

**PATENT TERM DURATION
AND ITS CALCULATION
(Online and By Hand)**

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Chapter 17

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PATENT TERM DURATION AND ITS CALCULATION

I. OVERVIEW: PATENT TERM MEASURED FROM U.S. APPLICATION *FILING DATE* HAS NO UPPER LIMIT, BUT NO MORE THAN 20 YEARS MEASURED FROM *ISSUE*

It is possible for a patentee to obtain a U.S. utility or plant patent that has a term of *more* than 17 years from *issue*. Even when subjected to dilatory or inefficient processing or prosecution of an application by the USPTO, a *diligent applicant* can enjoy a patent term of at least a full 17 years from grant of the patent. If *both* the applicant and the USPTO are diligent, a patent's term can theoretically approach asymptotically close to 20 years from *issue* if the actions of the applicant and the USPTO asymptotically approach the speed of light after the application is filed.

All this results from that part of the American Inventors Protection Act (Public Law 106-113) entitled *Patent Term Guarantee Act of 1999* (subtitle D of AIPA), which affects term duration from *issue* of a U.S. patent by *adding* day-for-day credits (i.e., adjustments) to the 20 years *from filing term* (that first came upon the U.S. patent law scene on June 8, 1995, through the Uruguay Round Agreements Act (URAA)).

The potential for a 20-year term-from-*issue*, despite the required statutory 20-year term-from-*filing*, exists because:

(1) specified dilatory examination or processing of an application by the USPTO constitutes a *first basis* for adjustments, i.e., credits or extensions (all of which are synonymous terms), to the 20-year-from-filing term;

(2) USPTO and applicant faultless events such as secrecy orders, interferences, and *successful* appeals by the applicant constitute *second bases* for adjustments to that term; and

(3) application pendency longer than three years (subject to certain *exclusions* that lengthen that three-year period) constitutes a *third basis* for adjustments to the 20-year-from-filing term.

The statute provides for *decreasing* (i.e., offsetting) *adjustment credits* via day-for-day *reductions* or *debits* (those terms are synonymous). Those debits arise from specified dilatory prosecution

events caused by the *applicant* which offset adjustments (i.e., credits or extension days) that may have accrued to the 20 years from filing term. Note, however, that unless there exist cumulative, temporally non-overlapping, patent term adjustment credits as a consequence of events attributable to the three bases for adjustments set forth above, there will be no reduction or offset of any adjustment credits by any debits, because there will be no credits from which the debits can be offset.

This lack of offset when, and because, no adjustments accrued that otherwise would have resulted from applicant procrastination, it should be noted, is no true gift to the applicant. This is so because the applicant's dilatory prosecution *itself* automatically diminishes the patent term by extending the period of prosecution. The applicant's delay, in short, uses up days of the 20-year term measured from the filing date, which results, in turn, in a decrease in patent term measured from the issue date, quite independently of whether or not adjustments or reductions are applicable.

The overarching, controlling, and completely accurate (albeit very *general*) rule for determining patent term under the *Patent Term Guarantee Act* of AIPA can be simply stated, as here set forth.

Every day of application prosecution:

(1) *always postpones* the date of *issuance* of a patent by one day; and

(2) it will also *decrease* the *length* of patent term measured from *issuance* by one day – *unless* a day of adjustment (extension) was generated that is not offset by a day of reduction (debit).

But in the Patent Term Guarantee arena, the devil is very much in the details, as the reader will see beginning with Section II.

Let us first consider the statute in broad compass. For *original* patents (excluding design patents) that issue on U.S. applications first actually filed on and after May 29, 2000, the statute establishes:

1. Guaranteed Adjustment Basis (GAB) No. 1 (35 USC §154(b)(1)(A)) – *dilatory USPTO prosecution* results in the adjustment (extension) of the 20 years from filing term by increasing it one day for every day of delay throughout the dilatory periods;

2. GAB No. 2 (35 USC §154(b)(1)(C)) – unavoidable prosecution delays out of the control of either the USPTO or the applicant, i.e., *fault-free*, in the form of an interference, successful appeal of a rejected claim, and a government secrecy order delaying issuance of the patent, generate day-for-day adjustment (extension) for each of those three fault-free types of delay, cumulatively, to the extent that they do not temporally overlap each other – however, there is *no cap or limit* on the period of adjustment, quite unlike the five-year cap for this type of adjustment under URAA prior to May 29, 2000; and

3. GAB No. 3 (35 USC §154(b)(1)(B)) – whether or not the USPTO or the applicant is dilatory, the application must issue within a maximum of three years after filing or else a day-for-day adjustment (extension) will be made to the 20 years from filing term thereby to guarantee a term of 17 years from issue. However, *excluded* from the three-year maximum are days due to (1) interferences, secrecy orders, *all* patentability appeals, and (2) continued examination requests (RCEs) by the applicant (§154(b)(1)(B)(i)) as well as (3) applicant's requests for delays in prosecution (§154(b)(1)(B)(iii)). Consequently, although *exclusion* days extend the three-year period before GAB No. 3 adjustments accrue, the 17-year term guarantee remains potentially intact.

