Does Patent Term Adjustment Need Adjustment?

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In percentage terms, the Wyeth proposal has a much more dramatic effect in the pharma sample than the general sample,[85] increasing PTA by 60%. As with the general sample of patents examined in Table 5, here the period of A delay is generally larger than the period of B delay, making the period of B delay the differentiating factor. As expected, the average increase in PTA in the Wyeth proposal (168 days) closely corresponds to the period of B delay (196 days) in the pharma sample.

The PTO proposal has a less dramatic percentage effect on PTA, decreasing it by 47% (as compared to 62% in the general sample),[86] but interestingly the net result is virtually the same – 148 days of PTA as compared to 147 days in Table 5. This appears to be because the increases in B delay and applicant delay almost exactly offset one another, while A delay is ignored in the calculation.

Most strikingly, the applicant delay proposal increases PTA of pharma patents by an average of 76 days, or 27% – approximately half the gain observed for the Wyeth proposal in the pharma sample, and more than triple the average percentage increase seen in the general sample.[87] This gain is primarily attributable to the increase in applicant delay, though it is partially offset by the increase in B delay.

7. Conclusions

The data described in section 6 give a preliminary sense of how each theoretical proposal would operate in practice. Based on these data, the least equitable model is arguably the PTO proposal, which removes most PTO delay simply by deleting A delay from the calculation. It is difficult to see the benefit of this approach, given that it takes attention away from one of the

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[85] $t(128)=3.10$, $p=0.0012$.
[86] $t(171)=2.24$, $p=0.013$.
[87] $t(111)=4.80$, $p=2.5\times10^{-6}$.

biggest problems facing the PTO: its initial examination backlog. By maintaining A delay as part of the PTA calculation, the PTO is, at least in some sense, held accountable for its backlog, and the applicant can recover this time at the end of the patent term. This analysis is fully consistent with the legislative history of AIPA, which provides that most applicants will receive "considerably more" than 17 years of patent term.[88]

The Wyeth proposal, as previously discussed, corrects certain of the distortions of the standard PTA calculation while introducing others. The 60% jump in PTA in the case of pharma patents reflects, in part, the "windfall" nature of the Wyeth calculation, which adds A delay and B delay together without considering whether the former causes the latter.

The applicant delay proposal appears to be the least extreme and most targeted intervention. In the general sample, the average effect on PTA is quite small; however, in the case of the pharma sample, in which average applicant delay is significantly increased, the effect on PTA is much larger. In fairness terms, at first glance this may seem exactly backwards: Why should less diligent applicants be rewarded with more PTA? What such an analysis ignores is that, as discussed above, in many cases the applicant has been penalized not once but twice for his or her own delay – once at the "front end," when the patent issues, and again at the "back end," when the patent expires. By selectively removing the latter penalty only in those cases in which applicant delay did not cause PTO delay, the net effect is to restore greater patent term to those applicants who delay more. Yet seen as a corrective measure that turns the current "double" penalty on applicants into a "single" penalty, the applicant delay proposal arguably provides the fairest outcome, avoiding the distortions seen in both the Wyeth proposal and the PTO proposal, as well as the standard interpretation of the present statute.

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[88] H.R. Rep. No. 106-464, at 126 (1999) (Conf. Rep.).

Thus, if the PTA statute becomes a target for patent reform in the near future – as could happen if <u>Wyeth</u> is affirmed by the Federal Circuit and is perceived as an undeserved windfall for applicants – the applicant delay proposal may offer an attractive middle-ground approach that is relatively modest in its overall impact but that best fits Congress's intent "to compensate applicants fully for USPTO-caused administrative delays."[89]

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[89] <u>Id.</u>