

RCEs HAVE NO IMPACT ON PTA IF FILED AFTER THE THREE YEAR DEADLINE HAS PASSED

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I. ACRONYMS AND DEFINITIONS

Let's get the acronyms and definitions out of the way:

USPTO -United States Patent and Trademark Office

PTA - Patent Term Adjustment. An amount of time the USPTO adds to the base term of the patent, due to delays in issuing the patent.

RCE - Request for Continued Examination. A request filed by a patent applicant after prosecution in their application is closed, for additional consideration by the USPTO of patentability of their patent application.

AIA - The America Invents Act.

EDVA - The Eastern District of Virginia federal district court.

DDC - The District Court for the District of Columbia federal district court.

II. IMPACT OF AN RCE ON PTA

Exelixis, Inc. v. Kappos, (E.D. Va. 11/1/2012) is an important case affecting the term of patents issuing from a substantial fraction of patent applications; almost all applications in which one or more RCEs have been filed. In Exelixis, the Court concluded that the USPTO has been incorrectly calculating PTA in those patents in a manner resulting in substantially less PTA than that to which the patents were entitled. Applicants should therefore *re-review to redetermine* PTA in any allowed application before paying the issue fee, because the time at which the issue fee is paid is the deadline for contesting the USPTO's pre-issuance PTA determination. Patentees should also review the PTA accorded to their patents issued within the last 180 days to see whether they were short changed on PTA. This is because 180 days from date of issuance of a patent is the time allotted by statute for filing a civil action contesting the PTA accorded by the USPTO.

In Exelixis, Judge Ellis held that "RCE's have no impact on PTA if filed" more than three years after the patent application was filed. The Court's decision makes clear that the USPTO procedure of failing to count application pendency time occurring after the filing of an RCE which was filed more than 3 years after the filing date of the application, as PTA, is generally not in accordance with law.

Judge Ellis concluded that 35 USC 154(b)(1)(B), titled "GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY" meant what the title said. That, if the USPTO had not concluded prosecution within 3 years, then the USPTO had to include the additional application pendency beyond 3 years as part of "B" type PTA regardless whether the applicant filed an RCE after the three year date.

III. THE COURT'S ANALYSIS OF 35 USC 154(b)(1)(B)

What 35 USC 154(b)(1)(B) says, in relevant part, is that:

(B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY. ... if the issue of an original patent is delayed due to the failure of

the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States, not including— (I) any time consumed by continued examination of the application requested by the applicant under section 132(b) [sic; by filing an RCE] ..., the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

Judge Ellis concluded that the “*not including*” referred back to the “*within 3 years after the actual filing date of the application in the United States*” and therefore only applied to RCEs filed during the first three years after the application's filing date. (Stating that: "In other words, the 'not including' portion of subparagraph (B), followed by (I), (ii), and (iii), clearly and unambiguously modifies and pertains to the three year period and does not apply to, or refer to, the day for day PTA remedy.")

The USPTO, by rule 37 CFR 1.703(b)(1), had subtracted from putative PTA “(1) The number of days, if any, in the period beginning on the date on which a request for continued examination [RCE] of the application under 35 U.S.C. 132(b) was filed and ending on the date the patent was issued.” This rule is not consistent with the Court’s conclusion that 35 USC 154(b)(1)(B) (“B” type PTA) does not apply to RCEs filed after the three year period, because the rule is not conditional on the filing of an RCE within 3 years from the application's filing date. Arguably, the rule is also not consistent with 35 USC 154(b)(1)(B) because the rule does not specify that the ending for the period of time subtracted from putative PTA is the date three years after the filing date of the application.

Judge Ellis also concluded that "Subparagraph (B)'s second calculation is simply a day for day addition to the PTA for every day beyond the end of the three year clock until the patent issues. ... subparagraph (B) makes clear that once the three year clock has run, PTA is to be awarded on a day for day basis regardless of subsequent events." He also concluded that "In sum, the plain and unambiguous language of subparagraph (B) requires that the time devoted to an RCE tolls the running of the three year clock if the RCE is filed within the three year period. And, put simply, RCE's have no impact on PTA if filed after the three year deadline has passed."

