

August 18, 2014

Mail Stop Comments – Patents Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Attention: Mr. Kery Fries Senior Legal Advisor Office of Patent Legal Administration Office of the Deputy Commissioner for Patent Examination Policy

Re: Comments to Notice of Proposed Rulemaking Changes to Patent Term Adjustment in View of the Federal Circuit Decision in Novartis v. Lee, Docket No.: PTO-P-2014-0023

Dear Mr. Fries:

McCarter & English, LLP ("McCarter") thanks the United States Patent and Trademark Office (the "USPTO") for the opportunity to comment on its recent proposal to change the rules of practice pertaining to the patent term adjustment ("PTA") provisions of 35 U.S.C. § 154(b) in view of the decision by the U.S. Court of Appeals for the Federal Circuit in *Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014).

McCarter is a firm with a full-service intellectual property practice serving clients ranging from Fortune 100 companies to mid-market and emerging growth companies to universities to individuals in patent prosecution, patent litigation and postgrant review proceedings before the USPTO. For a number of years, McCarter has litigated PTA issues on behalf of firm clients, including Novartis AG ("Novartis"). Indeed, this firm represented Novartis before the Federal Circuit in *Novartis AG v. Lee*, the case that precipitated this proposed rulemaking. As such, McCarter is extremely familiar with the relevant PTA rules as well as the Federal Circuit ruling in *Novartis AG v. Lee*.

Partner T. 973.848.5388 F. 973.297.3981 schristie@mccarter.com

Scott S. Christie

McCarter & English, LLP Four Gateway Center 100 Mulberry Street P.O. Box 652 Newark, NJ 07102 T. 973.622.4444 F. 973.624.7070 www.mccarter.com

BOSTON

HARTFORD

NEW YORK

NEWARK

PHILADELPHIA

STAMFORD

WASHINGTON, DC

WILMINGTON

. . .

I. AMENDMENTS PROPOSED BY THE USPTO

The text of the proposed amendments to 37 C.F.R. §§ 1.703 and 1.704 as provided in the Federal Register (79 Fed. Reg. 34681, 34685) is shown below:

§1.703 Period of adjustment of patent term due to examination delay.

(b) The period of adjustment under § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application and ending on the date a patent was issued, but not including the sum of the following periods:

(1) The number of days, if any, in the period beginning on the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date the patent was issued of mailing of a notice of allowance under 35 U.S.C. 151, unless prosecution in the application is reopened, in which case the period of adjustment under § 1.702(b) also does not include the number of days, if any, in the period or periods beginning on the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was filed or the date of mailing of an action under 35 U.S.C. 132(b) was filed or the date of mailing of an action under 35 U.S.C. 132, whichever occurs first, and ending on the date of mailing of a subsequent notice of allowance under 35 U.S.C. 151;

§ 1.704 Reduction of period of adjustment of patent term.

(a) The period of adjustment of the term of a patent under \S 1.703(a) through (e) shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution (processing or examination) of the application.

(c) Circumstances that constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application also include the following circumstances, which will result in the following reduction of the period of adjustment set forth in § 1.703 to the extent that the periods are not overlapping:

> (12) Submission of a request for continued examination under 35 U.S.C. 132(b) after a notice of allowance under 35 U.S.C. 151 has been mailed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the date of mailing of the notice of allowance under 35 U.S.C. 151 and ending on the date the request for continued examination under 35 U.S.C. 132(b) was filed;

The USPTO proposes to amend 37 C.F.R. $\S1.703(b)(1)$ to establish that the time period from the mailing of the notice of allowance to patent issuance will accrue as Type B PTA, "unless the Office actually resumes examination of the application after allowance." 79 Fed. Reg. at 34682. The USPTO states that such an amendment is required to implement the decision of *Novartis AG v. Lee. Id.* The USPTO further proposes to amend 37 C.F.R. \$1.704(c) to characterizes submission of an RCE after a notice of allowance has been mailed as a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. *Id.* The USPTO rationalizes this proposed change as a means to ensure that applicants do not obtain multiple periods of PTA under 35 U.S.C. \$154(b)(1)(B) for the time after a notice of allowance as a consequence of delaying issuance of the application by filing RCEs after a notice of allowance. *Id.* at 34683.

