011	A...	Response after Non-Final Action		8.2	28
31	01/24/2012		XT/G	Request for Extension of Time - Granted			0
30	08/03/2011		ELC_RVW	Electronic Review			0
29	08/03/2011		EML_NTF	Email Notification			0
28	08/03/2011		MCTNF	Mail Non-Final Rejection			0
27	07/29/2011		OAR	Office Action Review			0
26	07/28/2011		CTNF	Non-Final Rejection			0
24	05/24/2011		FWDX	Data Forwarded to Examiner			0
23	05/18/2011		ELC	Response to Election / Restriction Filed			0
22	05/18/2011		XT/G	Request for Extension of Time - Granted			0
21	03/31/2011		ELC_RVW	Electronic Review			0
20	03/31/2011		EML_NTF	Email Notification			0
19	03/31/2011	10/27/2009	MCTRS	Mail Restriction Requirement	520		0.5

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