

REPORT

DISTRICT COURTS EXPAND PATENT TERM EXTENSIONS

November 20, 2012

On November 1, the U.S. District Court for the Eastern District of Virginia, in *Exelixis, Inc. v. Kappos*, held that the USPTO is incorrectly reducing patent term adjustment (PTA) for time consumed by an RCE filed more than three years after the actual filing date of a patent application. In summary, the court held that, subject to reductions for Applicant Delay, the term of a U.S. patent should be extended by the entire amount of time that examination continues after an RCE is filed, if the first RCE is filed more than three years after the actual filing date of the patent. Citing that decision, the U.S. District Court for the District of Columbia reached the same result in its November 15 decision in *Novartis AG v. Kappos*.

The USPTO has two months to appeal each decision. If the decisions ultimately stand, the USPTO will be required to change how it calculates the amount of PTA for patents in which an RCE was filed after the expiration of the three year period. In the meantime, these decisions provide basis for efforts to control prosecution to maximize patent term extensions and increase such extensions in forthcoming and recently issued patents. We present below a discussion of these decisions and their effects, as well as our recommendations regarding patent applications and issued patents that may be affected by the decisions.

I. Background

Under 35 U.S.C. §154(b), an applicant is entitled to PTA to compensate for the following categories of USPTO delay:

"A" delay accrues when the USPTO fails to take certain actions during the examination and issuance process within specified time frames;

"B" delay accrues if the USPTO fails to issue a patent within three years of the actual U.S. filing date of the application, subject to certain enumerated exceptions;¹ and

"C" delay accrues when an application is subject to an interference, secrecy order, or successful appellate review.

Time consumed in examination of an application after a first RCE is filed tolls the "B" delay three-year period. (The extension of patent term due to these delays is also reduced by the amount of

¹ For PCT U.S. National Stage applications, the USPTO construes the actual U.S. filing date to be the earlier of (a) the expiration date of the 30-month time limit from the earliest priority date of the international application; and (b) the filing date of an express request to commence the National Stage coupled with satisfaction of all the 35 U.S.C. §371 National Stage entry requirements.

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Applicant Delay, if any. Applicant Delays are enumerated in the USPTO rules.)

The *Exelixis* and *Novartis* decisions address the tolling of "B" delay. Currently, to calculate the amount of "B" delay PTA, the USPTO deducts (a) the number of days between the day a first RCE was filed and the issue date from (b) the number of days in excess of three years between the actual filing date and the issue date, regardless of when the RCE is filed. The issue in these decisions was whether such a deduction is appropriate in situations in which an RCE was filed after the three-year period.

Both decisions held that the time consumed in examination after a first RCE is filed tolls the running of the three-year period for "B" delay PTA if, and only if, the RCE is filed within the three-year period. That is, RCEs filed after the three-year period ends have no effect on PTA. Consequently, the courts held that the USPTO's reduction of "B" delay PTA when a first RCE is filed after the three-year period is contrary to law.

II. Analysis

As noted above, the USPTO has two months from each decision to file an appeal. If the USPTO files appeals, it will probably be several months before decisions on the appeals are issued. If the decisions ultimately stand, it may take additional time for the USPTO to update its systems and PTA-calculating software to comply with the decisions.

In the meantime, numerous patents have already issued and additional patents will issue in which the USPTO has reduced "B" delay PTA based on an RCE filed after the three-year period. If the *Exelixis* and *Novartis* decisions stand, some of these issued patents would be eligible for hundreds of days of additional PTA, but only if a PTA correction proceeding is timely filed. Also,

strategically timing the filing of RCEs in certain situations during prosecution of pending patent applications could result in significant additional PTA in the resulting patents.

A. Deadlines For Initiating PTA Correction Proceedings

Once a patent issues, the amount of PTA identified on the cover of the patent can be used to determine how "B" delay was calculated. There are two options for challenging the amount of "B" delay PTA identified on the cover of a patent. The first option is to file in the USPTO a Request for Reconsideration of the PTA identified on the patent. Such a Request must be filed within two months after the issue date of the patent. The second option is to file a civil action in the U.S. District Court for the Eastern District of Virginia, within 180 days after the issue date of the patent. Neither of these deadlines is extendible.

B. Actions That May Be Taken To Increase PTA

There are two categories of issued patents that may qualify for revision of the USPTO's PTA determination: (1) patents that are beyond two months but within 180 days after their issue date, and (2) patents that are within two months after their issue date. PTA calculations should also be taken into account with pending patent applications in which (3) a Notice of Allowance has been mailed but a patent has not yet been issued, and (4) a first RCE needs to be filed.

1. Patents That Are Beyond Two Months But Within 180 Days After Their Issue Date

The only option to have the amount of PTA reconsidered beyond two months after the issue date of the patent is to file a civil action in the U.S. District Court for the Eastern District of

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Virginia within 180 days after the issue date of the patent. Because pursuing a civil action is costly, the amount of additional PTA gained by a successful challenge and the value of such additional PTA should be considered in determining whether to pursue a civil action. However, if the USPTO does not appeal the *Exelixis* or *Novartis* decisions, or if it loses on appeal, the costs should be very low for litigation.