For the following reasons, McCarter respectfully submits that these proposed amendments to 37 C.F.R. §§ 1.703 and 1.704 are not supported by the holding of *Novartis AG v. Lee* and, moreover, inappropriately penalize patentees through deprivation of Type B PTA not only for instances where a subsequent request for continued examination ("RCE") does not result in any further actual examination, but also for delay not initiated by an applicant

II. THE PROPOSED AMENDMENTS TO 37 C.F.R. §§ 1.703 AND 1.704 RUN CONTRARY TO THE DECISION IN *NOVARTIS AG V. LEE*

The Federal Circuit in *Novartis AG v. Lee* neither contemplated nor mandated a revision to PTA regulations to address anything other than a correction to the Office's misinterpretation of 35 U.S.C. § 154(b) to include the period of time between allowance and issuance after an initial period of continued examination as cognizable Type B PTA. Indeed, the *Novartis* Court took great care to indicate that events after allowance that resume examination are "exceptional":

The common-sense understanding of "time consumed by continued examination," 35 U.S.C. § 154(b)(1)(B)(i), is time up to allowance, but not later, unless examination on the merits resumes.

The PTO identifies several circumstances in which affirmative action is taken to resume examination after allowance, perhaps based on new information submitted by applicants in fulfillment of their continuing duty to disclose information material to patentability, 37 C.F.R. § 1.56. But such circumstances are exceptional, and an appropriate adjustment can be made when they occur. For none of the three applications at issue does the PTO identify any "continued examination of the application" that occurred after the notice of allowance was mailed. The possible existence of these exceptional cases does not support a general rule excluding time between allowance and issuance.

Novartis AG v. Lee, 740 F.3d 593, 602 (Fed. Cir. 2014) (emphasis added) (citations omitted). The *Novartis* Court clearly determined that the type of general rules now proposed by the USPTO are unwarranted and unnecessary.

Furthermore, the USPTO's proposed amendments to 37 C.F.R. §§ 1.703(b)(1)and 1.704(c) treat post-allowance prosecution time differently depending on whether an RCE already had been filed. If an RCE previously has been filed, the USPTO proposes to exclude from accrual of Type B PTA all prosecution time that occurs post-allowance. However, if no RCE previously has been filed, prosecution time that occurs postallowance may accrue as Type B PTA. Such a dichotomy is in tension with *Novartis AG v. Lee*, which held that time spent in continued examination does not count toward

. . .

Type B PTA accrual, regardless of when the continued examination begins, but that time from allowance to issuance does count toward Type B PTA accrual, regardless of whether it is a continued-examination case. *See Novartis*, 740 F.3d at 601-02. The *Novartis* Court dictates that the USPTO may not distinguish between continued-examination cases and non-continued-examination cases in this manner, contrary to the proposed amendments to 37 C.F.R. §§ 1.703(b)(1) and 1.704(c)(12).

The USPTO's attempt to reach beyond the rulings of *Novartis AG v. Lee* is reckless and will produce disruptive and contentious results. It is not appropriate to extend *Novartis AG v. Lee* in this manner, particularly when patent term is at stake, with each day of term having a potential value of millions of dollars to a patentee. The USPTO should exercise appropriate restraint and caution by revising the PTA regulations only in a manner that comports with the holding of *Novartis AG v. Lee*.

Accordingly, we submit that implementing the decision in *Novartis AG v. Lee* requires no amendment to 37 C.F.R. \$1.704(c) and only the following amendment to 37 C.F.R. \$1.703(b)(1):

§1.703 Period of adjustment of patent term due to examination delay.

(b) The period of adjustment under § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application and ending on the date a patent was issued, but not including the sum of the following periods:

> (1) The number of days, if any, in the period beginning on the date on which **a** <u>an initial</u> request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date the patent was issued of mailing of **a** <u>an initial</u> notice of allowance under 35 U.S.C. 151, unless prosecution in the application is reopened, in which case the

> period of adjustment under § 1.702(b) also does not include the number of days, if any, in the period or periods beginning on the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was filed or the date of mailing of an action under 35 U.S.C. 132, whichever occurs first, and ending on the date of mailing of a subsequent notice of allowance under 35 U.S.C. 151;

III. THE PROPOSED AMENDMENT TO 37 C.F.R. § 1.704 ALSO IS UNWARRANTED BECAUSE FILING AN RCE DOES NOT CONSTITUTE A FAILURE TO ENGAGE IN EFFORTS TO CONCLUDE PROCESSING OR EXAMINATION OF AN APPLICATION

The USPTO's proposed amendment to 37 C.F.R. 1.704(c)(12) likewise is inappropriate because it already has conceded that the mere filing of an RCE by a patent applicant does not constitute failure to prosecute in a timely manner.

