

WYETH V. KAPPOS: THE UNITED STATES PATENT OFFICE IS FORCED TO CHANGE COURSE

By John C. Freeman\*

The United States Patent Office ("USPTO") was established in 1790 with the mission to determine whether an invention merited a patent. Such a patent conveys a monopoly to the owner of the patent that allows the owner to prevent others from making, using, offering to sell, or selling the invention in the United States. According to the U.S. Constitution, the monopoly has a finite period for enforcement. In 1994, Congress decided to change the way the term was calculated from being measured from the date of grant of a patent to being measured from the date of filing of a patent application. Later, Congress recognized that laws were needed to address delays during examination of a patent application which could lead to the shortening of the term of the patent. As with most patent laws, the USPTO presented rules to address the laws regarding delays during examination. While most of the rules regarding delays were straightforward, there were several instances where the USPTO did not address the statutory changes through its rules. One such instance was exposed by the Court of Appeals for the Federal Circuit (CAFC), which held in the case Wyeth v. Kappos that the USPTO implemented rules regarding delay that were contrary to the intent of Congress' laws.

I. History of Determining Patent Term

A. Before June 7, 1995

Historically, the term of a U.S. patent has been a fixed number of years as measured from the date of grant of the patent. At the inception of the U.S. Patent Office in 1790, Congress adopted the English Statute of Monopolies, which allowed for patents to have a term of fourteen years or less. This term was revised to seventeen years with the Patent Act of 1861 and continued with the passage of the Patent Act of 1952 until the adoption of a new standard in 1995. One constant from 1790 to 1995 was that the actions of the USPTO never had an effect on the term of a patent since this period of time was measured from the date of grant.

B. From 1995 to Today

The calculation of a patent's term began to change drastically in 1994 with the adoption of an "Agreement on Trade-Related Aspects of Intellectual Property" ("TRIPS") by the United States during the "Uruguay Round" trade talks in accordance with the General Agreement on Tariffs and Trade (GATT). The TRIPS agreement included standards regarding

various intellectual property rights. Regarding patents, Article 33 of the TRIPS agreement stated that "[t]he term of protection available shall not end before the expiration of a period of twenty years counted from the filing date." Faced with Article 33's mandate along with opposition from certain Republicans in Congress, the Clinton Administration negotiated a compromise to adopt Article 33 wherein legislation passed establishing a two-prong approach. In one prong, any patent that was granted from an application pending as of June 7, 1995 would have a term equal to the greater of seventeen years from grant or twenty years from the filing of the application. The second prong regarded patents granted from a patent application filed on or after June 8, 1995, wherein such patents would have a term of twenty years from the filing. The end result was that the longer time taken to prosecute a patent application filed on or after June 8, 1995 would result in shortening the term of a patent. In essence, actions taken by both applicants of patent applications and the USPTO could result in the lessening of patent term.

II. Regulation of Term by Congress

A. Regulation of Inventions Subject to Regulatory Review

Congress has not favored any action by a regulatory agency effectively shortening the term of a patent. This is evidenced by Congress' passage of various statutes that provide additional term to a patent to compensate for delays in enforcing the patent due to a federal review of such inventions as compositions and new drug products. Laws, such as 35 U.S.C. §§ 155, 155A and 156, provide for the granting of extra patent term when regulatory review of certain inventions cause a shortening of the term. Specifically, Section 156 restores patent term for certain drug products, medical devices, food additives, and color additives subject to regulatory review prior to marketing by the Food and Drug Administration.

B. Regulation of Term Due to Procedures of the USPTO

1. Applications Filed on or After June 8, 1995

With the adoption of the two-prong approach for determining patent term, Congress turned its attention to the USPTO. Recognizing that certain examination procedures instituted by the USPTO could cause a reduction in term, Congress took the unprecedented step of enacting legislation in 1994 that reinstated term due to delays by the USPTO for patent applications filed on or after June 8, 1995. In particular, Congress granted additional term to a patentee who prevailed on the merits of any legal issue raised regarding a claim in such procedures as interference and appeal.

