

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No.: PTO-P-2010-0006]

**Interim Procedure for Patentees to Request a Recalculation of the Patent Term
Adjustment to Comply with the Federal Circuit Decision in Wyeth v. Kappos
Regarding the Overlapping Delay Provision of 35 U.S.C. 154(b)(2)(A)**

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice.

SUMMARY: The United States Patent and Trademark Office (USPTO) is modifying the computer program it uses to calculate patent term adjustments in light of Wyeth v. Kappos, No. 2009-1120 (Fed. Cir., Jan. 7, 2010). The USPTO expects to complete this software modification by March 2, 2010. In the meantime, the USPTO is providing patentees with the ability to request a recalculation of their patent term adjustment without a fee as an alternative to the petition and fee required by 37 CFR 1.705(d). In order to qualify, a form requesting a recalculation of the patent term adjustment must be submitted no later than 180 days after the patent has issued and the patent must be issued

prior to March 2, 2010. In addition, this procedure is only available for alleged errors that are specifically identified in Wyeth. The USPTO is deciding pending petitions under 37 CFR 1.705 in accordance with the Wyeth decision. This notice also provides information concerning the Patent Application Information Retrieval (PAIR) screen that displays the patent term adjustment calculation.

DATES: EFFECTIVE DATE: The procedure set forth in this notice is effective on [Insert date of publication in the FEDERAL REGISTER].

APPLICABILITY DATE: The procedure set forth in this notice is applicable only to patents issued prior to March 2, 2010, in which a request for recalculation of patent term adjustment in view of Wyeth is filed within 180 days of the day the patent was granted.

FOR FURTHER INFORMATION CONTACT: The Office of Patent Legal Administration by telephone at (571) 272-7702, or by mail addressed to: Mail Stop Comments-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

SUPPLEMENTARY INFORMATION: Under 35 U.S.C. 154(b)(1), an applicant is entitled (subject to certain conditions and limitations) to patent term adjustment for the following reason: (1) if the USPTO fails to take certain actions during the examination and issue process within specified time frames (35 U.S.C. 154(b)(1)(A)), which are known as the "A" delays; (2) if the USPTO fails to issue a patent within three years of the

actual filing date of the application (35 U.S.C. 154(b)(1)(B)), which are known as the “B” delays; and (3) for delays due to interference, secrecy order, or successful appellate review (35 U.S.C. 154(b)(1)(C)), which are known as the “C” delays. 35 U.S.C. 154(b)(2)(A) provides that “[t]o the extent that periods of delay attributable to grounds specified in [35 U.S.C. 154(b)(1)] overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.” The USPTO interpreted this provision as covering situations in which a delay by the USPTO contributes to multiple bases for adjustment (the “pre-Wyeth” interpretation of 35 U.S.C. 154(b)(2)(A)). See Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 FR 34283 (June 21, 2004). The United States Court of Appeals for the Federal Circuit, however, recently held in Wyeth that the USPTO’s interpretation of 35 U.S.C. 154(b)(2)(A) was too strict, and that periods of delay overlap under 35 U.S.C. 154(b)(2)(A) only if the periods which measure the amount of adjustment under 35 U.S.C. 154(b)(1) occur on the same calendar day.

The USPTO makes patent term adjustment determinations by a computer program that uses the information recorded in the USPTO’s Patent Application Locating and Monitoring (PALM) system, except when an applicant requests reconsideration pursuant to 37 CFR 1.705. See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 FR 56365, 56370, 56380-81 (Sept. 18, 2000) (final rule). The USPTO is in the process of revising the computer program it uses to calculate patent term adjustment to calculate overlapping delays consistent with the Federal Circuit’s

interpretation of 35 U.S.C. 154(b)(2)(A) in Wyeth. The USPTO expects the revisions to the patent term adjustment computer program to be in place for use on the patents issuing on March 2, 2010.