Nor is there anything odd about excluding RCE time from the calculation of B delay when the USPTO has chosen not to include RCE time in the list of delays that are due to failure of an applicant "to engage in reasonable efforts to conclude prosecution of the application," which are set out in its regulations at 37 C.F.R. § 1.704. *See* 35 U.S.C. § 154(b)(2)(C). RCEs serve a valuable function in the patent application process and not every RCE reflects a failure to engage in reasonable efforts.

See Brief for the United States Patent and Trademark Office filed May 13, 2013, Novartis v. Rea (Fed. Cir. 13-1160), at 35. Despite this admission, the USPTO now contends that an RCE does constitute a failure to engage in efforts to conclude processing or examination of an application, but only if that RCE is filed after allowance. It defies logic that an RCE, which when filed before allowance, *e.g.*, to submit an information disclosure statement ("IDS"), is appropriate conduct in furtherance of prosecution somehow transforms into activity that fails to constitute efforts to conclude processing or examination simply because a notice of allowance already has been mailed.

The USPTO asserts that the amended §1.704(c) will prevent an applicant from obtaining multiple periods of Type B PTA for the time after allowance as a consequence of delaying issuance by filing multiple RCEs. But, the USPTO's most recent statistics reinforce that such concerns are speculative at best. No RCE is ever filed in approximately 75% of all patent applications. Where RCEs are filed at all, only one is filed in approximately 18% of all applications, and two are filed in only 5% of all applications. Applications in which three RCEs are filed constitute the remaining 2%. *See* Statistics Related to RCEs, at slide 5, *available at* http://www.uspto.gov/patents/init_events/rce_outreach.jsp. Applicants are not engaging in serial RCE filings because the goal of an RCE is to achieve valid patent issuance, not endless prosecution delay.

Furthermore, to the extent the USPTO fears that applicants may file an unlimited number of RCEs, it ignores that an applicant has a legal right to engage in RCE practice. *See* 35 U.S.C. § 132(b). The Office previously considered regulatory revisions to RCE practice, including limiting the number of RCEs that an applicant could file, yet rescinded the proposed rules in the face of withering criticism from the patent bar and a lawsuit that sought to prevent the rules from taking effect. *See USPTO Rescinds Controversial Patent Regulations Package Proposed by Previous Administration*, Press Release, 09-21 (Oct. 8, 2009), *available a*t http://www.uspto.gov/news/09 21.jsp.

If the USPTO desires to implement new procedural rules governing RCE practice – like limiting the number of RCEs per application, limiting the permissible bases for second or third filed RCEs, or progressively increasing fees for successive RCEs – there is a process through which it may do so. *See Tafas v. Doll*, 559 F.3d 1345, 1351-53, 1359 (Fed. Cir. 2009), *reh'g en banc granted, opinion vacated*, 328 F. App'x 658 (Fed. Cir. 2009). But absent a change in the current statutory regime, applicants are within their rights to pursue continued examination of their applications

by engaging in RCE practice and should receive PTA according to the plain language interpretation of the statute, including Section 154(b)(1)(B)

IV. ALTERNATIVE PROPOSED AMENDMENTS TO 37 C.F.R. § 1.703

As demonstrated above, the only amendment to 37 C.F.R. \$1.703(b)(1) required by *Novartis AG v. Lee* excludes the time period between the filing of an initial RCE and the mailing of an initial notice of allowance from accrual as Type B PTA. In the event that the USPTO does not embrace this position, McCarter proposes alternative revisions to the 37 C.F.R. \$1.703(b)(1).