"To the extent that periods of delay attributable to grounds specified in [GAB Nos. 1-3] overlap, the period of any adjustment granted ... shall not exceed the actual number of days the issuance of the patent was delayed." 35 USC §154(b)(2)(A). Thus, any *delay* caused by two or more GAB events that take place on the *same* day results in only *one* day of extension. [The USPTO's surprising, indeed flawed, *interpretation* of the meaning of the preceding sentence in the statute with respect to GAB No. 3 results, as will be seen, in *inconsistent* and extraordinarily complex calculation requirements for determining patent term adjustment.]

Offsetting any adjustment days that *may* accrue, the statute provides for:

Required Reduction Bases (RRB) (Debits) to GABs (Extensions) (35 USC §154(b)(2)(C)) based upon dilatory prosecution by the applicant (as defined by statute and Rules of Practice) that impose a reduction (debit) of one day for every day of applicant delay *applied against any adjustments* that result from events within Guaranteed Adjustment Bases 1-3.

Quite importantly, adjustments provided under §154(b) cannot extend the life of a patent beyond the date established by a terminal disclaimer. 35 USC §154(b)(2)(B).

This new lease on an original U.S. patent's life is applicable only if the application from which the patent issues is *actually* filed on or after May 29, 2000, which is the effective date of the Act's amendment of 35 USC §154(b) that provides for the patent term guarantee. The phrase "original patent" excludes reissue patents because the term of a reissue patent is fixed by the term of the original or parent patent from which the reissue emanates (Chapter 23).

Design patents are excluded from patent term guarantee because their term, by statute, does not fall under the 20-year-from-filing regimen, but rather is a fixed term of 14 years from issue.

Patent applications *not* subject to the benefits of the patent term guarantee statute, whenever filed, according to its legislative history, are applications *initially* filed as international applications (PCT), even those designating the U.S. and filed in the USPTO as a Receiving Office (Chapter 26). When the international application reaches its *national* stage of prosecution in the United States, or when a *continuation* of the international application that has not yet reached the national stage is filed in the U.S., it then is considered "actually" filed. If the "actually" filed date is before May 29, 2000, the three-year pendency guarantee is not applicable. "Otherwise, an applicant could obtain up to a 30-month extension of a U.S. patent merely by filing under PCT, rather than directly in the USPTO, [thereby] gaining an unfair advantage in contrast to strictly domestic applications." Statements on Introduced Bills and Joint Resolutions (Senate – November 17, 1999) Subtitle D – Patent Term Guarantee. (Chapter 26, *infra*, explains how this could occur in PCT procedure.)

The "actual" filing date of a nonprovisional application from whence the original patent issues is its initial filing date; for a *continuing* application thereof it is the filing of the continuing application itself. The date of a "request for continued examination" ("RCE") (Chapter 6) under 35 USC §132(b) does not constitute a filing date of an application at all (examination is simply reopened for a fee after it had been closed), and so it cannot be an "actual filing date" of an application for which patent term guarantee applies.

Although a nonprovisional that claims the benefit of the filing date of an earlier provisional application under 35 USC §111(b)(5) may use that earlier date against prior art, the earlier date is *not* the "actual" filing date of the nonprovisional for patent term guarantee purposes. Therefore, when the nonprovisional and provisional filing dates straddle May 29, 2000, the nonprovisional is entitled to the benefits of patent term guarantee as well as early protection against prior art.

In summary, then, an application has a *limitless* term extension (PTA) potential from its *filing date* which is equal to the three cumulative, temporally non-overlapping GABs for extension adjustments now provided in 35 USC §154(b)(1). That total extension will be diminished day-for-day (RRB) if applicant delays in concluding prosecution, as provided in 35 USC §154(b)(2)(C), 37 CFR §1.704(b) and (c), and also for any other of applicant's *undefined* delaying events which in the USPTO's view constitute *de facto* delays in prosecution even though those unspecified delays are not specifically set forth in Rule 1.704(b) and (c) or the statute.