Patentees should note that the patent term adjustment provisions of 35 U.S.C. 154(b) are complex, there are numerous types of communications that are exchanged between applicants and the USPTO during the patent application process, the PALM system was not originally designed for the purpose of calculating patent term adjustment as provided in 35 U.S.C. 154(b), and one or more of the time frames specified in of 35 U.S.C. 154(b)(1)(A) and (B) are not met presently in a high percentage of the patents. In addition, revisions to the patent term adjustment computer program necessary to calculate overlapping delays consistent with the Federal Circuit's interpretation of 35 U.S.C. 154(b)(2)(A) in Wyeth significantly increases the complexity of the patent term adjustment computer program. Thus, for patents issuing on or after March 2, 2010, a patentee who believes that the patent term adjustment calculation for his or her patent is not correct must file a request for reconsideration under 37 CFR 1.705(d) that complies with the requirements of 37 CFR 1.705(b)(1) and (b)(2) within two months of the date the patent issued. The USPTO is modifying and will continue to modify the patent term adjustment computer program as it becomes aware of situations in the patent term adjustment computer program where it is not correctly calculating the applicable patent term adjustment.

Requests for Reconsideration of the Patent Term Adjustment indicated in the Patent:

37 CFR 1.705(d) provides, in part, that any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued and must comply with the requirements of 37 CFR 1.705(b)(1) and (b)(2).

35 U.S.C. 154(b)(4) provides that an applicant dissatisfied with a determination made by the Director under 35 U.S.C. 154(b)(3) shall have remedy by a civil action against the Director filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent.

The USPTO is providing an optional procedure under which patentees seeking a revised patent term adjustment in a patent issued prior to March 2, 2010, may request that the USPTO recalculate the patent term adjustment without a request for reconsideration under 37 CFR 1.705(d) (or fee), provided that the patentee's sole basis for requesting reconsideration of the patent term adjustment in the patent is the USPTO's pre-Wyeth interpretation of 35 U.S.C. 154(b)(2)(A) and such a request is filed within 180 days of the day the patent was granted. The USPTO is providing a Request for Recalculation of Patent Term Adjustment in View of Wyeth form (PTO/SB/131) for use in making such a request. The Request for Recalculation of Patent Term Adjustment in View of Wyeth form (PTO/SB/131) is available on the USPTO Web site at <http://www.uspto.gov/forms/index.jsp>. This procedure and Request for Recalculation of Patent Term Adjustment in View of Wyeth form (PTO/SB/131) are applicable only for patents that issue prior to March 2, 2010. The USPTO will deny as untimely any request for recalculation of patent term adjustment indicated on a patent that is **not** filed within

180 days of the day the patent was granted. Patentees are reminded that this is an optional procedure, and that any patentee who wishes to preserve his or her right to review in the United States District Court for the District of Columbia of the USPTO's patent term adjustment determination must ensure that he or she also takes the steps required under 35 U.S.C. 154(b)(3) and (b)(4) and 37 CFR 1.705 in a timely manner.

The fee specified in 37 CFR 1.18(e) is required for a request for reconsideration under 37 CFR 1.705 (37 CFR 1.705(b)(1)), and the USPTO may only refund fees paid by mistake or in excess of that required (35 U.S.C. § 42(d)). Therefore, the procedure set forth in this notice is **not** a basis for requesting a refund of the fee specified in 37 CFR 1.18(e) for any request for reconsideration under 37 CFR 1.705, including any previously filed request that was solely based on the USPTO's pre-Wyeth interpretation of 35 U.S.C. 154(b)(2)(A).

The procedure set forth in this notice and the Request for Recalculation of Patent Term Adjustment in View of Wyeth form (PTO/SB/131) may not be used to request a reconsideration of the patent term adjustment indicated in the notice of allowance in an application that has not yet issued as a patent. If the application issues as a patent prior to March 2, 2010, the optional procedure set forth in this notice and the Request for Recalculation of Patent Term Adjustment in View of Wyeth form (PTO/SB/131) may be used to request recalculation of the patent term adjustment provided on the patent. It is expected that for applications issuing as patents on or after March 2, 2010, the patent

term adjustment calculation will be consistent with the Federal Circuit's interpretation of 35 U.S.C. 154(b)(2)(A) in Wyeth.

