

**Keywords:** patent term adjustment; prosecution delays; 35 U.S.C. § 154(b); statutory interpretation

**General:** The Federal Circuit holds that 35 U.S.C. § 154(b) expressly permits a patent term adjustment including delays resulting from § 154(b)(1)(A) and delays resulting from § 154(b)(1)(B), less overlapping periods of delays, rather than merely a patent term adjustment equivalent to the greater of delays resulting from § 154(b)(1)(A) or delays resulting from § 154(b)(1)(B).

*Wyeth and Elan Pharma Int'l Ltd. v. Kappos*

No. 2009-1120 (Fed. Cir. Jan. 7, 2010)

**I. Facts**

Wyeth and Elan Pharma own U.S. Patent Nos. 7,179,892 (the '892 patent) and 7,189,819 (the '819 patent). During the prosecution of each of their respective applications, the PTO undisputedly caused delays that would entitle Wyeth to patent term adjustments under 35 U.S.C. § 154(b)(1)(A) and § 154(b)(1)(B).

In summary, 35 U.S.C. § 154(b) was amended in 1999 under the American Inventors Protection Act ("AIPA") to protect patent applicants from prosecution delays which would consume the effective term of their patents. This protection came in the form of three "guarantees" in § 154(b)(1). Section 154(b)(1)(A) guarantees prompt patent and trademark office responses, and extends the patent term by one day for each day the PTO fails to meet certain examination deadlines. Section 154(b)(1)(B) guarantees no more than a three year patent application pendency and extends the patent term by one day for each day after the end of the three year period until the patent is issued (subject to certain other exclusions). Section 154(b)(1)(C) guarantees adjustments relating to delays resulting from interference proceedings, secrecy orders, and appeals.

The guarantees of § 154(b)(1) are subject to certain limitations under § 154(b)(2), which includes a general limitation that restricts the period of adjustment when periods of delay overlap. Section 154(b)(2) also provides for a reduction in any patent term adjustment for prosecution delays by the applicant.

By applying different interpretations of this general limitation under § 154(b)(2), Wyeth and the PTO calculated different periods of adjustment. Specifically, under the PTO's interpretation, overlaps between different periods of delay can occur any time during the pendency of the patent application, such that if a patent had incurred delays from both § 154(b)(1)(A) and § 154(b)(1)(B) ("A delays" and "B delays," respectively), only the greater of A delays or B delays, and not the combination of the two, would be the appropriate patent term adjustment. Under Wyeth's interpretation, an overlap occurs when an A delay occurs after the three-year anniversary of the filing date (i.e., when an A delay and a B delay occur at the same time).

The '892 patent incurred 610 days of A delay, and 345 days of B delay. Of the 610 days of A delay, 51 occurred more than three years after the application was filed. During prosecution, Wyeth caused 148 days of delay, and so under § 154(b)(2)(C), any adjustment would be reduced by that amount.

The PTO calculated the total adjustment for the '892 patent to be 462 days (i.e., 610 (the greater of A delay and B delay) – 148 (applicant delay)).

Wyeth calculated the total adjustment to be 756 days (i.e., 610 (A delay) + 345 (B delay) – 51 (A delay occurring more than three years after filing) – 148 (applicant delay)).

The '819 patent incurred 336 days of A delay and 827 days of B delay. Of the 336 days of A delay, 106 occurred more than three years after the application was filed. During prosecution, Wyeth caused 335 days of delay.

The PTO calculated the total adjustment for the '819 patent to be 492 days (i.e., 827 (the greater of A delay and B delay) – 335 (applicant delay)).

Wyeth calculated the total adjustment to be 772 days (i.e., 336 (A delay) + 827 (B delay) – 106 (A delay occurring more than three years after filing) – 335 (applicant delay)).

Wyeth filed petitions for reconsideration of the adjustments with the PTO, and then filed this action in the district court. Both parties filed motions for summary judgment, and the district court granted Wyeth's motion, finding that the PTO had misinterpreted 35 U.S.C. § 154(b)(2).

## II. Issue

Did the district court err in its interpretation of 35 U.S.C. § 154(b)(2)?

## III. Discussion

No. The Federal Circuit found no ambiguity in the terms “periods of delay” and “overlap” in the language of 35 U.S.C. § 154(b)(2). The “overlap” limitation in the statute only arises when periods of delay resulting from the violations of the three guarantees provided by 35 U.S.C. § 154(b)(1) actually overlap. Each of the guarantees expressly define the circumstances and periods under which they apply, and so any overlap between the guarantees can only be interpreted to cover delay periods which may be classified by more than one guarantee (e.g., both an A delay and a B delay).

An A delay may begin from the date the PTO misses an examination deadline and ends when the PTO takes the appropriate action. A B delay can only begin three years after the filing date of the application and ends when the application issues (subject to certain exclusions). Thus, A delays and B delays have different timelines, and there is no “overlap” of the two delay periods unless A delays and B delays occur at the same time. The Federal Circuit explained that under the PTO's “strained interpretation,” a B delay can occur any time after the application is filed, since an “overlap” has been interpreted to be any overlap in time. This interpretation is contrary to the language of § 154(b) in which a B delay does not start until three years after the application is filed.

The PTO argued that using both A and B delays to adjust a patent term would be double counting delays, because A delays ultimately lead to B delays. Further, the court's interpretation of the statute may lead to imbalanced treatment of similarly-situated patentees. However, the Federal Circuit upheld the proper interpretation of the statute, stating that “this court does not take upon itself the role of correcting all statutory inequities....”

