

Intellectual Property

Patent Law

Patent Term

Clock Management: Patent Term Adjustment, Extension, and Terminal Disclaimer



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On December 1, 2011, the U.S. Patent and Trademark Office (“PTO”) issued new regulations relating to the calculation of the term of a U.S. patent. The announcement was the latest of many concerning the legal framework for calculating patent term, or the amount of time that a patent remains in force, which can be of critical importance to patentees, competitors, and investors. This article provides an overview of the complex landscape of patent term calculation, highlights the basic principles, namely patent term adjustment, patent term extension, and terminal disclaimer, and explains how competing aspects of the law have been resolved by the courts.

The Uruguay Round Agreements Act (“URAA”), which went into effect in 1995, changed the patent term calculation in the United

States. Prior to the URAA, for more than 200 years, the term of a U.S. patent was a fixed number of years (most recently, 17 years) from the date the patent issued. Under the fixed-term-after-issue regime, patent term was essentially independent of the amount of time it took the PTO to review the patent application. The URAA essentially adopted the international system in which the term of a patent expires on the date that is 20 years from the filing date of a patent application or earliest applicable priority date.¹ Thus, under the current twenty-years-from-filing regime, if it takes two years for a patent to issue, the effective term of the patent is 18 years. If it takes 12 years for the application, or a series of related applications to be reviewed—as sometimes happens, for various legitimate and unfortunate reasons—the effective term of the patent when it finally issues will only be eight years.

Some members of Congress worried that patentees would be disadvantaged by the new twenty-years-from-filing patent term because of the possibility that the delay at the PTO would excessively shorten the effective patent term. Thus, the American Inventors Protection Act of 1999 (AIPA) was passed and established procedures for adjusting patent term such that a diligent patentee ideally receives a patent term akin to that before the URAA: approximately 17 years of patent term from issue regardless of the delay at the PTO during its review of the application.

Patent Term Adjustment

Patent term adjustment (“PTA”) under the AIPA rests on three statutory “guarantees,” as follows: (1) a “guarantee of prompt [PTO] responses,”² by which the term of a patent is increased one day for each day the PTO does not take certain required actions on a timely basis; (2) a “guarantee of no more than three-year

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application pendency,”³ by which the term is adjusted one day for each day in excess of three years taken by the PTO to provide an initial examination on the merits; and (3) a “guarantee . . . for delays due to interferences, secrecy orders, and appeals,”⁴ by which the term is adjusted one day for each day the application is involved in an interference proceeding, subject to a secrecy order, or on appeal.

To ensure that patent term adjustment benefits only those patentees who are diligent, the AIPA also requires *reduction* of accumulated adjustment where certain acts are not timely performed by the patentee. The details as to how to calculate a reduction in accumulated patent term adjustment were left for the most part to the PTO to establish by way of regulation. The new rules mentioned at the beginning of this article are the latest work product of that regulatory effort. Under the current regulations,⁵ a reduction in accumulated adjustment can be imposed when a patentee fails to take various actions within certain time limits, and whenever a patentee takes certain enumerated actions that tend to cause delay.

The frequency with which patents accumulate substantial term adjustment has increased since the enactment of the American Inventors Protection Act. The extent to which patent term adjustment has become routine may be surprising to some, since the American Inventors Protection Act provides the PTO with at least three years to conduct an initial review of every patent application. According to a survey conducted by Professor Dennis Crouch of the University of Missouri, however, an astounding 80 percent of patents receive patent term adjustments due to PTO delay. Of that group, the average adjustment is about 600 days—approaching two years.⁶ Many patents issued today receive patent term adjustments on the order of three or more years.⁷ The high frequency and substantial amounts of such adjustments have had a significant effect on the economic value of patents.

Patent Term Extension

Since 1984, patent term extension (PTE) has been available to compensate patentees for certain regulatory delays associated with the Food and Drug Administration (FDA). The Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act) provides that patents on certain drug-related products can receive term extensions based on the time consumed by FDA regulatory review, subject to certain restrictions.⁸ Although both PTA and PTE extend the patent term beyond its original date, the key differences between PTA and PTE are that the former applies to all patented technologies, and is based on delay within the PTO, whereas the latter applies only to certain drug-related technologies, and is based on delays that occur at the FDA.

Terminal Disclaimers

Prior to the URAA, when two or more related patents claimed obvious variations of the same invention, a mechanism was needed to prevent each patent from receiving its own 17 years of patent term. Otherwise, if the second patent issued four years after the first, the patentee could obtain a total of 21 years of aggregate patent term on the same inventive concept. This issue had been addressed by permitting the patentee to disclaim terminal portions of the terms of the later patents, such that all related patents expire at the same time. The enactment of the URAA was expected to lessen the importance of terminal disclaimers. Indeed, the U.S. Court of Appeals for the Federal Circuit, which hears all appeals involving substantive patent law, recently remarked that “unjustified patent term extension” as a justification for requiring terminal disclaimers has “limited force” in many cases today, because of the Uruguay Round Agreements Act.⁹ Nevertheless, over the last ten years or so, the number of patents that issue with terminal disclaimers has increased. It is not uncommon for a PTO examiner to automatically assume that a terminal disclaimer is required in every related application.