2. Applications Filed on or After May 29, 2000

After passage of the 1994 legislation, it became apparent to Congress that the procedures being relied on for additional term were too limiting. Consequently, Congress passed

\* John C. Freeman is a partner with the law firm Brinks Hofer Gilson & Lionone. Mr. Freeman was a patent examiner at the United States Patent Office for four years and for the past twenty years has specialized in the prosecution of patents filed in the United States and abroad. Unless otherwise identified, the views expressed in this article are those of the author and not necessarily those of his firm and past, present, or future clients.

comprehensive legislation on November 29, 1999 applying to original (i.e., non-reissue) utility (i.e., non-design) patent and plant applications filed on or after May 29, 2000, the date of enactment of the legislation (“the 1999 legislation”). The 1999 legislation had three major components, titled: 1) Guarantee of Prompt Patent and Trademark Office Responses, 2) Guarantee of No More than 3-year Application Pendency, and 3) Reduction of Period of Adjustment. The first two components are of central importance regarding the discussion to follow and cover delays in the patent prosecution process caused by the USPTO and for which the patentee would be rewarded extra patent term beyond the twenty years from filing term. The third component is of interest in that it recognized for the first time that patent applicants themselves could fail to engage in reasonable efforts to prosecute their own patent applications. The 1999 legislation explicitly set forth that the failure of a patent applicant to respond to a USPTO “rejection, objection, argument, or other request” within three months would result in any extension of patent term owed to the patent applicant being reduced by the number of days the patent applicants’ response was beyond the three-month time limit.<sup>9</sup> Congress also directed the USPTO to “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.”<sup>10</sup>

a. Guarantees of Prompt Responses and No More than Three-Year Patent Application Pendency

The first two major components of the 1999 legislation previously mentioned are set forth below:

(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 the 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.<sup>11</sup>

Distilling the above sections, the 1999 legislation placed time limits on the USPTO to respond to certain acts by patent applicants and government bodies per 35 USC § 154(b)(1)(A). In addition, the 1999 legislation presented in 35 USC § 154(b)(1)(B) set a time limit of three years from the date of filing for the USPTO to issue a patent. The patent term is extended one day for each day that the USPTO goes beyond the time limits mentioned above. Also, the patent term extension due to USPTO delay is reduced by the number of days of delay caused by the patent applicant.<sup>12</sup>

b. Treatment of “Overlap” of Multiple Delays

Congress recognized that there would be instances where the USPTO could have multiple delays occurring on the same day. In this situation, the 1999 legislation stated that:

To the extent that periods of delay attributable to grounds specified in paragraph (1) [35 USC § 154(b)(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. (bracketed material added).<sup>13</sup>

III. USPTO Establishes Patent Term Adjustment Rules

The foundation of patent term adjustment established by Congress presented the USPTO with the opportunity to establish rules concerning the legislation. Indeed, Congress mandated that the USPTO establish regulations to identify circumstances that constituted a failure of a patent applicant

to engage in reasonable efforts to conclude prosecution of a patent application.<sup>14</sup> Congress also directed the USPTO to issue regulations to establish procedures for the application for and determination of any patent term adjustment.<sup>15</sup>

*A. USPTO Proposes Its Rules*

Faced with the above-mentioned mandates to police itself, the USPTO proposed rules on March 31, 2000 to administer and determine patent term adjustments pursuant to the 1999 legislation.<sup>16</sup> The proposed rules presented fifteen specific instances that would constitute unreasonable efforts by a patent applicant and, therefore, subject the subsequently-issuing patent to a reduced patent term adjustment.<sup>17</sup> The USPTO announced in its proposed rules that no public hearing would be held. Furthermore, the USPTO asserted that there was not sufficient time to conduct a notice and comment rulemaking procedure and accept comments during a sixty-day comment period due to the six month time period from the November 29, 1999 passage date to the May 29, 2000 effective date of the provisions of the Patent Term Adjustment law.<sup>18</sup> The proposed rules also set forth a procedure for determining and petitioning patent term adjustments. The proposed rules were finalized on October 18, 2000 without comments made by the USPTO.

