Dear Mr. Fries,

Please consider the following written comments to the notice of proposed rulemaking related to Changes to Patent Term Adjustment in View of the Federal Circuit Decision in Novartis v. Lee.

1. There are instances where events beyond the control of the applicant require the filing of an RCE after receipt of notice of allowance. Provisions should be made in the rule to address such situations so not ALL RCE filings immediately erase accumulated patent term adjustment. Examples include:
   a. Prior art or other information material to patentability that is first received by the applicant after payment of the issue fee, such as in an office action from a foreign country or activity in a related pending application (Quick Path Information Disclosure Statement (QPIDS) provides a vehicle to possibly avoid an RCE, however the RCE must be filed in a QPIDS request in the event the examiner deems the cited prior art material to patentability. Thus it is the examiner, not the applicant who determines whether an RCE filing is warranted.)
   b. Failure of action by the USPTO before the deadline for payment of the issue fee, such as when the USPTO is alerted to an error in the claims indicated as allowed and no supplemental notice of allowance is received by the issue fee payment deadline; or failure to receive an examiner initiated IDS by the issue fee payment deadline; or no indication from the USPTO that a 312 amendment is accepted and will be entered by the issue fee payment deadline.

2. Discussion of Specific Rules - Section 1.703(b)(1) provides “If prosecution in the application is reopened, the time consumed by continued examination of the application under 35 U.S.C. 132(b) also includes 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.” (emphasis added)

The underlined text appears to negate any accumulated patent term adjustment due to the USPTO voluntarily and/or unilaterally re-opening prosecution after notice of allowance, such as when an IDS in compliance with 37 CFR 1.97(d) is filed by the applicant and the examiner deems the cited art material to patentability and re-opens prosecution in order to issue an office action. Such circumstances do not “constitute failure of the applicant to engage in reasonable efforts to conclude processing or examination.” Accordingly, the period of time associated with the USPTO re-opening of prosecution after notice of allowance should be included in the calculation of PTA to the extent to which the period defined by 35 U.S.C. 154(b)(1)(B) exceeds three years.

3. The rules should be amended to allow for another mechanism (besides the filing of an RCE) for submission of prior art which was unintentionally (see 37 CFR 1.137(d)) not submitted to the USPTO within 30 days or within 3 months. In view of the broad reach of 37 CFR 1.56 of “Each
individual associated with the filing and prosecution of a patent application” which is construed as including individuals that are remote from the U.S. patent examination/prosecution, such as foreign associates in other countries prosecuting corresponding patent applications in other languages. In such situations, there are instances where information material to patentability is not made available to a practitioner with authority to prepare and file an information disclosure statement with the USPTO until more than 30 days or 3 months after initial receipt of the information by a remotely located individual (such as a foreign associate) due to, for example, delays in obtaining a translation, mail delays, etc. Thus, an exception to the 1 and 3 month rule should be available when the delay in filing an IDS was unintentional.

Thank you for considering my comments.

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