The other, more permissive, side of the required reduction bases (RRB) coin resides in §154(b)(2)(C)(ii), which specifies that applicant's failure to respond to an Office action within the three months required by that section will be *waived* by the USPTO if the applicant's delay was "in spite of all due care." Exculpatory *examples* given by the USPTO at MPEP §2734 are:

(A) a showing that the original three-month period was insufficient to obtain the test data necessary for an affidavit or declaration under 37 CFR §1.132 that was submitted with a reply filed outside the original three-month period;

(B) a showing that the applicant was unable to reply within the original three-month period due to a natural disaster;

(C) a showing that applicant was unable to reply within the original three-month period because testing was required to reply to an Office action, and the testing necessarily took longer than three months; or

(D) a showing that the applicant was unable to reply within the original three-month period due to illness or death of a *sole* practitioner of record who was responsible for prosecuting the application.

A proper showing by the applicant will result in reinstatement of the adjustment that had been reduced, but for no more than a period of three months. Rule 1.705(c)(2).

In consequence, an applicant need *never* have a patent term less than 17 years from issue, thereby reestablishing the property right that URAA took away by fiat on June 8, 1995.

Nonetheless, the reestablishment of that property right is derived from a complicated statute and from complex USPTO rules. Obtaining the proper term to which an applicant is entitled, therefore, involves extremely detailed, intricate record keeping and formidable calculations, which must be done to ensure attaining one of the major objectives for having filed an application in the first place.

Moreover, an applicant's *acceptance* of an incorrectly lengthy, i.e., overstated, patent term adjustment as calculated by the USPTO can constitute inequitable conduct by the applicant and patent practitioner under Rule 1.56, as discussed below in Section V., *Incorrectly Overstated PTA by the USPTO That Is Not Rejected by the Applicant Can Establish Inequitable Conduct (Rule 1.56) and Unenforceability*.

II. PATENT TERM GUARANTEE ADJUSTMENTS (EXTENSIONS)

A. **Guaranteed Adjustment Basis (GAB) No. 1 – Failure of USPTO to Act Within Specified Time Periods Extends Term Measured From *Filing Date* (The 14-4-4-4 Months Deadlines)**

If the USPTO causes delay in the issuance of an original patent because of failure to act within specified time periods after any of the defined prosecution events set forth in four clauses, i-iv, of 35 USC §154(b)(1)(A), then the 20 years from filing term of the patent:

shall be extended 1 day for each day *after* the end of the period specified ... until the action ... is taken.
[Emphasis added.]

Let us consider individually and serially those four clauses of prosecution events and the statutory time constraints for response imposed on the USPTO relative to each clause.

1. Fourteen-Month Period Beginning After Filing Date (Corresponding to Clause (i) of 35 USC §154(b)(1)(A))

a. Type of Act, i.e., "Notification" by USPTO, That Halts the Running of the 14-Month Period

The USPTO must act no "later than 14 months *after*" (emphasis added) an application is "filed under section 111(a) [a nonprovisional application]" or after an international application's requirements are fulfilled for entering the national stage in the U.S. under 35 USC §371.

(Should the reader care to see the precise words of any part of the Patent Term Guarantee Act, it appears in its entirety as Appendix A at the end of this Chapter 17.)

But what *type* of USPTO *act* halts the running of the 14-month period in satisfaction of the statutory requirement? The USPTO must:

provide at least one of the *notifications* under section 132 of this title or a notice of allowance under section 151. [Emphasis added.]

35 USC §154(b)(1)(A)(i). The notice of allowance (35 USC §151) and an *Ex parte Quayle* action pose no difficulty in understanding and applying. But what other notifications does §132 embrace? Those are, according to §132, "notifications" forthcoming "on examination" of the application, i.e., after examination has begun under 35 USC §131. As such, they comprise the rejection of a claim, and "any objection or any requirement made" after examination has begun.

The reader may surmise that this requirement, detailed in MPEP §2731, poses no significant burden on the USPTO. Thus, for example, if at any time during 14 months after the filing date the examiner mails (i) a written restriction requirement or (ii) a written requirement for an election of species or (iii) a written requirement to include in the drawings a claimed element not already shown or (iv) a

written request for drawings *not* required to understand the invention but of which the invention admits for better understanding, then the notification within 14 months is satisfied.