A. <u>The USPTO Cannot Exclude from Type B PTA the Period Beginning on</u> the Date on which an RCE is Filed After Issuance of an Initial Notice of Allowance and Ending on the Date of Mailing of a Subsequent Notice of Allowance Unless Examination is Actually Reopened

The USPTO proposes to exclude from Type B PTA accrual one of two time periods for activities occurring after allowance, whichever occurs first: (1) the number of days in the period or periods beginning on the date on which an RCE of the application under 35 U.S.C. §132(b) was filed and ending on the date of mailing of a subsequent notice of allowance under 35 U.S.C. §151; or (2) the number of days in the period or periods beginning on the date of mailing of an action under 35 U.S.C. §132 and ending on the date of mailing of a subsequent notice of allowance under 35 U.S.C. §151. We respectfully submit that the USPTO is prohibited from including the first period of exclusion in the proposed amendment to 37 C.F.R. §1.703(b)(1) based upon the express language in *Novartis v. Lee*.

There is no justification for excluding the period from filing of a subsequent RCE to mailing of a subsequent notice of allowance from Type B PTA unless the filing of this subsequent RCE triggers the mailing of an office action under 35 U.S.C. §132. Indeed, it is instructive to note that one of the patents included in the *Novartis* lawsuit, *i.e.*, U.S. Patent No. 7,973,031 (the "031 patent"), had three RCEs filed during

. . .

pendency. The first RCE was filed with a response to a final office action; the second was filed after an initial notice of allowance in order to submit an IDS to the Office in compliance with 37 C.F.R. §1.56; and the third was filed after a second notice of allowance, again in order to submit an IDS to the Office in compliance with 37 C.F.R. §1.56. These second and third RCEs (with IDSs) **did not** cause the USPTO to issue any office action that reopened examination.

The *Novartis* Court clearly states that for the '031 patent, "the PTO [does not] identify any 'continued examination of the application' that occurred after the notice of allowance was mailed." See *Novartis*, 740 F.3d at 602. If the *Novartis* Court did not view the filing of the two RCEs after the initial and second notices of allowance during prosecution of the '031 patent as continued examination where no further examination actually took place, then the USPTO cannot possibly rationalize an amendment to 37 C.F.R. §1.703(b)(1) that proposes to now treat such activity as continued examination. This proposal by the USPTO is, in fact, a direct contradiction to the findings of the Federal Circuit. Should the USPTO persist in including reference to activity occurring after an initial notice of allowance in 37 C.F.R. §1.703(b)(1), it cannot conceivably include RCE filings that do not actually cause the resumption of examination.

To address this inconsistency, we propose the following amendment to 37 C.F.R. (1.703)(1) that removes reference to RCE filings after an initial notice of allowance, and instead focuses on whether **actual** examination is reopened by the mailing of an action:

§1.703 Period of adjustment of patent term due to examination delay.

(b) The period of adjustment under § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an

international application and ending on the date a patent was issued, but not including the sum of the following periods:

(1) The number of days, if any, in the period beginning on the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date the patent was issued of mailing of a notice of allowance under 35 U.S.C. 151, unless prosecution examination in the application is reopened after the mailing of an initial notice of allowance under 35 U.S.C. 151, in which case the period of adjustment under § 1.702(b) also does not include the number of days, if any, in the period or periods beginning on the date on which a request for continued examination of the application under 35 U.S.C. 132, whichever occurs first, and ending on the date of mailing of a subsequent notice of allowance under 35 U.S.C. 151.

B. The USPTO Cannot Exclude from Type B PTA the Period Beginning on the Date of Mailing of an Action under 35 U.S.C. §132 After Issuance of an Initial Notice of Allowance and Ending on the Date of Mailing of a Subsequent Notice of Allowance Unless the Action was Necessitated by Applicant-Initiated Activity.

