Questions and Answers related to Wyeth v. Kappos

Q1. Will the USPTO provide patentees an opportunity to request recalculation of patent term adjustment (PTA) in light of *Wyeth v. Kappos*?

Yes. The USPTO has provided an interim procedure in which patentees may submit a "Request for Recalculation of Patent Term Adjustment in View of *Wyeth*" form (PTO/SB/131) (i.e., "Interim Request for Recalculation form"), without a fee, as an alternative to the petition and fee required by 37 CFR 1.705(d). *See 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), 75 FR 5043 (February 1, 2010).*

Q2. What are the requirements for using the newly-created Interim Request for Recalculation form?

To be eligible to use the Interim Request for Recalculation form: (1) The patent must have issued before March 2, 2010; (2) the Interim Request for Recalculation form must be filed within 180 days of the grant of the patent or within two months of a decision under 37 CFR 1.705(d); (3) The sole reason for requesting recalculation of the PTA is the USPTO's pre-*Wyeth* interpretation of 35 U.S. C. 154(b)(2)(A); (4) a 35 U.S.C. 111(a) application must have been filed on/after May 29, 2000 or an international application must have an international filing date on/after May 29, 2000; and (5) Patentee must not have commenced a civil action under 35 U.S.C. 154(b)(4)(A).

Q3. If I filed the Interim Request for Recalculation form within 180 days of the patent issue date, will I still get a decision on my request if more than 180 days have elapsed since the patent issued?

Yes. The USPTO will provide patentees a decision on a timely filed Interim Request for Recalculation form even if more than 180 days have elapsed since the patent issued. The USPTO will also provide patentees a decision on a timely filed reconsideration request pursuant to 37 CFR 1.705(d) even if more than 180 days have elapsed since the patent issued.

Q4. Does the request for recalculation of PTA toll the time for filing a civil action under 35 U.S.C. 154(b)(4)(A)?

No. If a patentee wishes to commence a civil action under 35 U.S.C. 154(b)(4)(A), it must file such an action with the 180-day period set forth in the statute. The filing of the Interim Request for Recalculation form or alternatively, the filing of request for reconsideration of the patent term adjustment indicated in the patent pursuant to 37 CFR 1.705(d), will not toll the time for filing the civil action. The statute requires that the civil action be filed "within 180 days after the grant of the patent."

Q5. Will the patentee or assignee be provided an opportunity to dispute the USPTO's recalculation determination?

Yes. The patentee or assignee will have 30 days or one month, whichever is longer, after the mailing of the USPTO's recalculation determination to reply to the determination. If the patentee or assignee does not reply within the time period, the USPTO will issue a certificate of correction reflecting the PTA recalculation. If the patentee or assignee does reply to the recalculation determination, the Office will consider the reply and then issue the certificate of correction, or revise the determination, as appropriate.

Q6. When will the USPTO begin responding to patentees' Interim Request for Recalculation forms?

On April 16, 2010, the USPTO deployed an automated system for generating recalculation determinations in response to requests for recalculation. The USPTO designed the automated system to: (1) filter out forms that do not meet the eligibility requirements set forth in the USPTO's February 1, 2010 interim guidance; (2) recalculate PTA in accordance with *Wyeth*; (3) mail recalculation determinations to eligible patentees or assignees; (4) provide patentees or assignees an opportunity to reply to recalculations, and revise PTA determinations in response, if appropriate; and (5) *sua sponte* issue the certificate of correction reflecting the recalculation of PTA. and is now in the process of mailing these recalculation determinations to patentees. The USPTO will begin processing certificate of corrections within approximately two months for patentees who do not request reconsideration of the recalculation determination.

Q7. When will the USPTO's PTA computer software be modified to reflect the Federal Circuit's interpretation of 35 U.S.C. 154(b)(2)(A)?

Patents issuing on or after March 2, 2010, do reflect the Federal Circuit's interpretation of the PTA statute as set forth in *Wyeth*. The computer program has also been modified to reflect that the three-year pendency provision of 35 U.S.C. 154(b)(1)(B) in international applications is measured from the date the national stage commences under 35 U.S.C. 371(b) or (f) in the international application.

Q8. Is any fee required for submission of the Interim Request for Recalculation form?

No. The interim procedure permits patentees to request PTA recalculation without a fee as an alternative to the petition and fee required by 37 CFR 1.705(d).

Q9. Can patentees submit the Interim Request for Recalculation form more than two months after the patent has issued (*i.e.*, beyond the time frame specified in 37 CFR 1.705(d) for filing a request for reconsideration of PTA)?

Yes. The interim procedure permits patentees to submit such requests within 180 days from the issue date of the patent, if the patent issued prior to March 2, 2010.

Q10. Can applicants submit the Interim Request for Recalculation form before the patent issues?

