

## Federal Circuit's Wyeth Decision Likely to Lead to Longer Patent Terms

The Federal Circuit yesterday issued a decision in *Wyeth v. Kappos* that will significantly extend the life of some patents that issue after patent prosecution delays caused by the PTO. In *Wyeth*, the Federal Circuit rejected the PTO's statutory interpretation and method of calculating patent term adjustments under 35 U.S.C. § 154(b) in favor of a method of calculation that complies with the plain language of the statute and more fully compensates patentees for delays in prosecution and issuance.

With *Wyeth*, patentees are no longer subject to an effective 17-year patent-term cap when PTO delays cause a patent to issue after three years from filing. Patentees generally will not only receive adjustments that guarantee a 17-year term (when an application remains pending more than three years), but also potentially further term restoration if PTO delays trigger Section 154(b)'s protection.

After Congress, in 1994, changed the patent term of a United States patent from 17 years from issuance to 20 years from filing, harmonizing the U.S. patent term with most worldwide patents, Congress amended 35 U.S.C. § 154(b) in 1999 to provide patent term adjustments for delays in issuance caused by the PTO. Adjustments are provided, among other reasons, for PTO delays in meeting specified examination deadlines ("A delays") and for the PTO's failure to issue a patent within three years after the filing of the application ("B delays"). Under the PTO's interpretation of § 154(b), A delays and B delays always overlapped. Because the statute limits patent term restoration for PTO-caused delays to the number of non-overlapping days (number of days of "actual" delay), under the PTO's reading, a patentee was only entitled to a patent term adjustment equal to the longer of the amount of A delay or the amount of B delay.

In *Wyeth*, the Federal Circuit rejected the PTO's interpretation of § 154(b). The Court held that because the B delay could not begin until three years after the patent application was filed, any PTO delay in meeting specified deadlines (A delay) occurring in the first three years after filing could not overlap with delays in issuance beyond three years after filing (B delay). Thus, rather than adopting the PTO's "greater of A-or B-delay" approach, the court clarified that a patentee is entitled to a patent term adjustment under § 154(b) equal to the number of days of A delay prior to the three-year mark plus the number of days of B delay, which commence after the three-year mark and continue to accrue until the patent is issued (excluding the applicable number of days of applicant delay), significantly extending the life of both *Wyeth* patents at issue in the case.

By treating A delays occurring during the first three years of prosecution and B delays occurring after the three-year mark as cumulative rather than overlapping, the Federal Circuit's decision in *Wyeth* may also significantly extend the life of many patents that experience PTO delays during prosecution. Patentees who generate ongoing royalties or rely on patent exclusivity in marketing their products throughout the life of their patents will be able to harness the Federal Circuit's decision to extend the amount of time for which they are able to generate value from their patents.

In the wake of *Wyeth*, the many similar lawsuits pending around the country challenging patent term calculations will likely be resolved by summary judgment and result in longer patent terms for the patents

involved. Further, patentees who have previously been granted a patent term adjustment should take a second look at the way in which their adjustment was calculated to determine if they may be entitled to additional adjustments under the statutory interpretation promulgated by the Federal Circuit in *Wyeth*. One looming issue, however, is whether and to what extent patents for which the time to challenge patent term adjustment has expired will be entitled to additional patent term adjustment under *Wyeth*. Finally, given the *Wyeth* decision and the possible additional extensions of patent terms it supports, any third parties preparing to enter markets upon patent expiration need to reevaluate the timing of potential product launches.

Ropes & Gray's Intellectual Property group regularly counsels clients on these issues. If you have any questions about *Wyeth* and its effect on your business activities, please do not hesitate to contact your regular Ropes & Gray contact.