Moreover, it is not appropriate for the period between post-allowance mailing of an office action triggered by filing of an RCE and the subsequent notice of allowance to be excluded from Type B PTA under all circumstances. The *Novartis* Court suggested that there are "exceptional" circumstances after allowance that could give rise to resumption of examination, *Novartis*, 740 F.3d at 602, but the USPTO's proposed amendment to 37 C.F.R. §1.703(b)(1) provides no analysis of, nor guidance concerning, what constitutes an "exceptional" circumstance post-allowance that may prohibit Type B PTA accrual. By neglecting to provide such analysis and guidance, the USPTO, *inter alia*, fails to distinguish between applicant-initiated activity and USPTO-initiated activity, essentially penalizing an applicant for all activity after a notice of allowance that gives rise to examination even if the applicant had no responsibility for the further

continued examination. This outcome runs contrary to the position taken by the USPTO itself in *Novartis AG v. Lee*, which was acknowledged by the Federal Circuit:

As already noted, the PTO has explained that 154(b)(1)(B) is best understood as making distinctions based on **whether certain delays are attributable to the PTO**. On that basis the PTO has properly insisted that continued examinations are not to be distinguished according to when they are initiated. By the same token, allowance-to-issuance time is not to be distinguished according to whether there is a continued examination in a prosecution. Either way such time is plainly attributable to the PTO

Id. (emphasis added). The policy behind the enumerated exclusions in 35 U.S.C. \$154(b)(1)(B) is that these "delays are not 'due to the failure of' the Office to move the process along." *Id.* at 601. In keeping with the findings of the *Novartis* Court, focusing on USPTO responsibility does not distinguish **when** a particular activity is initiated (*i.e.*, pre- or post-allowance), but rather **who** initiated that activity. Therefore, even if the USPTO insists on excluding examination that occurs after a notice of allowance from Type B PTA accrual, the USPTO cannot legitimately exclude any such examination time that is attributable to the USPTO, in accordance with 35 U.S.C. \$154(b)(1)(B)(i).¹

The following is a proposed amendment to 37 C.F.R. §1.703(b)(1) that further modifies McCarter's proposed revisions requiring the triggering of an actual reopening of examination to also differentiate between applicant-initiated activity and other types of activity after the mailing of an initial notice of allowance:

§1.703 Period of adjustment of patent term due to examination delay.

(b) The period of adjustment under § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a)

¹ 35 U.S.C. §154(b)(1)(B)(i) excludes only "time consumed by continued examination of the application *requested by the applicant* under 135(b)." (emphasis added).

or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application and ending on the date a patent was issued, but not including the sum of the following periods:

(1) The number of days, if any, in the period beginning on the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date the patent was issued of mailing of a notice of allowance under 35 U.S.C. 151, unless prosecution examination in the application is reopened in response to activity by applicant after the mailing of an initial notice of allowance under 35 U.S.C. 151, in which case the period of adjustment under § 1.702(b) also does not include the number of days, if any, in the period or periods beginning on the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was filed or the date of mailing of an action under 35 U.S.C. 132 necessitated by the applicant-initiated activity, whichever occurs first, and ending on the date of mailing of a subsequent notice of allowance under 35 U.S.C. 151;

V. ALTERNATIVE PROPOSED AMENDMENTS TO 37 C.F.R. § 1.704

As set forth above, no amendment to 37 C.F.R. \$1.704(c) is required either by *Novartis AG v. Lee* or by the USPTO's misguided attempt to improperly characterize the mere filing of an RCE by a patent applicant as a failure to prosecute in a timely manner. Should the USPTO reject this conclusion, McCarter proposes alternative revisions to 37 C.F.R. \$1.704(c)(12) to make an exception for an RCE filed as part of the QPIDS procedure that is accompanied by an IDS having a statement in compliance with \$1.704(d). Furthermore, the USPTO should amend 37 C.F.R. \$1.97 to make the QPIDS procedure permanent.

In the notice of proposed rulemaking, the USPTO states that the IDS provisions of 37 C.F.R. §1.704(d) will not apply to the proposed 37 C.F.R. §1.704(c) because an applicant can avail itself of the IDS rules of 37 C.F.R. §§1.97 and 1.98 to file an IDS after allowance without the need for filing an RCE, and the USPTO has the QPIDS procedure for filing an IDS even after payment of the issue fee. However, McCarter respectfully submits that the current IDS rules and procedures do not allow applicants

to comply with 37 C.F.R. §1.56 adequately without risking substantial loss of Type B PTA.

The QPIDS pilot program has been extended to run through September 30, 2014. This program allows an applicant to file an IDS after payment of the issue fee by waiving 37 C.F.R. §1.97(d), which normally disallows any filing of an IDS after payment of the issue fee. To take advantage of the QPIDS program, an applicant must file, *inter alia*, an IDS with a 37 C.F.R. §1.97(e) timeliness statement, a conditional RCE, and a conditional petition to withdraw from issue. If, upon review of the items in the IDS, an examiner does not believe that further action is required, the RCE fee will be refunded, and no further action will take place, except to pass the application to issuance.