No. Applicants should not submit the form for any application that has only received a determination with the notice of allowance. The USPTO does not calculate the amount of "B" delay until the grant of the patent. Accordingly, an Interim Request for Recalculation filed prior to payment of the USPTO calculates the "B" delay will be deemed ineligible for the recalculation.

Q11. Can the Interim Request for Recalculation form be submitted via EFS-Web?

Yes. The Office has created a specific document code, PET.PTA.RCAL, for such submissions and the document description is Request for Recalculation in view of Wyeth.

Q12. Can the Interim Request for Recalculation form be submitted by mail?

Yes. The request should be mailed to the following address: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Q13. Can patentees file an Interim Request for Recalculation form with a certificate of mailing or transmission under 37 CFR 1.8?

Yes, the USPTO will determine whether the request is timely filed based on the date indicated on the certificate filed in compliance with 37 CFR 1.8.

Q14. Can patentees request recalculation of PTA in view of *Wyeth* <u>and</u> reconsideration of the PTA based on other provisions of 37 CFR 1.702-1.704 using the Interim Request for Recalculation form?

No. For example, if patentees believe the "B" delay is inaccurate but also believe that the USPTO improperly reduced the PTA under 37 CFR 1.704(c)(10), patentees must file a timely request for reconsideration of the PTA pursuant to 37 CFR 1.705(d). Patentees would not be eligible to use the Interim Request for Recalculation form.

Q15. Should a patentee submit an Interim Request for Recalculation form if the patentee had previously submitted a request for reconsideration under 37 C.F.R. § 1.705(d), and such request has not been decided?

No. The USPTO will consider the request for reconsideration pursuant to 37 CFR 1.705(d), and render a decision in accordance with *Wyeth*, if the request was timely

filed under 37 CFR 1.705(d). Patentees cannot withdraw the request for reconsideration of PTA under 37 CFR 1.705(d), request a refund, and then submit a request for recalculation of PTA in view of *Wyeth* (Form PTO/SB/131).

Q16. Can patentees submit an Interim Request for Recalculation form more than 180 days after the patent was granted?

No, 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* (the Interim Request for Recalculation form may be used).

Q17. Can the Interim Request for Recalculation form be used for patents that issue on or after March 2, 2010?

No. Patents issuing on or after March 2, 2010 will reflect a PTA calculation in accordance with *Wyeth*. A patentee can still file a request for reconsideration of the patent term adjustment under 37 CFR 1.705(d) after March 2, 2010.

Q18. Can patentees file one Interim Request for Recalculation form and enclose an itemized list of patents for which recalculation is being requested?

No. Patentees must file a separate Interim Request for Recalculation form for each patent. *See* 37 CFR 1.4(b).

Q19. Should patentees use an Interim Request for Recalculation form for a patent that issued within three years of the filing date?

Patentees should <u>not</u> file a request for recalculation of PTA in the following situations:

a) the patent is issued from an application filed under 35 U.S.C. § 111(a) and the time period between the filing date of the application and the date of filing of the first RCE or the issue date, whichever is the earlier, is less than three years; or

b) the patent is issued from an international application and the time period between the date of national stage commencement under 35 U.S.C. § 371(b) or (f) and the date of the filing of the first RCE or the issue date, whichever is the earlier, is less than three years.

Please note that in these situations, there would have no "B" delay, and therefore there is no overlapping time period.

Q20. Will the Office *sua sponte* recalculate the PTA of all patents that have issued in the last 180 days and mail a new PTA determination where a discrepancy is identified?

No. The Office will recalculate the PTA for patentees who timely submit the Interim Request for Recalculation form or who timely request reconsideration of the PTA under 37 CFR 1.705(d).

Q21. How will the patentee know how many additional days of PTA the USPTO has determined in the recalculation?

The USPTO will mail a recalculation determination to patentees and will *sua sponte* issue a certificate of correction pursuant to 37 CFR 1.322. Patentee will be given one month or thirty (30) days whichever is longer to file a reply if patentee disagree with the recalculation.

Q22. If the 180-day expires on a weekend, will an Interim Request for Recalculation form filed on the next succeeding business day be considered timely?

Yes. See 35 U.S.C. 21(b).

Q23. Who can sign the Interim Request for Recalculation form?

The form can be signed by (1) a patent practitioner of record appointed in compliance with 37 CFR 1.32(b); (2) a patent practitioner not of record who acts in a representative capacity under the provisions of 37 CFR 1.34; (3) an assignee as provided for under 37 CFR 3.71(b); or (4) all of the applicants for patent, unless there is an assignee of the entire interest and such assignee has taken action in the application in accordance with 37 CFR 3.71.

Q24. Can I file a request for reconsideration of the patent term adjustment if the recalculation results in less PTA?

Yes. Patentee must file a request for reconsideration of the patent term adjustment within 30 days or one month, whichever is longer, to dispute the recalculated amount of patent term adjustment. Patentees cannot simply request that the old calculated be reinstituted but must shown how the USPTO erred in the recalculation.