Starting midway in 2003, patents that were filed shortly after May 29, 2000 were being granted. Such patents on their face qualified for a patent term adjustment for being granted more than three years from their filing dates pursuant to 35 U.S.C. § 154(b)(1)(B). During this time frame, this author’s law firm identified situations where there could be significant patent term adjustments when other previously occurring delays were added on to the three-year delay. In particular, based on its reading of the statute, the author’s law firm determined that USPTO delays that occurred for failure to meet examination deadlines and delays that occurred for failure to grant a patent within three years of filing the application were cumulative in general. Since the USPTO had not previously commented on this scenario, discussions were held with USPTO personnel to confirm that the law firm’s interpretation was correct. Instead, the USPTO personnel indicated that this interpretation was in error.<sup>19</sup>

*B. USPTO Interprets Congress’ Intent on How to Determine Patent Term Adjustment*

Based on its knowledge that the author’s law firm and several other law firms had a contrary interpretation of calculating three-year delay, the USPTO published its interpretation of how to determine patent term adjustment based on failure to grant a patent within three years of filing the application. In particular, the USPTO amended its Patent Term Adjustment rules in 2004. This amendment included rule 37 C.F.R. §1.703(f) regarding the treatment of the overlap of delays. The 2000 and 2004 versions of Rule 703(f) are set forth in the table at the bottom of the page, wherein deletions made to the 2000 version are bracketed and additions are underlined.

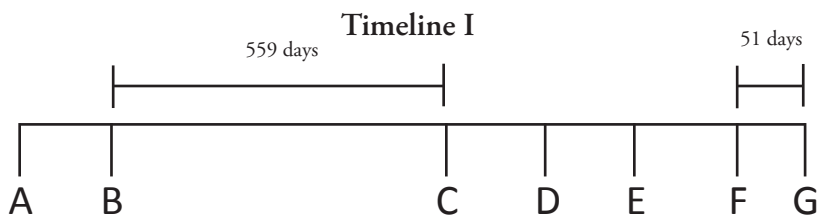
Only one change was made to the rule: by referring to “periods of delay” instead of “periods of adjustment.” The change on its face appeared to be for the sole purpose of using language consistent with the statute. However, in its comments to the amended rules, the USPTO stated that the amendments were necessary since the previous rules “mised applicants into believing” that delays that occurred prior to the three-year anniversary of the filing of the patent application do not “overlap” with a delay due to granting a patent after the three-year anniversary. In other words, the USPTO in 2004 interpreted 35 USC § 154(b)(2)(A) prohibition against counting multiple delays that “overlap” as not being confined to situations wherein the delays occur in the same period of time. This interpretation would reduce the amount of delay attributed to the USPTO for granting a patent after the three-year anniversary of the filing of the patent application.

**IV. The USPTO is Challenged by Wyeth**

*A. Petition Filed*

Wyeth and Elan Pharma International Ltd. (collectively called “Wyeth”) filed a petition with the USPTO that challenged the USPTO’s determination of patent term adjustment for their U.S. Patents Nos. 7,179,892 (‘the 892 patent’) and 7,189,819 (‘the ‘819 patent’). The USPTO calculated extensions of

2000 Version of 37 C.F.R. § 1.703(f)	2004 Version of 37 C.F.R. § 1.703(f)
(f) The adjustment will run from the expiration date of the patent as set forth in 35 U.S.C. 154(a)(2). To the extent that periods of adjustment attributable to the grounds specified in §1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed. The term of a patent entitled to adjustment under § 1.702 and this section shall be adjusted for the sum of the periods calculated under paragraphs (a) through (e) of this section, to the extent that such periods are not overlapping, less the sum of the periods calculated under § 1.704. The date indicated on any certificate of mailing or transmission under § 1.8 shall not be taken into account in this calculation.	(f) The adjustment will run from the expiration date of the patent as set forth in 35 U.S.C. 154(a)(2). To the extent that periods of [adjustment] <u>delay</u> attributable to the grounds specified in §1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed. The term of a patent entitled to adjustment under § 1.702 and this section shall be adjusted for the sum of the periods calculated under paragraphs (a) through (e) of this section, to the extent that such periods are not overlapping, less the sum of the periods calculated under § 1.704. The date indicated on any certificate of mailing or transmission under § 1.8 shall not be taken into account in this calculation.



A=3/12/2003 filing date                      B=5/12/2004 14-month date                      C=11/22/2005 Restriction Requirement  
D=3/12/2006 3-year anniversary of filing                      E=8/31/2006 Issue Fee Paid  
F= 4 months from payment of Issue Fee                      G=2/20/2007 grant date of '892 patent

terms for the '892 and '819 patents as 462 days and 492 days, respectively. Wyeth calculated extensions of 756 days and 722 days, respectively.

