

REPORT

FEDERAL CIRCUIT MODIFIES PTO'S FORMULA FOR DETERMINING PATENT TERM ADJUSTMENT

January 22, 2010

The U.S. Patent and Trademark Office (PTO) determines the amount of patent term extension in accordance with its interpretation of the Patent Term Guarantee provisions of the American Inventors' Protection Act (35 U.S.C. §154(b)(1)).¹ On January 7, the Federal Circuit issued a decision in *Wyeth v. Kappos*² that requires the PTO to change the way it calculates the amount of patent term extension. This decision will increase the amount of patent term extension for some forthcoming patents, and provides a basis for challenging the PTO's patent term extension determination in some recently issued patents. We present below a discussion of the *Wyeth* decision and its effects, as well as our recommendations regarding patents affected by the decision.

I. Background

There are three "guarantees" for patent term adjustment (PTA) to compensate for prosecution delays caused by the PTO under 35 U.S.C. §154(b)(1)(A)–(C). In general, paragraph A provides PTA for delays by the PTO in promptly responding to certain events ("A delay");³ paragraph B provides PTA if a patent does not

issue and a Request for Continued Examination (RCE) is not filed within three years of its actual filing date ("B delay"); and paragraph C provides PTA for other special delays ("C delay"). In each case, the PTA is subject to other limitations, including the limitation that, to the extent that periods of delay "overlap," the period of adjustment cannot exceed the actual number of days the issuance of the patent was delayed. *See* 35 U.S.C. §154(b)(2). Prior to the *Wyeth* decision, the PTO has calculated PTA as the greater of A delay or B delay, but never a combination of both.

II. The *Wyeth* Decision

Wyeth was granted patents on two applications that each had A and B delays. A portion of the A delays occurred less than three years after the applications were filed. The PTO used its "greater-of-A-or-B" rubric to calculate the amount of PTA. After filing unsuccessful petitions for reconsideration of the adjustments with the PTO, *Wyeth* filed suit. The district court granted summary judgment to *Wyeth*, rejecting the PTO's interpretation as contrary to the plain language of the statute. The district court held that A delays that occur less than three years after the filing date of the application do not overlap with B delays and that such A delays should be added to the B delays in calculating PTA. The PTO appealed the decision.

decision on Appeal reversing all rejections of at least one claim, and issue a patent within four months of payment of the Issue Fee.

¹ See our February 11, 2002 Special Report.

² Appeal No. 2009-1120 (Fed. Cir. January 7, 2010)

³ In general, to avoid generating A delay, the PTO must issue a first substantive Office Action or Notice of Allowance within fourteen months after the filing date of the application, issue an Office Action or Notice of Allowance within four months after an applicant files a response to an Office Action or after issuance of a

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The Federal Circuit found that the A and B guarantees expressly designate when and for what period they each respectively apply. The "period of delay" for purposes of the A clause runs from the date the PTO misses the specified deadline to the date the PTO takes the required action. The "period of delay" under the express language of the B clause runs from the three-year mark after filing until the application issues or an RCE is filed.

The court found that no "overlap" happens unless the violations occur at the same time. If an A delay occurs on one day and a B delay occurs on a different day, those two days do not "overlap." Before the three-year mark, no "overlap" can occur between an A delay and the B delay because the B delay has not yet begun. The Federal Circuit stated that the PTO's interpretation that B delay can occur anytime after the application is filed was "strained" and that the clear and unambiguous statutory language was "intolerant" of the PTO's interpretation. Accordingly, the Federal Circuit affirmed the district court's decision.

III. Analysis

The *Wyeth* decision affects how the PTO will calculate PTA in the future. The PTO announced on January 21 that it will not seek further review of the *Wyeth* decision, and that it will issue guidance for expediting requests for recalculation of PTA by the PTO in light of that decision. Many patents may be entitled to receive additional patent term extension. However, until the PTO implements its new procedures for calculating PTA, issuing patents should be closely scrutinized to determine whether the PTA was calculated correctly, because the PTO determination is binding unless promptly challenged.

A. Patents That May Be Eligible For Recalculation of PTA

Numerous patents have already issued in which the PTO erroneously calculated the PTA based on its "greater-of-A-or-B" formula. Unfortunately, the options and time periods for challenging the PTO's determination of PTA are limited. To be eligible for recalculation of the PTA, a patent needs to meet the following requirements: (1) the patent is a utility or plant patent issuing on an application filed on or after May 29,

2000, (2) examination of the patent involved both A delays and B delays, with at least some portion of the A delays occurring prior to the three-year date of the actual filing date of the application, (3) the PTO's determination of the PTA was incorrect, (4) it has been 180 days or less since the patent issued, and (5) the patent is not subject to a terminal disclaimer that would negate further extension.

