

**Time Is Money: Federal Circuit Affirms *Wyeth*.**  
**Recent patentees encouraged to submit PTA reconsiderations.<sup>1</sup>**

Shoshana Marvin, M.S.\* & Dean L. Fanelli, Ph.D.\*\*

For patent holders in many industries, the length of the patent protection term can have an enormous impact on profits; in a billion-dollar industry, millions of dollars may be lost with even one day of lost patent protection. The Federal Circuit handed down good news for patentees in *Wyeth v. Kappos (Wyeth)* on January 7, 2010 when it affirmed the District Court for the District of Columbia's 2008 decision in *Wyeth v. Dudas*, and thereby required the United States Patent and Trademark Office (USPTO) to begin recalculating Patent Term Adjustments (PTAs) more favorably to patentees. The *Wyeth* decision affirms that the USPTO erroneously interpreted U.S.C. § 154(b) in a way that shortchanged patentees of valuable patent protection. The new *Wyeth* standard will thus increase the PTA calculation value for patents pending over three years.

For patent holders, PTA strategies and calculations should be updated to reflect the new *Wyeth* standard in order to maximize patent term. This is especially important in the pharmaceutical and biotechnology industry sectors because applicants frequently encounter the type of PTO delays affected by *Wyeth*.

While patents that issued on applications filed before June 8, 1995 had a seventeen-year protection term from grant, patents issued after this date are entitled to twenty years of protection from filing. See Pub. L. No. 103-456, § 532, 108 Stat. 4809, 4984 (1994). However, under the previous interpretation of 35 U.S.C. § 154(b), USPTO and applicant delays in prosecution could consume the effective terms of a patent. The American Inventors Protection Act amended the statute to compensate applicants for certain types of delay. The statute provides that "to the extent that periods of delay...overlap, the period of adjustment... shall not exceed the actual number of days the issuance of the patent was delayed." The issue in *Wyeth* involved a particular type of delay and in whose favor "overlap" should be interpreted. The American Inventors Protection Act amended the statute by providing applicant "guarantees" against three types of delay.

---

<sup>1</sup> This article reflects the authors' current personal thoughts on the subject matter and should not be attributed, in whole or in part, to Fanelli Strain & Haag PLLC, any of its attorneys or any of its clients. The Article is not meant to convey legal opinions or legal advice of any kind.

\* Shoshana Marvin, M.S. is an intern at the Intellectual Property Law Firm Fanelli Strain & Haag PLLC and a law student at The George Washington University Law School. Ms. Marvin can be reached at smarvin@law.gwu.edu.

\*\* Dean L. Fanelli, Ph.D. is a Managing Member at the Intellectual Property Law Firm Fanelli Strain & Haag PLLC. Dr. Fanelli can be reached at dfanelli@fshlegal.com.

The “A” guarantee provides that the USPTO will provide prompt office responses by extending the patent terms for one day for each day the USPTO does not meet certain examination deadlines. For example, a first action on a patent application must be mailed within fourteen months of filing. The “B” guarantee extends the term of the patent for one day for each day issuance is delayed due to the USPTO’s failure to “issue a patent within three years after the actual filing date of the application in the United States.” “C” delay takes place when an application is involved in an interference or appeal, or is involved in a secrecy order; however, the C guarantee is not at issue in *Wyeth*. The USPTO’s undercalculation of PTA was caused by an improper interpretation of the statute that amounted to a “Greater-of-A-or-B” rubric, which the Federal Circuit rejected in *Wyeth*.

According to the USPTO’s previous “period of delay” definition, the B period started with the *filing* of the application, not three years later. Thus, “overlap” between A and B adjustments could arise immediately during the pendency of a patent application. Using this framework, the PTO would use either the greater of the A or B delay to determine the appropriate adjustment but never combine the two. In 2008, the District Court sided with *Wyeth* in its action seeking an order directing the USPTO to grant an adjustment using an *A-plus-B* rubric. The District court stated, “[t]he problem with the USPTO’s interpretation is that it considers the application delayed under the B clause during the period before it has been delayed.” See *Wyeth v. Dudas*, 580 F.Supp 2d 138, 142 (D.D.C.2008).

The Federal Circuit affirmed that B delay begins when the USPTO fails to “issue a patent within 3 years after the actual filing date... [and] ends when the patent is issued,” so B delay cannot start running until three years after the application is filed. And the “actual number of days the issuance of the patent was delayed” refers to each day covered by the A-period in addition to each day covered by the B-period. Thus, the correct standard for PTAs for issued patents is the *sum* of A-delay and B-delay.

This change could result in longer PTAs, particularly with regard to pharmaceutical and biotech applicants that often experience both A-delay and B-delay. As a practical matter for patentees, consideration must be given whether to file a continuations or requests for continued examination (RCE). For example, while an RCE does not preclude any already earned adjustment periods for A or B adjustments prior to a first RCE filing, an RCE filing blocks any future B-delay credits. However, the right to earn adjustment periods continues for A events after any RCE filing.

Under *Wyeth*, patent holders have an opportunity to accumulate longer and more valuable patent terms by taking the new standard under consideration when developing patent strategies. Because the USPTO has announced it will not seek further review of the *Wyeth* decision, patentees whose patents recently issued should take immediate action by contacting their counsel to submit a PTA reconsideration form in order to take full advantage of potential additional days of patent protection.