

Articles

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A Major Change in Patent Term Adjustment Calculus on Appeal to the Federal Circuit: Steps Applicants May Need to Consider to Preserve Rights

IP Buzz

On November 1, 2012, Judge T.S. Ellis of the U.S. District Court for the Eastern District of Virginia decided *Exelixis, Inc. v. Kappos* (Case No. 1:12-cv-00096). Ruling against the U.S. Patent & Trademark Office (USPTO), Judge Ellis granted summary judgment to the Patentee and held that a Request for Continued Examination (RCE) filed more than three years *after* the effective filing date of a patent application has no impact on Patent Term Adjustment (PTA). (**See November 2012 IP Buzz**). Since the *Exelixis* decision, there have been a few important developments.

On December 31, 2012, the USPTO filed its notice of appeal in *Exelixis*. Given the traditional pace of the Federal Circuit, we expect the Federal Circuit will decide the appeal around the end of 2013.

In addition, since *Exelixis*, approximately fifty cases have been filed by Patentees in the Eastern District of Virginia seeking to take advantage of the decision. As of this writing, it is not clear whether the Court's other judges will adopt Judge Ellis' reasoning, follow *Exelixis*, and quickly grant summary judgment to the patentee. Instead other judges could stay a case relying on *Exelixis* pending outcome of the USPTO's appeal – as was done when *Wyeth v. Kappos* was pending during appeal.

Finally, on November 15, 2012, in *Novartis A.G. et al. v. Kappos*, the U.S. District Court for the District of Columbia (Case No. 1:10-cv-01138-ESH) sided with the reasoning of *Exelixis* and issued a similar ruling. Here again, the USPTO will likely appeal. Thereafter, we anticipate that the USPTO will either move to consolidate the *Novartis* and *Exelixis* appeals or instead request that the *Novartis* appeal be stayed pending the outcome of the *Exelixis* appeal.

Since decision in *Exelixis*, the USPTO has not yet issued a notice as to how it is handling PTA calculations for affected patents. Nor is the USPTO likely to provide any guidance until the issue is resolved by the Federal Circuit or Supreme Court. While the ultimate outcome of *Exelixis* cannot be predicted, if a patentee does not properly and timely challenge the PTO's determination of PTA, then the patentee waives that right to challenge even if there is a subsequent court decision favorably affecting PTA. Accordingly, in the interim, patentees should take steps and preserve their rights for issued and soon to be issued patents affected by *Exelixis* and *Novartis*.

Patentees seeking to challenge the USPTO's determination of PTA can petition the USPTO for a recalculation and/or file a civil action. A civil action challenging a PTA calculation is subject to a 180-day statutory deadline measured from the issue date of the patent. Thus, if a Patentee is interested in pursuing a civil action to challenge the PTO's determination of PTA such a decision should be made well in advance of the 180-day deadline.

Venable's patent prosecutors and intellectual property litigators have considerable experience litigating in the Eastern District of Virginia. Our attorneys include many former Eastern District of Virginia judicial clerks and are leaders in the Northern Virginia Chapter of the Federal Bar Association. We welcome the opportunity to discuss and analyze with you the possibility of bringing an action in the Court to obtain a patent term adjustment. Please do not hesitate to contact us if have any questions regarding PTA calculations or challenging PTA with a civil action.

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