

PATENT TERM ADJUSTMENT UPDATE - NOVARTIS V. LEE

A recent ruling by the Federal Circuit in *Novartis AG v. Lee* resolved the issues raised in the *Exelixis I*, *Exelixis II* and *Novartis* decisions regarding the effect of a Request for Continued Examination (RCE) on patent term adjustment (PTA). The Federal Circuit's ruling states that although an RCE filed more than three years after an application's filing date will continue to have an impact on PTA, the time period after allowance until issuance should not necessarily be precluded from any B-term delay calculation. The ruling could significantly add to the terms of impacted U.S. patents.

Statute 35 U.S.C. 154(b)(1)(B) guarantees adjustment of a patent term if the patent is not issued within three years after the filing date of the application (i.e., "B-term delay"). If the patent takes longer than three years from the application filing date to grant, the life of the patent is extended one day for each day after the end of the three-year period until the patent has issued. This three-year guarantee is subject to the limitation of "any time consumed by continued examination of the application requested by the applicant." Prior to this decision, the United States Patent and Trademark Office (USPTO) interpreted the statute to read that the filing of any RCE would preclude any additional B-term delay. Thus, once an RCE was filed, an application would no longer be eligible for any B-term adjustment.

At issue in the *Novartis* case was whether or not PTA should be reduced by the time attributable to an RCE when the RCE is filed after expiration of the three-year date from filing. The Court partially upheld and partially reversed the USPTO's interpretation of the statute. The Court agreed with the USPTO that no adjustment of time is available for any time consumed by continued examination, even if the continued examination was initiated more than three years after the application's filing date. Thus, even if the first RCE for an application is filed more than three years after the application's filing date, no PTA is available under B-delay during the time consumed by continued examination.

The Court, however, rejected the USPTO's argument that the time between allowance and issuance is considered "time consumed by continued examination" and therefore would be excluded from PTA. The Court ruled that an "examination" presumptively ends at allowance because prosecution is closed and there is normally no further examination on the merits. Thus, the

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Court ruled that unless examination on the merits resumes, the time period from the notice of allowance until the application issues is eligible for consideration under B-term delay.

Accordingly, the effect of the Court's decision on an RCE is that instead of an RCE terminating the B-delay "clock," an RCE merely tolls the B-delay clock from the time an RCE was filed until the application is allowed. The takeaway is that a recently issued patent that failed to issue within three years of the filing date of the application may benefit from a review by patent counsel.