What happens when a patent has both a terminal disclaimer and PTE? The Federal Circuit confronted that question in *Merck & Co. v. Hi-Tech Pharmacal Co.*¹⁰ *Merck* was a patent infringement action, based on abbreviated new drug applications, where the patent-in-suit had been rejected as claiming a mere obvious variation of what had been claimed in an earlier patent. The patentee overcame the obviousness-type double patenting rejection by filing a terminal disclaimer, linking the expiration of the patent-in-suit to that of the earlier patent, which had already expired; however, the patent-in-suit also had a term extension of 1,233 days based on regulatory review undertaken by the FDA.¹¹

The defendant argued that the patent-in-suit had expired together with the earlier patent, by operation of the terminal disclaimer. The patentee, on the other hand, argued that the term of the patent-in-suit extended 1,233 days past the expiration date of the earlier patent, such that the patent-in-suit was still in force. In an analytical decision, the Federal Circuit found for the patentee, holding that the goals of (1) remedying obviousness-type double patenting and (2) compensating for time lost to FDA regulatory review can both be achieved by (1) first limiting the term of the patent to that of the first patent, by way of the terminal disclaimer, and then (2) extending that term as mandated by the patent term extension statute.¹²

What happens when a patent has a terminal disclaimer and PTA? The Federal Circuit has not yet confronted that fact pattern directly, though it has indicated that the outcome should be different for patent term adjustment. In *Merck*, in the course of drawing a distinction with the patent term extension statute, which does not refer to terminal disclaimers, the Federal Circuit stated that the patent term adjustment statute “expressly excludes patents in which a terminal disclaimer was filed from the benefit of a term adjustment for PTO delays.”¹³ In future cases, it is likely the Federal Circuit will follow this reading of the patent term adjustment statute, and not apply a patent term adjustment to go beyond a patent term as dictated by a terminal disclaimer.

It is worth noting, however, that the *Merck* court did not quote the actual language of the PTA statute. The relevant portion of the statute uses the term “specified date,” as follows: “No patent the term of which has been disclaimed beyond a specified date may be adjusted . . . beyond the expiration date specified in the [terminal] disclaimer.”¹⁴ There is a distinction between a terminal disclaimer which refers to a date certain, and thus is independent of the actual expiration date of another patent, and a terminal disclaimer which does not mention a date certain, but rather is functionally linked to the expiration of the other patent.¹⁵ Most terminal disclaimers are in the latter category. One could argue that the term “specified date” limits that portion of the PTA statute to only those relatively few terminal disclaimers which specify actual dates; however, until the Federal Circuit has an opportunity to reconsider that aspect of its decision in *Merck*, the wise approach would be to assume the court meant what it said about the PTA statute, even though the only “debated question” in *Merck* involved the PTE statute.¹⁶

In general, PTE may be applied to a patent that contains a terminal disclaimer, whereas PTA likely cannot be applied to a patent that contains a terminal disclaimer beyond the disclaimed portion. There are additional considerations however that will likely come up when the Federal Circuit one day addresses this issue.

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¹ 35 U.S.C. § 154(a)(2).

² 35 U.S.C. § 154(b)(1)(A).

³ § 154(b)(1)(B).

⁴ § 154(b)(1)(C).

⁵ 37 C.F.R. § 1.704.

⁶ *Patent Term Adjustment (PTA) Statistics*, Patent Law Blog (Patently-O) (July 27, 2011), <http://www.patentlyo.com/patent/2011/07/pta.html>.

⁷ See Verne A. Luckow & Steven C. Balsarotti, *Statistical Analysis of Federal District Court Cases Seeking Longer Patent Term Adjustments in the Wake of Wyeth v. Kappos*, 10 J. Marshall Rev. Intell. Prop. L.J. 1 (2010).

⁸ See 35 U.S.C. § 156.

⁹ *In re Fallaux*, 564 F.3d 1313, 1318-19 (Fed. Cir. 2009).

¹⁰ 482 F.3d 1317 (Fed. Cir. 2007).

¹¹ *Id.* at 1390.

¹² *Id.* at 1323.

¹³ *Id.* at 1322.

¹⁴ § 154(b)(2)(B).

¹⁵ See PTO Manual of Patent Examining Procedure § 2701 (2010) (distinguishing between disclaimers that identify “specific dates” from those that do not).

¹⁶ *Id.* at 1321.