Although the entire prosecution history needs to be evaluated to determine whether a patent application was subject to A delay, many patents can be eliminated from consideration by first determining whether the patent is eligible for PTA due to B delay. If the patent issued less than three years after its "actual filing date in the United States," or if an RCE was filed in the application before the three year date, there is no B delay.⁴ If the patent is not eliminated from consideration under either of those conditions, then the patent may be eligible for PTA due to B delay.⁵

If the patent is eligible for PTA due to B delay, then it needs to be determined whether any A delay occurred prior to the three-year date of the actual filing date of the application. One of the common contributors to A delay is the failure of the PTO to issue a first substantive Office Action or Notice of Allowance within fourteen months after the filing date of the application. Such a delay would necessarily arise before any B delay could occur.

B. Challenging The PTO's Determination of PTA

The options for challenging the PTO's incorrect calculation of PTA, and the time periods in which to

⁴ If the first RCE was not filed until after the three year date, the amount of B delay excludes the number of days beginning on the date on which the RCE was filed and ending on the date the patent was issued.

⁵ The amount of B delay is also subject to other limitations. In addition, the "filing date" for purposes of calculating B delay can be different from the "filing" date used for calculating A delay in some circumstances. Please refer to our February 11, 2002 Special Report for an in-depth discussion on calculating A, B, and C delays.

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exercise those options, are limited. Although the PTO provides a vehicle for requesting reconsideration of the amount of patent term extension identified on the Notice of Allowance (i.e., A and C delay-based extension), this option is not available to correct errors in the PTO's treatment of B delays, because the PTO does not calculate the amount of B delay until it knows the issue date of the patent. Therefore, it cannot be determined whether the amount of B delay and/or the total amount of A delay and B delay calculated by the PTO is incorrect until the patent issues. Once the patent issues, the amount of patent term extension identified on the cover of the patent can be used to determine whether the B delay component was properly considered.

There are two options for challenging the amount of B delay patent term extension identified on the cover of a patent. The first option is to file with the PTO a request for reconsideration of the patent term adjustment indicated in the patent. Such a request must be filed within two months of the date the patent issued. The second option is to file a civil action in the U.S. District Court for the District of Columbia within 180 days of the issue date of the patent. Neither of these deadlines is extendible.

Thus, there are three categories of patents/allowed patent applications that may require further action in view of the *Wyeth* decision: (1) patents that are beyond two months but within 180 days of their issue date, (2) patents that are within two months of their issue date, and (3) patent applications that have received a Notice of Allowance but have not yet issued as a patent.

1. Patents That Are Beyond Two Months But Within 180 Days Of The Issue Date Of The Patent

The only option to have the amount of patent term extension reconsidered beyond two months of the issue date of the patent is by filing a civil action in the U.S. District Court for the District of Columbia within 180 days of the issue date of the patent. Because pursuing a civil action is costly, the amount of additional patent term extension gained by a successful challenge and the value of such additional patent term extension should be considered in determining whether to pursue a civil action.

2. Patents That Are Within Two Months Of The Issue Date Of The Patent

Within two months of the issue date of the patent, in addition to the option of filing a civil action as discussed above, a request for reconsideration of the patent term adjustment indicated in the patent may be filed. The filing fee for filing a request for reconsideration of the patent term adjustment is \$200, and the attorney fees are far lower than those involved in a civil action. Thus, if a timely decision can be obtained from the PTO, this approach is much more cost-effective than filing a civil action. If the PTO decision does not issue within the 180-day period for filing a civil action, a civil action could be filed at relatively low expense, and then dropped if the PTO issues a favorable decision.

3. Patent Applications That Have Received A Notice Of Allowance But Have Not Yet Issued As A Patent

Even though the PTO cannot calculate the amount of B delay until the issue date of the patent is actually known, one can determine whether the patent term is likely to be eligible for adjustment for B delay by the time the patent issues. Thus, these applications may be flagged as requiring careful scrutiny of the amount of patent term extension identified on the cover of the Letters Patent once it is received. This will provide the patentee with additional time to decide what action, if any, will be taken if the amount of patent term extension is incorrect.

IV. Recommendations

We recommend the following actions:

- (a) Identify any important patents that have issued within the last 180 days that may be eligible for reconsideration of the PTA determination made by the PTO.
- (b) Determine for each such patent whether the PTA determination may be challenged by petition to the PTO or if it would be necessary to file a civil action. Consider the amount and value of additional patent term extension that would be gained by a successful challenge to determine whether to pursue a challenge.

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- (c) Review the amount of patent term extension identified on the cover of forthcoming patents to determine whether the B delay component was properly considered.
- (d) Upon receipt of a Notice of Allowance, consider whether the patent term is likely to be eligible for adjustment for B delay by the time the patent issues, to provide time to determine what action, if any, will be taken if the amount of patent term extension is incorrect.

Please let us know if you have any questions regarding any of the topics discussed above, or if you have any questions regarding PTA determinations for a specific matter.

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