There is some ambiguity regarding whether the tolling due to an RCE filed during the three year period extends to *after* the three year period. Dicta in the Exelixis opinion indicates that tolling continues after three year period. Some of my colleagues have privately indicated their belief that the tolling continues such that no "B" type PTA accrues once an RCE is filed within 3 years of the application's filing date. However, that dicta seems inconsistent with statutory language suggesting unconditional PTA for the period "after the end of that 3-year period until the patent is issued." Hence, this issue regarding how long "B" delay is tolled, is left open for decision in some other case challenging PTA determination.

IV. CHALLENGING THE USPTO'S PTA DETERMINATIONS, PRE-ISSUANCE

A. PTA DETERMINATIONS BY THE USPTO PRE-ISSUANCE

By rule, an applicant can only contest the USPTO's pre-issuance determination of PTA by doing so prior to or concurrent with paying the issue fee. 37 CFR 1.705(b) and (d). Accordingly, the applicant should calculate PTA before paying the issue fee to determine if the USPTO miscalculated the PTA. If the applicant filed a request to correct PTA prior to or concurrent with

paying the issue fee, that application issues into a patent, and the PTA on the issued patent fails to provide the requested PTA, the patentee has two months from the date of issue of the patent to file in the USPTO a petition asking the USPTO to provide the originally requested PTA. 37 CFR 1.705(d).

B. PTA DETERMINATIONS BY THE USPTO POST-ISSUANCE

Regarding rule 1.705(d), the following is significant. The USPTO published a notice October 6, 2009 at 1347 OG 49 titled "Notice Concerning Calculation of the Patent Term Adjustment under 35 U.S.C. § 154(b)(1)(B) involving International Applications Entering the National Stage Pursuant to 35 U.S.C § 371" (herein after "Notice"). The Notice facially dealt with the fact that the USPTO was having problems programmatically calculating the type B PTA in PCT national stage applications (371 applications). However, the Notice concluded with the statement that:

The USPTO does not calculate and inform the applicant of the patent term adjustment based upon the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B) in the notice of allowance because the USPTO must know the date the patent will issue to be able to calculate the patent term adjustment based upon this provision. Thus, reconsideration of the patent term adjustment indicated in the patent as it relates to the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B) is not considered a matter that could have been raised in an application for patent term adjustment under 37 CFR 1.705(b) (provides for reconsideration of the patent term adjustment indicated in the notice of allowance). Therefore, a request for reconsideration of the patent term adjustment calculation based on the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B) will be considered timely under 37 CFR 1.705(d) if filed within two months of the date the patent issued.

Subsequent to the Notice, the USPTO has been dismissing, as premature, all pre-issuance applications for PTA correction that include "B" type PTA on the basis that "B" type PTA is uncertain at the time of allowance. The USPTO has been suggesting to applicants that "B" type delay should only be raised via a post issuance 1.705(d) petition. However, the last sentence of rule 1.705(d) requires that "Any request for reconsideration under this section that raises issues that were raised, or could have been raised, in an application for patent term adjustment under paragraph (b) of this section shall be dismissed as untimely as to those issues." In other words, one cannot raise in a PTA issue post issuance 1.705(d) petition that which one could have but failed to raise in a pre-issuance application for PTA correction. At time of allowance, if there is accumulated "B" type PTA, that appears to require the filing of a pre-issuance application for PTA correction in order to preserve the right to again request the accumulated "B" type delay in a post issuance rule 1.705(d) petition. The Notice is also unclear because its title indicates that it only relates to 371 applications and therefore does not expressly apply to non 371 applications. In addition, the fact that the USPTO considers "B" type delay "a matter that could have been raised in an application for patent term adjustment under 37 CFR 1.705(b)" is factually incorrect. Whenever there is "B" type delay at time of allowance, the matter of "B" type PTA can be raised

in an application for patent term adjustment under 37 CFR 1.705(b). The fact that additional "B" type delay may accumulate until time of issuance does not change the existence and amount of "B" type PTA at time of allowance. Clearly, this accumulated "B" type delay could have been raised in a pre-issuance application for PTA correction. Accordingly, applicants and patentees relying upon the Notice as a basis to not file under 1.705(b) for "B" type PTA, pre-issuance, and only file for "B" type PTA, under 1.705(d), post issuance, may be faced with an argument in some subsequent litigation that their patent term ends without any benefit of "B" type PTA.