The Federal Circuit also examined the legislative history of the 1999 AIPA, first stating that “only a ‘most extraordinary showing of contrary intentions’ by Congress justifies a departure from the plain language of a statute.” *Garcia v. United States*, 469 U.S. 70, 75 (1984). The PTO brought to attention a House report analysis of the AIPA which guarantees diligent applicants “at least a 17-year term.” H.R. Rep. No. 106-464, at 125 (1994). The PTO offered that at that time, the average patent pendency was 25 months, meaning that most patents received more than a 17-year term. However, the Federal Circuit found that the PTO's interpretation would create a seventeen year term cap. The context of the House report does not suggest this cap, and instead suggests an intent to provide adequate protection for a patent term, which may often be “considerably more” than 17 years.

The PTO also offered legislative history analysis of § 154(b) before the enactment of AIPA, which only provided for C delays. Further, earlier versions of the AIPA added only A delays, and later, B delays. The PTO suggested that Congress did not intend to adjust for A delays when A delays

occurred during the first three years of prosecution. However, the Federal Circuit found these “ambiguous timing observations” to be “wholly irrelevant to the interpretation of the law itself.”

The PTO lastly contended that the PTO’s interpretation is entitled to deference, and cites *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984) and *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). However, the Federal Circuit found no reason to afford special deference to the PTO’s interpretation, as the language of the statute is unambiguous.

#### **IV. Conclusion**

The Federal Circuit affirmed the judgment of the district court, finding that the language of § 154(b) is clear and unambiguous, and is in contrast with the PTO’s interpretation. Specifically, the overlaps in periods of delay under § 154(b)(2) refer to delay periods which occur at the same time. If an A delay occurs on a different day than a B delay, then these two days do not overlap under § 154(b)(2).

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**§ 154. Contents and term of patent; provisional rights**

(b) Adjustment of Patent Term.—

(1) Patent term guarantees.—

(A) Guarantee of prompt patent and trademark office responses.— Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to—

(i) provide at least one of the notifications under section 132 of this title or a notice of allowance under section 151 of this title not later than 14 months after—

(I) the date on which an application was filed under section 111 (a) of this title; or

(II) the date on which an international application fulfilled the requirements of section 371 of this title;

(ii) respond to a reply under section 132, or to an appeal taken under section 134, within 4 months after the date on which the reply was filed or the appeal was taken;

(iii) act on an application within 4 months after the date of a decision by the Board of Patent Appeals and Interferences under section 134 or 135 or a decision by a Federal court under section 141, 145, or 146 in a case in which allowable claims remain in the application; or

(iv) issue a patent within 4 months after the date on which the issue fee was paid under section 151 and all outstanding requirements were satisfied,

the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.

(B) Guarantee of no more than 3-year application pendency.— Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States, not including—

(i) any time consumed by continued examination of the application requested by the applicant under section 132 (b);

(ii) any time consumed by a proceeding under section 135 (a), any time consumed by the imposition of an order under section 181, or any time consumed by appellate review by the Board of Patent Appeals and Interferences or by a Federal court; or

(iii) any delay in the processing of the application by the United States Patent and Trademark Office requested by the applicant except as permitted by paragraph (3)(C),

the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

(C) Guarantee or adjustments for delays due to interferences, secrecy orders, and appeals.— Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to—

(i) a proceeding under section 135 (a);

(ii) the imposition of an order under section 181; or

(iii) appellate review by the Board of Patent Appeals and Interferences or by a Federal court in a case in which the patent was issued under a decision in the review reversing an adverse determination of patentability,

the term of the patent shall be extended 1 day for each day of the pendency of the proceeding, order, or review, as the case may be.

(2) Limitations.—

(A) In general.— To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

(B) Disclaimed term.— No patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer.

(C) Reduction of period of adjustment.—

(i) The period of adjustment of the term of a patent under paragraph (1) shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.

(ii) With respect to adjustments to patent term made under the authority of paragraph (1)(B), an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of 3 months that are taken to respond to a notice from the Office making any rejection, objection, argument, or other request, measuring such 3-month period from the date the notice was given or mailed to the applicant.

(iii) The Director shall prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.

(3) Procedures for patent term adjustment determination.—

(A) The Director shall prescribe regulations establishing procedures for the application for and determination of patent term adjustments under this subsection.

(B) Under the procedures established under subparagraph (A), the Director shall—

(i) make a determination of the period of any patent term adjustment under this subsection, and shall transmit a notice of that determination with the written notice of allowance of the application under section 151; and

(ii) provide the applicant one opportunity to request reconsideration of any patent term adjustment determination made by the Director.

(C) The Director shall reinstate all or part of the cumulative period of time of an adjustment under paragraph (2)(C) if the applicant, prior to the issuance of the patent, makes a showing that, in spite of all due care, the applicant was unable to respond within the 3-month period, but in no case shall more than three additional months for each such response beyond the original 3-month period be reinstated.

(D) The Director shall proceed to grant the patent after completion of the Director's determination of a patent term adjustment under the procedures established under this subsection, notwithstanding any appeal taken by the applicant of such determination.

(4) Appeal of patent term adjustment determination.—

(A) An applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent. Chapter 7 of title 5 shall apply to such action. Any final judgment resulting in a change to the period of adjustment of the patent term shall be served on the Director, and the Director shall thereafter alter the term of the patent to reflect such change.

(B) The determination of a patent term adjustment under this subsection shall not be subject to appeal or challenge by a third party prior to the grant of the patent.