First, McCarter proposes that the USPTO make the QPIDS procedure permanent.² Many applicants have benefited from this procedure, and it is an excellent USPTO initiative, regardless of any changes to the PTA rules. Moreover, as described below, a permanent QPIDS procedure is necessary to avoid prevention of Type B PTA accrual in the event of protracted delay between payment of the issue fee and issuance of a patent.

Second, the time from payment of the issue fee to actual patent issuance is not a period generally under an applicant's control. While the USPTO certainly tries to issue patents within four months from payment of the issue fee to avoid a Type A PTA accrual under 35 U.S.C. \$154(b)(1)(A)(iv), there are many instances in which issuance can take substantially longer. The longer the period between payment of the issue fee and patent issuance, the more likely it becomes that art or official actions from other jurisdictions will become available, necessitating the submission of an IDS after payment of the issue fee. However, if an applicant is diligent in meeting the

² The current requirements for compliance with the QPIDS procedure should be included in an amendment to 37 C.F.R. $\S1.97$, *e.g.*, as a new subsection (j).

requirements under the QPIDS procedure, then compliance with rule 37 C.F.R. \$1.704(d) is completely feasible. Nevertheless, by virtue of the USPTO's proposed 37 C.F.R. \$1.704(c)(12), if prosecution is reopened by the examiner acting on an RCE under the QPIDS procedure, that applicant will be debited Type B PTA beginning on the date of mailing of the notice of allowance under 35 U.S.C. \$151 and ending on the date the subsequent RCE was filed.

McCarter respectfully submits that if an applicant makes the requisite statement under 37 C.F.R. §1.704(d) pursuant to the QPIDS procedure, it should not be debited Type B PTA if prosecution is reopened by an examiner acting on an RCE under this procedure – especially if there is protracted delay in issuance after payment of the issue fee (*e.g.*, more than four months). As noted above, the time between payment of the issue fee and patent issuance is not under an applicant's control, and the longer this period, the more likely art will become available. Furthermore, because the USPTO's proposal for amendment to 37 C.F.R. §1.704(c) is purportedly justified by discouraging the abusive filing of serial RCEs, this concern is ameliorated by conditioning withholding of Type B PTA under proposed 37 C.F.R. §1.704(c) on the requirement for a statement under 37 C.F.R. §1.704(d) during the QPIDS procedure.

To address this inconsistency, we propose the following amendment to 37 C.F.R. 1.704(c)(12) that carves out submission of an RCE with an IDS under the QPIDS procedure as follows:

§ 1.704 Reduction of period of adjustment of patent term.

. . .

(a) The period of adjustment of the term of a patent under \S 1.703(a) through (e) shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution (processing or examination) of the application.

(c) Circumstances that constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application also include the following circumstances, which will result in the following reduction of the period of adjustment set forth in § 1.703 to the extent that the periods are not overlapping:

•••

(12) Submission of a request for continued examination under 35 U.S.C. 132(b) after a notice of allowance under 35 U.S.C. 151 has been mailed, except to allow the submission of an information disclosure statement accompanied by a statement under § 1.704(d)(1) after payment of the issue fee under the QPIDS procedure described in § 1.97 (j), in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the date of mailing of the notice of allowance under 35 U.S.C. 151 and ending on the date the request for continued examination under 35 U.S.C. 132(b) was filed;

CONCLUSION

McCarter once again thanks the USPTO for the opportunity to be heard on its proposal to change the rules of practice pertaining to the PTA provisions of 35 U.S.C. § 154(b) in light of *Novartis AG v. Lee*. We believe that only 37 C.F.R. § 1703 need be amended, and only insofar as to exclude from accrual of Type B PTA the period between an initial RCE filing and mailing of an initial notice of allowance. In the alternative, McCarter is confident that the revisions it proposes to 37 C.F.R. §§ 1.703 and 1.704 are in alignment with *Novartis v. Lee* and the mandates of 35 U.S.C. §154(b).

Very truly yours,

Scott S. Christie