C. TOLLING BASED UPON FILING OF A 1.705(d) PETITION

By statute, a patentee can contest the USPTO's determination of PTA by filing a civil action within 180 days after issuance of the patent. Janssen Pharmaceutica, NV v. Kappos, (EDVA 2/10/2012)("180-day statute of limitations beginning from the date a patent issues, regardless of whether any request for reconsideration of PTA is pending before the USPTO"); *but see* Bristol-Myers Squibb Co. v. Kappos, 841 F. Supp. 2d 238, 242-43 (DDC 9/20/2012) ("Congress affirmatively intended for the tolling rule to apply to judicial review of patent term adjustment determinations"). Pursuant to changes implemented by the AIA, any civil action by the patentee to correct PTA can only be filed in the EDVA. 35 USC 154(b)(4)(A); Janssen, *supra*, at footnote 7. These two cases suggest a split in the District Courts regarding whether tolling applies when a post issuance PTA petition is filed in the USPTO. At least because jurisdiction for all patentee instituted PTA civil actions is now in the hands of the EDVA; and the decision concluding that tolling applied was in the DDC and is in apparent conflict with EDVA dicta; and the time for appeal by the USPTO of the DDC decision has not run (as of the writing of this article in November, 2012), the USPTO should appeal the DDC decision (in Bristol-Myers Squibb Co.). This is because a decision of the CAFC would be binding on the EDVA (as well as all other District Courts) and provide both patentees and the USPTO security in knowing the rule of law regarding tolling of 35 USC 154(b)(4)(A) resulting from filing a 1.705(d) petition, for both 154(b)(4)(A) patentee instituted civil actions and 154(b)(4)(B) third party challenges to accorded PTA.

D. IMPACT OF FAILING TO CONTEST PTA, PRE-ISSUANCE

Some of my colleagues have privately questioned whether a patentee's failure to contest pre-issuance PTA bars a civil action, based upon the doctrine of exhaustion of administrative remedies. Case law largely answers this question. From Darby v. Cisneros, 509 US 137, 154 (1993) and subsequent cases directed to PTA civil actions, it is very likely that the doctrine of exhaustion does not apply to such cases. In Darby, the Court stated:

But where the APA applies, an appeal to "superior agency authority" is a prerequisite to judicial review only when expressly required by statute or when an agency rule requires appeal before review and the administrative action is made inoperative pending that review. Courts are not free to impose an exhaustion requirement as a rule of judicial administration where the agency action has already become "final" under § 10(c).

Subsequent cases have construed a civil action for correction to PTA of an issued patent to be governed in essential respects, by the APA, as noted below. Civil actions for correction of

PTA, by the patentee, are specified by 35 USC 154(b)(4)(A). It reads:

(A) An applicant dissatisfied with a determination made by the Director under paragraph (3) shall have 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 grant of the patent. Chapter 7 of title 5 shall apply to such action. Any final judgment resulting in a change to the period of adjustment of the patent term shall be served on the Director, and the Director shall thereafter alter the term of the patent to reflect such change.

The reference "Chapter 7 of title 5 " is a reference to the Administrative Procedures Act (APA; which is codified at 5 USC et seq.). This suggests that the provisions of the APA apply to civil actions for PTA. The Court in Janssen agrees. Note 7 in Janssen reads:

Section 154(b)(4)(A)'s explicit reference to and incorporation of the APA completely undermines plaintiff's argument that defendants' reading repeals the APA by implication. The patent statute merely imposes an exclusive forum requirement and a statute of limitations on civil actions that, in all other respects, must proceed pursuant to APA procedures.