Consequently, a *ministerial* USPTO request within 14 months after filing, even when no substantive Office action is mailed until after that 14-month period, precludes any term adjustment (extension) under this clause of the statute. Consider a technology center that has a 21-month backlog of applications awaiting a first substantive action. It will take at least 21 months for the USPTO to mail such a substantive action (which is 7 months past the 14-month period); but term adjustment (extension) for the benefit of the applicant can be avoided, and often will be avoided, by the USPTO when an examiner's ministerial notification or requirement is mailed on or before the last day of 14 months after the applicant's filing date.

b. Pre-Examination Processing Acts Not Cognizable as Required "Notifications" by USPTO

As stated in the text section above, Patent Office notices and letters issued *prior* to the official *commencement of examination* of an application do not halt the flow of the 14-month period. The USPTO succinctly states that such documents:

issued as part of the pre-examination processing of an application are not notices issued as a result of an examination conducted pursuant to 35 U.S.C. 131, and thus are not notifications under 35 U.S.C. 132.

MPEP §2731.

The USPTO lists in MPEP §2731 only a small number of possible examples of non-notifications, such as:

- i. Notice of Incomplete Nonprovisional Application;
- ii. Notice of Omitted Item(s) in a Nonprovisional Application;
- iii. Notice to File Missing Parts of an Application;
- iv. Notice of Informal Application;

v. Notice to File Corrected Application Papers, With Filing Date Granted; or

vi. Notice to Comply With Requirements for Patent Applications Containing Nucleotide Sequences or Amino Acid Sequence Disclosures.

Those non-§132 "notices" *cannot*, therefore, constitute USPTO §132 notifications that will unburden the USPTO from its obligation to reply to the applicant within 14 months of the filing date.

Failure of an applicant to cure those deficiencies, which effectively delay commencement of examination, however, extends prosecution time from the filing date and, thereby, automatically decreases patent term. Moreover, those deficiencies *can* be the bases for applicant generated reduction offsets (RRB) against potential future USPTO generated adjustment extensions (GABs). These potential RRBs will be explained in text Section III., *infra*.

Thus, the reader should not believe that by filing an application in one of the incomplete modes set forth by Notices i. through vi. above, the applicant may gain some type of patent term extension benefit therefrom. Quite the contrary! As is discussed in text Section III., below, all these deficiency notices to which applicant fails to timely respond *will* generate reductions (i.e., debits or offsets) to any extension adjustment to which the applicant may be entitled:

equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.

35 USC §154(b)(2)(C)(i).

Admittedly, if no extension has been generated by any type of required adjustments (GAB Nos. 1-3), then the above potential reductions become moot because there is no adjustment in existence that can be reduced. However, during the pre-examination period to which all of the non-notification delays i. and iii.-vi. apply, it will never be possible to know anticipatorily that no adjustment will be forthcoming. To give up part of a potential extension by any one of such five pre-examination delays would be an unwise practice.

Preissuance publication under AIPA has created a new set of possible pre-examination delays, in addition to those set forth above, to which the reader should be alerted. (Preissuance publication of applications is the subject of Chapter 10, *supra*, in its entirety.) An important example flows from the USPTO requirement that at the time of filing a utility or plant application, its drawings must be in a form acceptable for publication, *even* if the applicant files a request for nonpublication (because subsequent events may require publication, nonetheless).

In order for the USPTO to meet its 18 month from filing (and variants thereof) publication obligation under AIPA, the USPTO immediately starts to prepare the drawings for publication. If the drawings are not in a form "suitable for reproduction" at the time the application is *filed*, the drawings will be objected to. Until corrected the application "*will not be placed on the files for examination.*" As a consequence, prosecution time is extended and patent term is diminished. Moreover, unlike past practice, "objections to the drawings in a utility or plant application will not be held in abeyance." Thus, a request for holding the objection in abeyance "will not be considered a *bona fide* attempt to advance the application to final action (§1.135(c))." In sum, with such objected-to drawings:

a. the USPTO objection is *not* a cognizable notification under 35 USC §132 within the 14-month period because examination is yet to begin; but

b. the informality of the drawings, until corrected, delays the initiation of examination which lengthens prosecution, decreases term, and generates potential reduction (offset) to any USPTO adjustment that may accrue later in the prosecution.

2. *Four-Month Period Beginning After Applicant's Reply Under 35 USC §132 (to Rejection, Objection, or Requirement) or Appeal to the Board of Patent Appeals Under 35 USC §134 (Corresponding to Clause (ii) of 35 USC §154(b)(1)(A))*

Whenever an applicant *replies* to a USPTO rejection, objection, or other requirement specified under 35 USC §132, or the applicant appeals to the Board of Appeals after a second or final rejection, the

USPTO must "respond ... within 4 months *after* the date on which the reply was *filed* or the appeal was *taken*." (Emphasis added.) 35 USC §154(b)(1)(A)(ii). If that response is not issued within that time, then just as with failure by the USPTO to respond within 14 months of filing,

the term of the patent shall extend 1 day for each day
after the end of the period ... until the action ... is taken.