*B. District Court Filing*

While Wyeth was waiting for the USPTO's decision to its petition, Wyeth filed suit in the United States District Court for the District of Columbia pursuant to 35 USC § 154(b)(4)(A). For simplicity, only the facts surrounding the prosecution of the '892 patent will be discussed in this article since they illustrate issues of interest similar to those regarding the '819 patent. The '892 patent was filed on March 12, 2003. Pursuant to the U.S. Patent Rules, Wyeth accrued 148 days of delay in prosecution/examination of the patent application. Regarding delays by the USPTO, the USPTO's first official action on the merits was the mailing of a Restriction Requirement on November 22, 2005 that resulted in the USPTO incurring a delay of 559 days for failing to mail a first action on the merits within fourteen months of filing an application pursuant to 35 U.S.C. § 154(b)(1)(A)(i) and 37 C.F.R. § 1.703(a)(1) and hereinafter referred to as the "fourteen-month delay." The USPTO incurred an additional delay of fifty-one days for failing to issue the '892 patent by December 31, 2006 within four months of the payment of the Issue Fee according to 35 U.S.C. § 154(b)(1)(A)(iv) and 37 C.F.R. § 1.703(a)(6). The '892 patent was granted on February 20, 2007.

During the district court case, both Wyeth and the USPTO agreed that Wyeth had delayed prosecution by 148 days. In addition, Wyeth and the USPTO agreed that the USPTO had committed delays in the amount of 610 days, as represented by the bracketed areas in Timeline I at the top of this page.

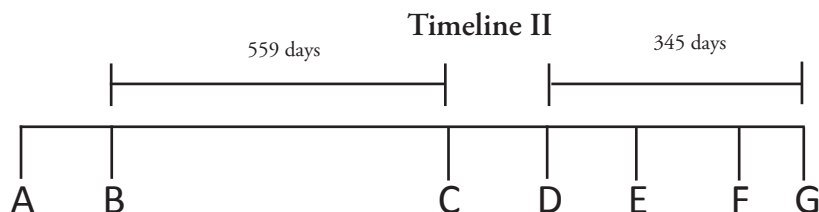
The main issue between Wyeth and the USPTO was whether the USPTO should be charged for additional delays for failing to issue a patent within three years of filing the application pursuant to 35 U.S.C. § 154(b)(1)(B) and 37

C.F.R. § 1.703(b). The USPTO asserted that while the delay occurred, the statute and rules prevented counting the delay since it "overlapped" with another delay. Wyeth asserted that the delay should be counted.

Wyeth's position was that additional delay should be attributed to the USPTO since the '892 patent was granted on February 20, 2007, which is 294 days after March 12, 2006, the three-year anniversary of the filing of the '892 patent. Wyeth's position, illustrated below in timeline II, adds the three-year delay represented by the bracketed areas below to timeline I.

Wyeth's calculation of the delay by the USPTO came to a total of 853 days, the sum of the fourteen-month delay of 559 days and 345 days resulting from the delay for failing to grant a patent three years from the filing date ("the three-year delay"). Note that the previously mentioned delay of fifty-one days shown in timeline I was not counted by Wyeth pursuant to 35 USC § 154(b)(2)(A) and 37 C.F.R. § 1.703(f) since it overlapped in time with the three-year delay shown by the right side bracket shown in timeline II. Thus, the total delay and patent term extension calculated by Wyeth was 756 days (559 days + 345 days - 148 days).

In contrast, the USPTO asserted that timeline I applied to the situation at hand. The USPTO's assertion was based on its interpretation of 35 USC § 154(b)(2)(A) set forth in the previously-mentioned interpretation of the 2004 change to the overlap provision of 37 C.F.R. § 1.703(f). From the USPTO's perspective, a three-year delay could begin prior to the three-year anniversary of the filing of the application. In the case of the '892 patent, the USPTO's position was that the three-year delay was caused by the previous delay of 559 days by the USPTO to render an action on the merits within 14 months of the filing date. Thus, the USPTO asserted that Wyeth would be rewarded twice for the same delay under Wyeth's interpretation and, thus, the fourteen-month delay and the three-year delay "overlapped" one another. Such double compensation was not





Congress' intent, and Wyeth only merited the larger of the two delays, not both combined, as shown in the first timeline. Under the USPTO's interpretation, the total delay was 462 days (559 days + 51 days – 148 days).<sup>20</sup>

