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Exelixis Revisited: Conflict in Determining Patent Term Adjustment

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On January 28, 2013, the U.S. District Court for the Eastern District of Virginia issued a decision in *Exelixis, Inc. v. Kappos* (Case No. 1:12-cv-00574-LMB-TRJ), holding that the U.S. Patent and Trademark Office ("PTO") has been correctly calculating patent term adjustments ("PTA") for patent applications in which a Request for Continued Examination ("RCE") was filed more than three years after the filing date of the application. The decision comes on the heels of a November 1, 2012 decision by the same name - *Exelixis, Inc. v. Kappos* (Case No. 1:12-cv-00096-TSE-TCB) - that held exactly the opposite.

A summary of the November 2012 Exelixis decision ("Exelixis I") and a more detailed discussion of the issues involved in both Exelixis cases, can be found **here**.

Under the relevant statute, a patent applicant is entitled to receive an extension of patent term for each day beyond the three-year pendency of the application, excluding certain delays caused by the applicant. At issue in both *Exelixis* cases was whether, under the language of 35 U.S.C. § 154(b)(1), an applicant is entitled to PTA for the time an application spends in continued examination when an RCE is filed after the three-year pendency date. The PTO contended in both cases that the statute excludes from PTA any time consumed by continued examination, no matter when an RCE is filed. By contrast, Exelixis argued that the filing of an RCE after the three-year time period does not toll accruing B-delay, though it conceded that an RCE prior to the three-year time period does toll B-delay.

In *Exelixis I*, the Court sided with Exelixis and held that RCEs "operate only to toll the three year guarantee deadline, if, and only if, they are filed within three years of the application filing date." Thus, the Court held that RCEs filed after the three-year deadline passes have no effect on PTA. In contrast, the more recent *Exelixis* decision ("*Exelixis II*") sides with the PTO and holds that RCEs, no matter when they are filed, serve to toll B-delay. Under *Exelixis II*, time consumed by continued examination is always excludable from PTA calculation.

In particular, in ***Exelixis II***, the Court affirmed the PTO's interpretation of 35 U.S.C. § 154(b)(1), finding that "a reasonable interpretation of the statute and its legislative history support the conclusion that there is no reason to treat RCEs differently upon when they were filed, and that accordingly, the PTO's regulation deserves Skidmore deference because it is a reasonable conclusion as to the proper construction of the statute." The Court highlighted the statute's legislative history, which indicates that time consumed in continued examination "shall not be considered delay by the USPTO," and congressional concern "about the potential for applicants to manipulate procedural devices to prolong the PTO's examination" to the applicants' advantage.

The Court in *Exelixis II* also agreed with the PTO's decision to deny PTA for the period between the mailing of the notice of allowance and the issuance of the patent following continued examination. Despite Exelixis' arguments to the contrary, the Court found that this "delay emanates from the applicant's original failure to file an application fit for allowance" and, therefore, an applicant is precluded from accruing B-delay even during "otherwise routine processing [delays] that directly precede[ ] patent issuance."

Exelixis I was appealed to the U.S. Court of Appeals for the Federal Circuit late last year. It is likely that *Exelixis II* will be appealed as well, and consolidated with *Exelixis I* once the Federal Circuit assumes jurisdiction. The Federal Circuit is expected to issue a decision in late 2013.

By statute (amended January 14, 2013), patentees unsatisfied with the PTO's determination of PTA must first petition the PTO for a recalculation. If the patentee remains unsatisfied with the recalculation determination, she can file a civil action in the Eastern District of Virginia to challenge the PTO's recalculation. This civil action is subject to a 180-day deadline measured from the date of the PTO's recalculation decision. It is unlikely that the 180-day window will be tolled pending a decision in the Exelixis cases, although there is now no consensus on whether RCE time is excluded from PTA. Thus,

it remains imperative for patentees wishing to file a civil action challenging the PTO's calculation of PTA to file their case promptly after receiving a recalculation decision.

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.