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Recent Developments Relating to Patent Term Adjustments

2013-01-23

In the last few months, there have been important developments relating to patent term adjustment (PTA) determinations by the U.S. Patent and Trademark Office (PTO) under 35 U.S.C. § 154(b) and judicial challenges to those determinations.

The Deadline for Filing a Lawsuit Challenging a PTA Determination

Both the courts and Congress have recently addressed the procedure for bringing judicial challenges to PTA determinations.

First, in September 2012, the U.S. District Court for the District of Columbia affirmed a prior decision of the court holding that the 180-day deadline under 35 U.S.C. § 154(b)(4)(A) for filing a lawsuit challenging a PTA determination was tolled in the circumstances of that case by the patent holders' timely requests for reconsideration of the PTA determinations set forth in the patents at issue. See *Bristol-Myers Squibb Co. v. Kappos*, 2012 WL 4127636 (D.D.C. Sept. 20, 2012) (denying reconsideration of the decision published at 841 F. Supp. 2d 238). The reasoning of the *Bristol-Myers* court was recently adopted by another judge of the D.C. District Court in a November 15, 2012 decision. *See Novartis AG v. Kappos*, 2012 WL 5564736 (D.D.C. 2012). (WilmerHale was counsel for Bristol-Myers Squibb Co. in its successful challenge.)

Second, on January 14, 2013, President Obama signed into law H.R. 6621, which makes a number of "technical corrections" to the America Invents Act. Included within this law is a provision amending the PTA statute. Among other things, the provision changes the text of the provision of § 154(b) relating to lawsuits challenging PTA decisions. As amended, § 154(b)(4)(A) will include the following new language (in italics):

> An applicant dissatisfied with *the Director's decision on the applicant's request for reconsideration under paragraph 3(B)(ii) shall have exclusive remedy* by a civil action against the Director filed in the United States District Court for the Eastern District of Virginia within 180 days after *the date of the Director's decision on the applicant's request for reconsideration*.

The new law provides that "the amendments made by this Act shall take effect on the date of enactment of this Act, and shall apply to proceedings commenced on or after such date of enactment."

PTA Calculation When an RCE Is Filed More Than Three Years After Application

On November 1, 2012, the U.S. District Court for the Eastern District of Virginia held that the PTO has been improperly calculating PTA in cases where an RCE is filed more than three years after the patent application was submitted. *See Exelixis, Inc. v. Kappos*, 2012 WL 5398876 (E.D. Va. 2012).

Subject to certain exceptions, a patent holder is entitled to a patent term adjustment if (among other things) the PTO fails to issue the patent within three years of submission of the patent application. See 35 U.S.C. § 154(b)(1)(B). The PTO has long taken the position in calculating this so-called "B delay" that "any time consumed by an RCE is subtracted from the PTA awarded under subparagraph (B), regardless of when the RCE is filed." *Exelixis*, 2012 WL 5398876, at *5; see also 37 C.F.R. § 1.703(b). In a decision that could provide significant benefits to patent holders, however, the court in *Exelixis* rejected that interpretation.

Applying the "plain and unambiguous language" of § 154(b), the *Exelixis* court explained that "subparagraph (B) does not address RCE's filed after the running of the three year period nor does it require that the time consumed by an RCE filed after the running of the three year clock be deducted from the PTA." *Exelixis*, 2012 WL 5398876, at *7. In other words, "RCE's have no impact on PTA if filed after the three year deadline has passed." *Id*. at *8.

The reasoning of the *Exelixis* court was endorsed by the U.S. District Court for the District of Columbia in the November 15, 2012 *Novartis* decision. The *Novartis* court similarly found that "the PTO's interpretation is contrary to the plain and unambiguous language of § 154(b)(1)(B), and that it contravenes the structure and purpose of the statute." *Novartis* AG, 2012 WL 5564736, at *13.

Since the decision in *Exelixis*, a number of complaints have been filed in the Eastern District of Virginia invoking the *Exelixis* court's interpretation of § 154(b) and challenging PTA determinations in cases where RCEs were filed more than three years after the patent applications were submitted.

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Taken together, these developments provide important opportunities for patent holders to ensure that they have received the entire PTA to which they are legally entitled.