### C. District Court Strikes Down USPTO's Rule

Wyeth and the USPTO both filed motions for summary judgment in the district court based on the positions mentioned above. The district court first determined that the USPTO's interpretation of its rule was not entitled to deference under *Chevron v. NRDC*.<sup>21</sup> The district court found that the USPTO in general "does not have the authority to issue substantive rules, only procedural regulation regarding the conduct of proceedings before the agency" pursuant to 35 U.S.C. § 2(b)(2)(A).<sup>22</sup> Regarding the Patent Term Adjustment statute at hand, the district court further found that Congress gave the USPTO the power to "prescribe regulations establishing circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application" pursuant to 35 U.S.C. § 154(b)(2)(C)(iii).<sup>23</sup> The Patent Term Adjustment statute was silent regarding giving the USPTO the power to interpret the meaning of a particular term in the Patent Term Adjustment statute. Therefore, the district court held that *Chevron* did not apply to the USPTO's interpretation of "overlap."<sup>24</sup> Even if *Chevron* did apply, the district court held that the plain meaning of the statute prevented the USPTO's interpretation of "overlap" to be applied. In explaining its holding, the district court pointed out that "[t]he problem with the PTO's interpretation is that it considers the application delayed under § 154(b)(1)(B) during the period before it has been delayed."<sup>25</sup>

### D. The CAFC Strikes the Rule Down a Second Time

The USPTO appealed the district court's ruling to the Court of Appeals for the Federal Circuit (CAFC). On January 7, 2010, the CAFC affirmed the district court's decision in large part for reasons relied on by the district court. The CAFC held that the language of 35 USC § 154(b)(2)(A) was "clear that no 'overlap' happens unless the violations occur at the same time."<sup>26</sup>

The CAFC addressed a number of the issues raised by the USPTO. For example, the USPTO argued that its interpretation of the overlap language was consistent with Congress' intent to cap the term of any patent to seventeen years when the amount of three-year delay was greater than delays based on a failure to meet examination deadlines.<sup>27</sup> The CAFC pointed out that the legislative history of the statute tells a different story. The following comment presented in the Conference Report of the House of Representatives is enlightening on this point:

[S]ubtitle D removes the 10-year caps from the existing provisions, adds a new provision to compensate applicants fully for USPTO-caused administrative delays, and, for good measure, including a new provision guaranteeing diligent applicants at least a 17-year term by extending the term of any patent not granted within three years of filing. Thus, no patent applicant diligently seeking to obtain a patent will receive a term of *less than 17 years* as provided under the pre-GATT standard; *in fact, most will receive considerably more*.<sup>28</sup>

Based in part on the legislative history set forth above, the CAFC held that Congress intended that the statute should provide a minimum seventeen-year term for most patents.<sup>29</sup>

## V. The USPTO Changes Its Ways?

### A. USPTO Response to Wyeth—No Appeal and Interim Procedures

Shortly before the decision by the CAFC, the Senate confirmed David J. Kappos as the Under Secretary of Commerce for Intellectual Property and Director of the USPTO. Director Kappos made the decision that the USPTO would *not* appeal or request reconsideration of the decision made by the CAFC. On January 26, 2010, Director Kappos took steps to establish interim patent term adjustment-related procedures to be in effect until March 2, 2010, the scheduled date for the revision of the USPTO software used to calculate patent term adjustment in accordance with the decision of the CAFC. In addition, Director Kappos *sua sponte* waived the rules regarding deadlines for petitions requesting reconsideration of the patent term adjustment based solely on the CAFC's decision for patents granted within 180 days prior to March 2, 2010. Patent term adjustment petitions for patents granted before the 180 day cut-off would be denied as untimely due to the 180-day deadline to file a civil action in the United States District Court for the District of Columbia.<sup>30</sup> Patent term adjustment petitions for patents granted on or after March 2, 2010 would be processed as other patent term adjustment petitions were processed prior to January 26, 2010.

### B. USPTO Can Do More to Redress Patentees' Demands and to Avoid Potential Procedural Trap

The above actions by Director Kappos arguably provide evidence that the USPTO has changed how it is responding to Congress regarding examination delays caused by the USPTO. More can be done by the USPTO to address the demands of patentees. For example, Director Kappos has the power to prescribe regulations establishing procedures to determine patent term adjustments.<sup>31</sup> It could be argued that such power extends to prescribing regulations to rescind previous erroneous determinations with *Wyeth* issues that were made for patents granted prior to March 2, 2010 and perform another determination of the patent term adjustment.<sup>32</sup> As an alternative, corrective patent term adjustments could be made for those patents in which patent term adjustment petitions were filed and *Wyeth* issues that were raised were denied by the USPTO.