(Emphasis added.) 35 USC §154(b)(1)(A)(iv). This adjustment (A)(ii) is identical in its effect to the one for failure of the USPTO to meet the 14-month period requirement of clause (i) of subsection (b)(1)(A) above and the 4-month periods of clauses (iii) and (iv) of subsection (b)(1)(A) that follow below.

Consequently, the method of calculating the adjustment (extension) period, and determining the first and last adjustment days, are uniformly the same for all of the four clauses (A)(i)-(iv) as set forth above and below.

In order to determine whether an adjustment for USPTO delay is applicable under this clause (A)(ii), it is necessary to know:

- (1) the *date* applicant's reply was "filed" or the *date* the appeal was "taken"; and
- (2) the date the USPTO *responded* to those events.

There are five well-defined procedural mechanisms for filing the §132 reply or taking the appeal to the Board under this clause (A)(ii). Each, however, is procedurally very different from the others, and their details affect significantly what effective date is properly credited for "filing" the response or "taking" the appeal.

Although each of these "filing" and "taking" mechanisms during prosecution, as well as its effective date, is treated throughout this treatise in the appropriate chapter and section to which it is pertinent, their discussions are too scattered to be of concentrated value at this point for patent term consideration. Therefore, all are summarized in the table on the next page, to the extent they are material to establishing a date of "taking" or "filing" as a term-calculating datum. It would be worthwhile for the reader, at this point, to review the table that follows in this section.

Mechanism	Date of Complete Document "Filing" or "Taking"	Saturday, Sunday or Federal Holiday	Authority
(1) First class mail via U.S. Postal Service	Date received in USPTO evidenced by date stamp on document.	Will not be treated as received or date stamped until next business day.	Rule 1.6(a)(1)
(2) Hand delivery to USPTO	Date received in USPTO evidenced by date stamp on document.	Cannot be received and therefore cannot be date stamped until next business day.	Rule 1.6(c)
(3) Express Mail Post Office to addressee	Date deposited with USPS with <i>legible USPS</i> date stamp; otherwise date received in USPTO.	Effective on any day (many Post Offices are open on these days).	Rule 1.10(a)
(4) Certificate of mailing [cannot be used to obtain any application filing date]: (a) by First Class Mail (b) by facsimile	Date <i>actually</i> received and date stamped in USPTO. Certificate date only establishes timely submission. If by facsimile, the time and date that the last page is received in USPTO.	Will not be date stamped until next business day.	Rule 1.8
(5) Facsimile transmission [cannot be used to submit drawings or any correspondence under secrecy orders]	Date stamped when complete transmission received in USPTO, whose time zone controls.	Will be received but not date stamped until next business day.	Rules 1.6(a)(3); 1.6(d)(4) and 1.4(d)(1)(ii)

From the table, it is obvious that great care must be taken in figuring the date on which applicant's reply was "filed" or ex parte appeal was "taken." Because the mechanism used in filing a reply can affect the patent's term, it should be selected with care.

When so done, however, it is not difficult to mark the days that establish when a USPTO response is timely. What confounds the situation somewhat, however, is whether or not any USPTO response is required at all. For example, an *applicant's reply* to a restriction requirement or an election of species or a requirement for drawings typically *requires no response at all from the examiner*, unless applicant's reply is defective. (What *is* required from the examiner is an Office action responsive to the filed application within 14 months of the filing date, as discussed above.) It would seem, therefore, that *proper* replies to a restriction requirement by applicant would not be bases for initiating a four-month period for the USPTO to respond even though the replies are to §132 notifications of the USPTO.

The USPTO, it should be noted, holds itself to a higher standard. It is obliged, in its view, to respond *within four months* to applicant's reply, for example, to a *restriction requirement*, with either an Office action or other appropriate response. It may reasonably be presumed that the USPTO response must be by way of an Office action if the applicant's reply is proper, but only with a further notification if the reply is improper.

We now turn to "taking" an appeal. As a general proposition, an appeal to the Board of Appeals is "taken" from an examiner's rejection when the applicant files a *notice of appeal*. (Chapter 18, Petitions and Appeals.) After that event, the applicant is required to file an appeal brief within two months, which is extendible for up to five months (37 CFR §§41.37(e) and 1.136(a)), or the appeal is considered abandoned.

