## To the Office:

I am a registered practitioner writing on my own behalf regarding the proposed changes to 37 C.F.R. 1.703 and 1.704 in light of the CAFC's decision in Novartis v Lee. I believe the proposed rules miss an important aspect of the CAFC's decision.

Specifically, the proposed rules focus on the calculation of PTA time following the filing of an RCE. The proposed rules would establish that the filing of an RCE after the mailing of a Notice of Allowance constitutes a failure by the applicant to conclude prosecution of the application, and would deduct from the PTA adjustment any time consumed from the filing of the RCE until the mailing of a Notice of Allowance. However, the CAFC's decision, although promulgated in the context of a case in which there was continued prosecution, clearly states that it is applicable in all situations in which a Notice of Allowance has been mailed:

"We reject the PTO's view that the time after allowance, until issuance, is "time consumed by continued examination" and so is excluded from adjustments given to the patentee. Such time from allowance to issuance undisputedly would count toward the PTO's three-year allotment in a case not involving a continued examination. There is no basis for distinguishing a continued examination case... We reject the PTO's view that the time after allowance, until issuance, is "time consumed by continued examination" and so is excluded from adjustments given to the patentee. Such time from allowance to issuance undisputedly would count toward the PTO's three-year allotment in a case not involving a continued examination. There is no basis for distinguishing a continued examination case... The commonsense 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." [slip opinion at pp. 15-16; emphasis added]

The CAFC goes on at page 16 to state that unless for some reason examination must be resumed after a Notice of Allowance is mailed, the time after the mailing of a Notice of Allowance can <u>never</u> be counted against the applicant in the PTA calculation:

"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. In the present case, time after allowance was not time caused by the continued examination. Because the PTO applied the contrary view in calculating the patent term adjustment for the '155, '518, and '631 patents, those calculations must be corrected." [citations omitted, emphasis added]

Unfortunately, the proposed rules do not make it clear that actions of a patentee taken after the mailing of a Notice of Allowance that do not result in a resumption of examination cannot be deducted from the PTA calculation, regardless of whether that Notice of Allowance was mailed during initial prosecution or after the filing of an RCE. I think it would be useful if the Rules were to explicitly reflect this point.

To illustrate, per the CAFC's holding, the applicant's submission of, for example, a status inquiry after the payment of an issue fee, asking when the patent is due to issue, cannot count against the PTA determination. This is because such an inquiry does not cause prosecution to be re-opened and therefore cannot, in the words of 35 U.S.C. §154(b)(2)(C)(i), constitute a "period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application". The rules as currently written do not make this point clear, and even if the proposed changes to the rules are adopted, the rules would not make this point clear. They should. Please take this opportunity to incorporate language into the rules stating that an applicant's actions taken after the mailing of a notice of allowance that do not necessitate the resumption of examination will not result in time being deducted from the PTA.

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