The USPTO is deciding any currently pending request for reconsideration of the patent term adjustment indicated in the patent under 37 CFR 1.705(d) that was filed within two months of the date the patent issued consistent with the Federal Circuit's interpretation of 35 U.S.C. 154(b)(2)(A) in Wyeth. Patentees who received a decision on a request for reconsideration of the patent term adjustment indicated in the patent under 37 CFR 1.705(d) under the USPTO's pre-Wyeth interpretation of 35 U.S.C. 154(b)(2)(A) may file a request for reconsideration of that decision if such a request for reconsideration is filed within two months of the date of the decision on a request for reconsideration (37 CFR 1.181(f)). If the patentee's sole basis for requesting reconsideration of the decision is the USPTO's pre-Wyeth interpretation of 35 U.S.C. 154(b)(2)(A), the request for reconsideration need only state that reconsideration is being requested in view of the Federal Circuit's decision in Wyeth (the Request for Recalculation of Patent Term Adjustment in View of Wyeth form (PTO/SB/131) may also be used for this purpose).

Patentees seeking a revised patent term adjustment in a patent issued on or after March 2, 2010, must file a request for reconsideration under 37 CFR 1.705(d) that complies with the requirements of 37 CFR 1.705(b)(1) and (b)(2) within two months of the date the patent issued.

To the extent that the procedures adopted under the authority of 35 U.S.C. 2(b)(2) and 154(b)(3) require that any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued and include the information required by 37 CFR 1.705(b)(2) and the fee required by 37 CFR 1.18(e), these requirements are hereby sua sponte waived for patents that meet all of the following criteria: (1) the patent must be issued prior to March 2, 2010; (2) the patentee's sole basis for requesting reconsideration of the patent term adjustment in the patent is the USPTO's pre-Wyeth interpretation of 35 U.S.C. 154(b)(2)(A); and (3) the Request for Recalculation of the Patent Term Adjustment in View of Wyeth form (PTO/SB/131) is filed within 180 days of the day the patent was granted. See 37 CFR 1.183. This waiver does not apply to patents issued on or after March 2, 2010, to requests that the USPTO recalculate the patent term adjustment for alleged errors other than that identified in Wyeth, or to any request for reconsideration of the patent term adjustment indicated in the patent filed later than 180 days after the patent was granted.

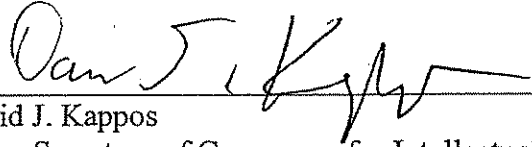
Paperwork Reduction Act: This notice involves information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The collection of information involved in this notice is covered by OMB control number 0651-0020.

Patent Term Adjustment Information Displayed in PAIR: The USPTO provides a patent term adjustment calculation screen that is viewable through PAIR. The patent term adjustment screen has been displaying the following information at the right hand

column: (1) USPTO delay days (the number of days of “A” and “C” delay); (2) Three Year Delay days (the number of days of “B” delay); (3) Applicant Delay days (the number of days by which the USPTO delay days will be reduced); and (4) the Total Patent Term Adjustment. Patentees who use the PAIR patent term adjustment calculation screen should note that it does not display the periods of delay which overlap and thus is not adequate for calculating the patent term under the Federal Circuit’s interpretation of 35 U.S.C. 154(b)(2)(A) in Wyeth. The USPTO plans to revise this screen to show: (1) the number of days of “A” delay; (2) the number of days of “B” delay; (3) the number of days of “C” delay; (4) the number of days of “A” delay that overlap with a day of “B” delay plus the number of days of “A” delay that overlap with a day of “C” delay (the provisions of 35 U.S.C. 154(b)(1)(B)(ii) prevent a “B” delay period and “C” delay period from overlapping); (5) the number of days of non-overlapping USPTO delay; (6) the number of days of applicant delay; and (7) the total patent term adjustment. The revised PAIR patent term adjustment screen, however, will not be ready by March 2, 2010. The USPTO expects the revised PAIR patent term adjustment screen to be ready by July of 2010.

Nothing in this notice shall be construed as a waiver of the requirement of 35 U.S.C. 154(b)(4) that any civil action by an applicant dissatisfied with a determination made by the Director under 35 U.S.C. 154(b)(3) be filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent.