Because the filing of a mere *notice* of appeal does not constitute anything to which the USPTO can or is obliged to reply, the statutory patent term guarantee obligation of the USPTO to reply within four months must be measured from some event other than the notice of appeal. And it is. The USPTO enacted 37 CFR §1.703(a)(4) to provide that the four-month period to reply by examiner's answer or notice of allowance, before adjustments can begin, is measured from the filing of

applicant's *appeal brief* (with the requisite fee). For patent term adjustment *only*, therefore, an appeal is *taken* when applicant's appeal brief is filed. For all other purposes it is taken upon filing of a notice of appeal.

It should be noted that although a notice of appeal to the Board does not require a signature, an appeal brief does. The "signature" forms that are acceptable by the USPTO, and under what circumstances, are set forth in 37 CFR §1.4(d) as amended effective September 21, 2004. More specifically, for all *prosecution papers*, the signature may be original or indirect such as by photocopy or facsimile transmission (37 CFR §1.6(d)). (For all correspondence with the Office of Enrollment and Discipline dealing with matters of enrollment, discipline, and registration to practice, however, the signature must be original. 37 CFR §1.4(e). The §1.4(e) matters, of course, have nothing to do with patent term adjustment.)

3. *Four-Month Period for USPTO to Act Beginning After Decision of the Board of Appeals or of a Federal Court (Corresponding to Clause (iii) of 35 USC §154(b)(1)(A))*

The date of a *final decision*, not appealed, of the Board of Patent Appeals and Interferences, 35 USC §§134 or 135, or the date of a *final judgment*, not appealed or appealable, of a Federal court, 35 USC §§141, 145, or 146, that decides the issue of patentability of appealed claims or priority of invention (see Chapters 18 (Appeals) and 24 (Interferences)) in which "allowable claims remain in the application," commences the running of a four-month period by the end of which the USPTO must *act* on the application involved, i.e., the USPTO must take the next step toward issuance. Failure to do so begins a day-for-day extension, the first of which is the day *after* the four-month period. 35 USC §154(b)(1)(A)(iii).

A Board's decision is final when there has been: (1) no request for rehearing made by the applicant; (2) no remand made or allowed by the Board to the examiner; (3) there *was* a remand which itself becomes a final decision *if* the remand is the Board's last action prior to the mailing of a notice of allowance (37 CFR §1.702(e)); or (4) no appeal filed for appellate review before the Federal Circuit and no

commencement of a civil proceeding before an appropriate U.S. District Court. If any of those proceedings do transpire, then the decision is not final until the proceeding is completed.

Whenever a decision *is* finally final, the USPTO must act within four months to take the next step in the process of issuing the patent, if one is to be issued. However, the day *after* the four-month period *after* the date of a final decision marks the first adjustment (extension) day if the USPTO has not before then acted with respect to "a case in which allowable claims remain in the application." 35 USC §154(b)(1)(A)(iii).

When a civil action is begun before an appropriate District Court or a judicial appeal taken to the Federal Circuit subsequent to a final Board decision, the four-month period for USPTO action begins when proceedings in the Federal court are considered terminated with respect to that appeal or civil action. An appeal to the Federal Circuit is terminated when its mandate is issued by the court. That occurs only after all reconsiderations, rehearings, rehearings en banc, and petitions for certiorari to the U.S. Supreme Court have been terminated. A civil action is terminated when the time to appeal the judgment of the court expires. 37 CFR §1.197(b).

4. *Four-Month Period to Issue Date Beginning After Payment of Issue Fee (Corresponding to Clause (iv) of 35 USC §154(b)(1)(A))*

The U.S. Patent Office must issue a patent no later than "4 months after the issue fee" is paid under 35 USC §151, "*and* all outstanding requirements" are satisfied. If not, a day-for-day adjustment (extension) is applied to the patent term.

"Outstanding requirements," if any, may include, for example, an examiner's requirement for change in the title of the patent or for the inclusion in the drawing of an element that was originally disclosed in the specification but not claimed until late in the prosecution of the application.

The USPTO represents that "Under the current publication process, utility ... patents are issued within about *four weeks* after the issue fee and any required publication fee are received in the Office."

MPEP §1306.03. If so, no adjustment day should be expected due to late issue more than four *months* after payment of the issue fee. It should be noted, however, when reckoning the four months from payment to the issue date, that U.S. patents are constrained to issue only on Tuesdays (even when that Tuesday is a Federal holiday) under the USPTO's unvarying procedure. Therefore, if the four-month period ends on a Monday, and the USPTO is *capable* of issuing the patent on that day, the patent will *not* issue until the next day, Tuesday. The result is a one-day adjustment for late issuance beyond the four months permissible period.