Since all new PTA civil actions will be heard in the EDVA, and it is that Court's law that the APA governs PTA actions, other than the requirements of forum and statute of limitations, it is very likely that the EDVA will conclude that all other provisions of the APA govern such PTA actions. As noted in Darby, the APA specifies that there is no doctrine of exhaustion, except where a statute governed by the APA or implementing regulations thereof specifically requires exhaustion. Neither 35 USC 154(b)(4)(A) (a statute apparently governed by the APA) nor the implementing USPTO regulations require exhaustion. This indicates that the EDVA will conclude that a patentee that failed to request the USPTO to correct PTA (that is, a patentee that failed to exhaust the administrative remedies) is not barred from PTA relief via a civil action pursuant to 35 USC 154(b)(4)(A).

It is also likely that the Court of Appeals for the Federal Circuit (CAFC) would agree with note 7 in Janssen, because Janssen's conclusions that the APA generally applies to patentee initiated PTA civil actions is consistent with how the CAFC reads the requirements of Darby and its progeny. Specifically, in Martinez v. US, 333 F. 3d 1295 (Fed. Cir. 2003), the CAFC quoted from earlier cases that the proposition that the statutory scheme dictated by Congress indicated whether Congress intended the doctrine of exhaustion to apply to any particular statutory section. That is relevant because it implies that the CAFC would agree with the Janssen Court's understanding of the statutory scheme applicable to civil actions under 35 USC 154(b)(4)(A).

E. **ADDITIONAL ISSUES**

Additional issues addressed judicially are (1) whether the pendency of a 1.705(d) petition in the USPTO bars a civil action until after the petition is decided and (2) whether APA forum selection instead of only the EDVA forum specified by 154(b)(4)(A), is available, when the patentee had filed, and as consequence of the filing of, a pre-issuance request for PTA correction.

In summary, relevant cases indicate that the EDVA is the exclusive jurisdiction for patentee initiated PTA civil actions and that an undecided 1.705(d) petition does not bar a patentee initiated PTA civil action. See Janssen, supra, Human Genome Sciences, Inc. v. Kappos, 738 F. Supp. 2d 120, 123 (DDC 2010); Bristol-Myers Squibb Co., supra.

Regardless of the ultimate harmonization of law on these issues, the prudent course of action is for an applicant to always request PTA correction in the USPTO pre-issuance, the patentee to always file a 1.705(d) petition post issuance, and the patentee to always file a 154(b)(4)(A) PTA civil action within 180 days of issuance of a patent, in the EDVA, whenever the USPTO's PTA determinations are believed to short change PTA.

V. **APPELLATE REVIEW OF EXELIXIS, INC. V. KAPPOS**

It is likely that the USPTO will appeal. This is because both patentees and the USPTO need certainty in the law on how PTA accrues and a district court decision provides insufficient certainty for those needs. Moreover, unlike 35 USC 154(b)(4)(A), which requires a PTA civil action instituted by the patentee to be filed in the EDVA, a 35 USC 154(b)(4)(B) PTA civil action by a third party is not so limited. Accordingly, it is likely that when it comes time for third party litigants to challenge in court patent term resulting from PTA determinations, that challenge will likely not occur in the EDVA, and therefore the EDVA's Exelixis decision will not be binding. Accordingly, the USPTO should appeal in this case in order to obtain a decision from the CAFC that would be binding on all District Courts, to thereby preclude third party challenges on that same issue in some court other than the EDVA. These end of term challenges would presumably arise during the putative PTA periods of patents, and therefore start cropping up in the near future.

Because the Exelixis case presents a pure issue of statutory construction, the CAFC will perform complete and independent review. In re Carlson, 983 F.2d 1032, 1035, 25 USPQ2d 1207, 1209 (Fed. Cir. 1992). However, Judge Ellis's decision indicates his belief that this issue was not even a close call. Accordingly, it is likely that the CAFC will also conclude that this issue was not even a close call, and affirm.

VI. **TIMING CONSIDERATIONS FOR THE FILING OF RCEs**

It is currently unclear whether 35 USC 154(b)(1)(B) tolling resulting from the filing of an RCE continues to the date of issuance. If it does, then the amount of PTA lost due to filing of an RCE shortly before 3 years after the date of filing of an application may greatly exceed the amount of PTA lost due to delays in filing the RCE until just after 3 years from the date of filing the application. These factors, along with projected time to allowance after the filing of an RCE, should be taken into account when deciding whether to delay filing of an RCE.

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