Date: 1/26/10

A handwritten signature in black ink, appearing to read "David J. Kappos", written over a horizontal line.

David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

REQUEST FOR RECALCULATION OF PATENT TERM ADJUSTMENT IN VIEW OF *WYETH**

Attorney Docket Number:	Patent Number:
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Filing Date (or 371(b) or (f) Date):	Issue Date:
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First Named Inventor:

Title:

PATENTEE HEREBY REQUESTS RECALCULATION OF THE PATENT TERM ADJUSTMENT (PTA) UNDER 35 USC 154(b) INDICATED ON THE ABOVE-IDENTIFIED PATENT. THE PATENTEE'S SOLE BASIS FOR REQUESTING THE RECALCULATION IS THE USPTO'S PRE-*WYETH* INTERPRETATION OF 35 U.S.C. 154(b)(2)(A).

Note: This form is only for requesting a recalculation of PTA for patents issued before March 2, 2010, if the sole basis for requesting the recalculation is the USPTO's pre-*Wyeth* interpretation of 35 U.S.C. 154(b)(2)(A). See Instruction Sheet on page 2 for more information.

Patentees are reminded that to preserve the right to review in the United States District Court for the District of Columbia of the USPTO's patent term adjustment determination, a patentee must ensure that he or she also takes the steps required under 35 U.S.C. 154(b)(3) and (b)(4) and 37 CFR 1.705 in a timely manner.

**Wyeth v. Kappos*, No. 2009-1120 (Fed. Cir., Jan. 7, 2010).

Signature	Date
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Name (Print/Typed)	Registration Number
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Note: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required in accordance with 37 CFR 1.33 and 11.18. Please see 37 CFR 1.4(d) for the form of the signature. If necessary, submit multiple forms for more than one signature, see below*.

*Total of _____ forms are submitted.

The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

**Instruction Sheet for:
REQUEST FOR RECALCULATION OF PATENT TERM ADJUSTMENT
IN VIEW OF *WYETH****
(Not to be Submitted to the USPTO)

This form is only for requesting a recalculation of PTA for patents issued before March 2, 2010, if the sole basis for requesting the recalculation is the USPTO's pre-*Wyeth* interpretation of 35 U.S.C. 154(b)(2)(A).

This form must be filed within 180 days of the day the patent was granted, with the following exception:

Patentees who received a decision from the USPTO under the USPTO's pre-*Wyeth* interpretation of 35 U.S.C. 154(b)(2)(A) may file a request for reconsideration of that decision if such a request for reconsideration is filed within **two months** of the date of the decision (37 CFR 1.181(f)). If the patentee's sole basis for requesting reconsideration of the decision is the USPTO's pre-*Wyeth* interpretation of 35 U.S.C. 154(b)(2)(A), the request for reconsideration need only state that reconsideration is being requested in view of *Wyeth* (this form may be used for this purpose if it is filed within **two months** of the date of the decision from the USPTO).

Do not use this form if the application has been allowed, but not yet issued as a patent.

- 1. For patents issued before March 2, 2010:** A request for reconsideration under 37 CFR 1.705(d) and the fee set forth in 37 CFR 1.18(e) are not required, provided that the patentee's sole basis for requesting recalculation of the PTA in the patent is the USPTO's pre-*Wyeth* interpretation of 35 U.S.C. 154(b)(2)(A) and this form is filed within 180 days of the day the patent was granted.
- 2. For patents issued on or after March 2, 2010 (do not use this form):** Patentees seeking a revised PTA in a patent issued on or after March 2, 2010, must file a request for reconsideration under 37 CFR 1.705(d) that complies with the requirements of 37 CFR 1.705(b)(1) and (b)(2) within two months of the day the patent issued.

For more information, see "Notice Concerning Calculation of the Patent Term Adjustment With Respect to the Overlapping Delay Provision of 35 U.S.C. 154(b)(2)(A)" available on the USPTO Web site at <http://www.uspto.gov/patents/law/notices/2010.jsp>.

**Wyeth v. Kappos*, No. 2009-1120 (Fed. Cir., Jan. 7, 2010).

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.