B. Guaranteed Adjustment Basis (GAB) No. 2 – Fault-Free, Unlimited Term Extension Measured From *Filing Date* Due to Interferences, Successful Appeals of Rejections, and Secrecy Orders

An interference, secrecy order, and successful ex parte appeal of a rejected claim to the Board of Appeals and Federal courts can each last many years through no fault of the applicant or the USPTO. Faultless though it may be, a sequence of interferences alone can last, and has lasted, more than 20 years on many occasions. A prime example is that of Gordon Gould's pioneering laser amplification patent. The greater the technological breakthrough the greater the likelihood that a pioneering inventor's application will be bogged down in interferences and both ex parte and inter partes appeals.

Effective for applications filed on and after May 29, 2000, the 20 years from filing term of a U.S. patent "shall be extended 1 day for each day of *pendency* of the proceeding [i.e., interference], order [i.e., secrecy order], or review [i.e., successful ex parte patentability appeal of a claim], as the case may be." 35 USC §154(b)(1)(C) (emphasis added). Moreover, all of these extensions are cumulative, except for those days on which they overlap. (Indeed, temporal overlap due to any and all bases for adjustment (extension) on any given day counts as only one day of adjustment.) 35 USC §154(b)(2)(A). Even though the issuance of a patent can be delayed very many years because of those cumulative delays, not a single day of the patent term, measured from *issue*, will be lost because of the benefit to the applicant of the cumulative adjustments (extensions). Although the patent will surely issue *later* because of such delays, the *length* of the term from the date of issue will not be diminished because of them.

The number of days of adjustment is equal to the nonoverlapping days *of pendency*: (1) of the interference proceeding (including all Federal court appeals or civil actions flowing therefrom); (2) of the successful *ex parte* appeal (including all (a) Federal court appeals or (b) civil actions flowing therefrom or (c) proper paid extensions of time to file papers during the appeal to the Board requested by the applicant); and (3) of the secrecy order. These pendency periods *include* the following days:

(1) Interference – the date the interference is declared through the date of the final decision of the Board or a Federal court's termination of proceedings (as discussed above in this chapter);

(2) *Ex parte* successful appeal – the date the notice of appeal is *filed* in the USPTO through the date of the final decision of the Board or a Federal court's termination of proceedings (as discussed above in this chapter); and

(3) Secrecy order – the date the secrecy order is signed through the date the order is rescinded, i.e., the period the proceedings are under seal.

[Editor's Note: Text continues on page 17.18]

C. Guaranteed Adjustment Basis (GAB) No. 3 – Guarantee of No More Than Three-Year Application Pendency for Diligent Applicant Whether or Not the USPTO Also Is Diligent

1. *A Simple, Straightforward Prosecution Can Last More Than Three Years Even Without Statutory Dilatory Delay by USPTO or Applicant – Thereby Generating Three-Year Guarantee Adjustments That Ensure a Minimum Term of 17 Years From Issue*

If prosecution could not in practice last longer than three years when neither the applicant nor the USPTO causes delay, and even when there have been no interferences, secrecy orders or appeals, then there would be no need for a guarantee of no more than a three-year application pendency. The reason is that the term would necessarily be 17 years from issue or more without statutory intervention. But even without the delay factors listed in the preceding sentence, prosecution in reality can, and often does, last more than three years, thereby establishing the need for the no more than three-year pendency guarantee of 35 USC §154(b)(1)(B), to ensure the possibility of a 17-year term from issue (the guarantee of which was taken away on June 8, 1995, by the 20 years from filing term of URAA).

Consider the following common hypothetical situation by way of example. An application is filed, the technology of which places it in a technology center having a 21-month backlog for a first substantive Office action after filing (a not uncommon situation). At the end of 14 months after filing (which is too soon for an Office action because of the backlog), the examiner issues a restriction requirement under §132, to which the applicant properly replies at the end of three months. Four months later, which is 21 months after the filing date, the examiner mails the first substantive Office action which was not earlier possible because of the 21-month backlog. At this point, neither the USPTO nor the applicant has been dilatory under any possible interpretation of the statute and rules. Nevertheless, 21 months already have passed, and the subsequent statutorily prompt and uncomplicated prosecution sequence set forth below readily extends prosecution beyond three years from filing.

(1) Applicant replies to the Office action at the end of three months (which is non-dilatory under the statute; elapsed time from application filing date is now 24 months).