The rescinding of patent term adjustments is especially important for patents granted within 180 days prior to March 2, 2010 and with petitions for reconsideration filed prior to January 26, 2010. In particular, the USPTO is required to give an applicant *only one* chance to request reconsideration of a patent term adjustment determination by the Director.<sup>33</sup> The interim procedures arguably give an applicant *two* chances to request reconsideration. This could lead to misleading an applicant who filed a request for reconsideration prior to January 26, 2010 that did not raise *Wyeth* issues and then filed a subsequent request that solely contained *Wyeth* issues. In such a scenario, the second request for reconsideration is arguably

invalid. Since the applicant was led to believe that the second request for reconsideration was proper, the applicant may not think to protect his or her rights regarding *Wyeth* by filing a civil action with the United States District Court for the District Court for the District of Columbia, as permitted by 35 U.S.C. § 154(b)(4)(A).

## VI. Conclusion

*Wyeth* is an interesting study on how an administrative agency, such as the USPTO in this case, reacts to a congressional statute enacted to spur the agency to correct a perceived deficiency of the agency. As the district court and, subsequently, the CAFC determined, the USPTO chose not to adequately address the deficiency with the rules it created. The CAFC's affirmance of the district court appears to have caused the USPTO to rethink its response. While the USPTO did not fully redress the demands of patentees, the patent community may pressure the USPTO to issue corrective patent term adjustments and fix related potential procedural problems in the near future.

## Endnotes

1 "Congress shall have the power . . . to promote the progress of science and useful arts by securing for *limited times* to authors and inventors the exclusive right to their respective writings and discoveries." U.S. CONST. art. I, § 8 (emphasis added).

2 Chisum, 16.04[1].

3 *Id.*

4 *Id.*

5 35 U.S.C. 154(a)(2).

6 35 U.S.C. §§ 155, 156.

7 35 U.S.C. § 155A.

8 35 U.S.C. § 154(b).

9 35 U.S.C. § 154(b)(2)(C)(i)-(ii).

10 35 U.S.C. § 154(b)(2)(C)(iii).

11 35 USC § 154(b)(1)(A)-(B).

12 35 USC § 154(b)(1)(C)(i).

13 35 USC § 154(b)(2)(A).

14 35 U.S.C. § 154(b)(2)(C)(iii).

15 35 U.S.C. § 154(b)(3)(A).

16 Fed. Reg. Vol. 65, No. 63, 3/31/2000.

17 37 C.F.R. § 1.704(e)(1)-(15).

18 It should be noted that the USPTO offered to receive comments that would be available for public inspection. Some rules were changed in response to the comments.

19 While the USPTO asserted a different position, the author's law firm continued to calculate patent term adjustments based on both its interpretation and that of the USPTO in case a client wished to challenge the USPTO's interpretation.

20 Note that under the USPTO's interpretation, an additional delay of fifty-one days between points F and G of the first timeline was incurred since the delay due to late granting of the patent was not caused by the fourteen-month delay between points B and C.

21 467 U.S. 837 (1984).

22 *Wyeth v. Dudas*, 580 F. Supp. 138, 141 (D.D.C. 2008). Jon W. Dudas

was the Under Secretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office at the time of *Wyeth*'s filing in the district court.

23 *Id.*

24 *Id.*

25 *Id.* at 142 (italics as original).

26 *Wyeth v. Kappos*, 93 U.S.P.Q.2d 1257, 1260 (Fed. Cir. 2010). Jon W. Dudas was eventually replaced by David J. Kappos on August 7, 2009.

27 *Id.* at 1261.

28 H.R. Rep. No. 106-464, at 125 (1994) (emphasis added).

29 *Wyeth v. Kappos*, 93 U.S.P.Q.2d 1257, 1260 (Fed. Cir. 2010).

30 *See* 35 U.S.C. §154(b)(4).

31 35 U.S.C. §154(b)(3)(A).

32 Based on an unscientific sampling of the author's docket of cases patented from 2006 to 2009, around nine percent of the patents had *Wyeth* issues.

33 35 U.S.C. § 154(b)(3)(B)(ii).

