

REPORT

**FEDERAL CIRCUIT HOLDS THAT "TIME CONSUMED
IN CONTINUED EXAMINATION"
ENDS AT ALLOWANCE FOR PTA DETERMINATIONS****January 30, 2014**

On January 15, the Federal Circuit issued a decision in *Novartis AG v. Lee* that requires the U.S. Patent and Trademark Office (USPTO) to change the way it calculates the amount of patent term adjustment (PTA) for patents in which a Request for Continued Examination (RCE) is filed. In summary, the Federal Circuit held that the "time consumed in continued examination" ends on the date a Notice of Allowance is mailed, and thus, for purposes of PTA determination, does not include the time between allowance and issuance, unless prosecution on the merits is reopened.

The USPTO has been counting the entire time from when an RCE is filed to when the patent issues as "time consumed in continued examination." The *Novartis* decision will increase the amount of PTA for some forthcoming patents, and may provide a basis for challenging the USPTO's PTA determination in some recently issued patents.

I. Analysis

As reported in our November 20, 2012 Special Report, "District Courts Expand Patent Term Extensions,"¹ the District Court ruled in favor of Novartis, finding that the term of a 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. In particular, the District Court determined that the USPTO's reduction of "B" delay PTA when a first RCE is filed after the three-year period is contrary to law.

On appeal, the Federal Circuit reversed in part and remanded the case for a redetermination of the proper PTA. Specifically, the Federal Circuit agreed that the USPTO's reading of 35 U.S.C. §154(b)(1)(B)(i) was correct, i.e., no "B" delay PTA is available for any time consumed in continued examination, even if the RCE was filed more than three years after the actual filing date of the application. The Federal Circuit reasoned that this is consistent with (i) the statutory text, which does not set a time-of-initiation restriction for RCEs, and (ii) the underlying policy in PTA calculations that if delays are not "due to the failure" of the USPTO, then they should not count toward the three-year period allotted to the USPTO to issue a patent.

The Federal Circuit nonetheless agreed with Novartis on the issue of when "time consumed in continued examination" ends. In particular, the Federal Circuit rejected the USPTO's argument that the time between allowance and issuance is "time consumed by continued examination" and should be excluded from "B" delay PTA. The Federal Circuit pointed out that the allowance-to-issuance time would count toward the USPTO's three-year allotment in a case not involving an RCE, and concluded that there was no basis for treating an RCE case differently. The Federal Circuit also

¹ Available in English and Japanese in the Resources section of our website, www.oliff.com.

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noted that the common-sense understanding of "time consumed by continued examination" is time up to allowance, but not later, unless examination on the merits is reopened.

II. Recommendations

It will likely take several months for the USPTO to update its systems and PTA-calculating software to comply with the *Novartis* decision. In the meantime, numerous patents in which RCEs were filed have already issued, or will issue, for which the USPTO has not counted the allowance-to-issuance time in its "B" delay PTA calculations. Some of these issued patents may be eligible for several months of additional PTA, but the additional PTA can only be obtained if a Request for Reconsideration of PTA is timely filed with the USPTO.

A patentee is given a two-month period after the issue date of the patent, extendible for up to five additional months, to file with the USPTO a Request for Reconsideration of the PTA indicated on the patent. Thus, patents that are within seven months after their issue date would be eligible for filing such a request pursuant to the *Novartis* decision.²

We recommend that our clients immediately take the following actions:

- (1) Identify any important patents that have issued within the last seven months from applications in which an RCE was filed.
- (2) Review the amount of PTA identified on the cover of patents newly issuing from applications in which an RCE was filed.

- (3) For each such patent identified in (1) and (2), consider the amount and value of additional PTA that would be gained by requesting reconsideration of the PTA indicated on the patent pursuant to the *Novartis* decision (i.e., consider the amount of possible additional PTA based on the allowance-to-issuance time discussed above).
- (4) Upon receipt of Notices of Allowance, flag applications in which an RCE was filed, and promptly consider whether the USPTO's PTA determination should be challenged if the allowance-to-issuance time is not included in the amount of PTA identified on the Letters Patent.

Of course, please do not hesitate to contact us if there are any questions or if we can provide assistance with PTA determinations for a specific matter.

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² The USPTO changed its rules in this regard, effective April 1, 2013. Now, for all patents issuing on or after January 14, 2013, the two-month deadline for filing such a Request may be extended up to five months, i.e., as late as seven months after the issue date of the patent.