2. Patents That Are Within Two Months After Their Issue Date

Within two months after the issue date of a patent, in addition to the option of filing a civil action as discussed above, a patentee may file in the USPTO a Request for Reconsideration of the PTA identified on the patent. The filing fee is \$200, and the attorney fees are far lower than those involved in a civil action. Thus, this approach is much more cost-effective than filing a civil action. If the USPTO does not issue a decision within the 180-day period for filing a civil action, a precautionary civil action could be filed at relatively low expense, and then dropped if the USPTO issues a favorable decision.²

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

The USPTO does not calculate the amount of "B" delay until the issue date of the patent is actually known. However, at allowance, an

² In fact, the precautionary civil action might not be necessary. On January 27, 2012, in *Bristol Meyers Squibb Co. v. Kappos*, the U.S. District Court for the District of Columbia held that a timely filed request for reconsideration of the PTA with the USPTO tolls the 180-day deadline to file a civil action. On September 20, 2012, the district court denied the USPTO's motion for reconsideration of the decision. The USPTO has until November 20, 2012 to appeal the decision.

application in which a first RCE was filed after the three-year period should be flagged as requiring careful scrutiny of the amount of PTA to be 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 RCE time is not included in the amount of PTA identified on the Letters Patent.

4. Patent Applications In Which A First RCE Is Needed

The USPTO may revise its rules to try to avoid applicant manipulation of RCE filing dates to maximize patent terms. Meanwhile, however, if an RCE is needed in an application that has not yet passed the three-year date, it may be possible to time the filing of the RCE to maximize the amount of "B" delay PTA.

For example, if a Final Rejection is received within three months before the three-year date, the RCE could be filed within the three-month response period but after the three-year date without having to pay extension fees or accruing Applicant Delay. If the Final Rejection is received between three and six months prior to the three-year date, the RCE could be filed after the three-month response period and after the three-year date with payment of the appropriate extension fees. This will accrue up to three months of Applicant Delay for the time between the three-month deadline and the date of filing the RCE, which would usually be overbalanced by the benefit of the resulting "B" delay PTA. The amount of Applicant Delay could be minimized by instead filing a Notice of Appeal on the three-month response date to the Final Rejection, and then filing an RCE, within three months after filing the Notice of Appeal. Currently, the government fees for extensions of 1, 2, and 3 months are respectively \$150, \$570, and \$1,290,

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and the government fee for filing a Notice of Appeal is \$630. These fees are expected to increase in March 2013.

Conceivably, the filing of an RCE could be delayed by more than fifteen months from the issue date of a Final Rejection. This could be achieved by filing a Notice of Appeal on the six-month date from the issuance of the Final Rejection, then filing an Appeal Brief on the seven-month date from the filing of the Notice of Appeal. Appellants have two months from the issue date of an Examiner's Answer to file a Reply Brief or an RCE to reopen prosecution. Under this strategy an applicant can delay the filing of an RCE for more than fifteen months. Of course, this strategy would also require payment of fees for a three-month extension of time, a five-month extension of time, a Notice of Appeal, and an Appeal Brief. It would also accrue seven months of Applicant Delay. However, the USPTO often takes far longer than seven months to examine an application after an RCE is filed. Thus, such a strategy may be worthwhile in some patent applications in which commercial value is likely to be very high at the end of the patent term.

For each case in which it would be possible to strategically delay the filing of an RCE until after the three-year date, careful consideration will need to be given to the amount and value of additional PTA that would be gained from the delay.

III. Recommendations

We recommend that our clients immediately take the following actions, regardless of whether the USPTO appeals the *Exelixis* and *Novartis* decisions:

- (1) Identify any important already-issued patents that have issued within the last 180 days from applications in which an RCE was first filed more than three years after the actual filing date of the application.
- (2) Review the amount of PTA identified on the cover of patents newly issuing from applications in which an RCE was first filed more than three years after the actual filing date of the application.
- (3) Determine for each such patent in (1) and (2) whether the PTA determination may be challenged by a Request for Reconsideration in the USPTO or if it would be necessary to file a civil action. Consider the amount and value of additional PTA that would be gained by a successful challenge to determine whether to pursue a challenge.
- (4) Upon receipt of Notices of Allowance, flag applications in which an RCE was first filed more than three years after the actual filing date of the application, and promptly consider whether the USPTO's PTA determination should be challenged if the RCE time is not included in the amount of PTA identified on the Letters Patent.

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(5) For each case in which a first RCE will be needed before the three-year date, consider the proximity of the upcoming three-year date, the cost of waiting, and the amount and value of additional PTA that might be gained from waiting to file the RCE after the three-year date.

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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