(2) Examiner responds at the end of four months (non-dilatory under the statute; elapsed time is now 28 months).

(3) Applicant replies at the end of three months so as to place application in allowable condition (non-dilatory under the statute; elapsed time, 31 months).

(4) Examiner mails notice of allowance at the end of four months (non-dilatory under the statute; elapsed time, 35 months).

(5) Applicant pays issue fee at the end of three months (non-dilatory under the statute; elapsed time, 38 months).

(6) USPTO issues patent at end of one to four months (non-dilatory; total elapsed time, 39 to 42 months).

The net result is a prosecution period of three years plus three to six months, in an uncomplicated scenario in which neither the applicant nor the USPTO is dilatory. Fortunately for the applicant, §154(b)(1)(B) *effectively* reduces the 39 to 42 months from filing pendency to three years by *extending* the 20 years from filing term by:

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

The happy ending is a patent term, the last day of which is 17 years from issue.

2. *When Calculating the Three-Year Guaranteed Pendency Period (GAB No. 3), All Statutory Exclusions From the Three-Year Period Will Effectively Lengthen the Three-Year Period and Delay the Beginning of Adjustments (Extensions)*

a. *Exclusions From GAB No. 3 Adjustments Because They Are Also GAB No. 2 Extensions*

An application can actually be in prosecution very much longer than three years *without* triggering any adjustment (extension) despite the *three-year pendency* guarantee of §154(b)(1)(B). This can

occur for several reasons. The first is because an adjustment (extension) may have *already* been made through another, different guarantee adjustment basis. Thus, if an *extension* has already been applied based upon an interference, secrecy order, or successful appeal (GAB No. 2), it will not be duplicated for credit to the three-year pendency guaranteed adjustment basis by the express language of GAB No. 3. It will be *excluded* because it was or will be granted under GAB No. 2.

b. The *Other* Exclusions From GAB No. 3 Adjustments *Because* They Are Due to Delays Requested or Caused by the Applicant

GAB No. 3, which specifies that all GAB No. 2 adjustments be *exclusions* from the three-year pendency guarantee in order to preclude duplication of adjustments, also provides for *additional exclusions* beyond the three of GAB No. 2. The first and least noticeable *additional exclusion* is with respect to appeals to the Board and Federal courts that have *no counterpart extensions* in GAB No. 2, §154(b)(1)(C), namely *losing* an appeal. *Losing* an appeal generates an exclusion *not* because an extension for an appeal had already been obtained under GAB No. 2, which *is* the case for a *successful* appeal, but because, presumably, the applicant improperly delayed issuance of the patent through a nonmeritorious appeal.

Thus, the three-year pendency guarantee §154(b)(1)(B) (GAB No. 3) *excludes* prosecution periods from the three-year pendency guarantee for *both failed and successful* appeals.

Two additional *specific* and important categories of exclusions from the three-year pendency guarantee are explicitly set forth in §154(b)(1)(B) (GAB No. 3) as items (i) and (iii). Item (B)(i) provides that "any time consumed by continued examination ... requested by the applicant [RCE]" is excluded from the three-year pendency guarantee. This is understandable because without the RCE, the application would either issue in its pre-RCE form if any claims stand allowed, or the applicant would have to appeal (or abandon the application). In either event, no adjustment would have to be made under the three-year pendency guarantee.

Item (iii) of subsection (b)(1)(B) also adds an *exclusion* for "any delay in processing of the application ... requested by the applicant." The reader should note that there are two important categories of applicant-requested "delays in processing of the application," which on their face would appear clearly to be required to be treated as exclusions from the three-year pendency period under item (iii) – but they are *not* so treated by the USPTO. One is applicant-requested-and-permitted delays specified in Rule 1.103. The other is applicant-requested-and-paid extensions to reply *beyond* three months under Rule 1.136(a) to any "rejection, objection or requirement" of the examiner under 35 USC §132. The USPTO has offered no public explanation for *not* treating these two categories of applicant-requested delays as exclusions.

D. How to Combine (*Not* Necessarily Add) Extensions for All Three Adjustment Bases to Arrive at the Total GAB Nos. 1-3 Adjustment Days

1. Overview

When a prosecution involves only GAB No. 1 (14-4-4-4) and GAB No. 2 (interference, secrecy order, successful appeal) delays, the procedure for combining the adjustment days is linear and straightforward, i.e., they are simply added, except that each day that experiences more than one adjustment event counts only as one adjustment day. The statute, Rules, and USPTO interpretations thereof all coincide. (But, as discussed at various points above in this chapter, reasonable people may well disagree as to whether the USPTO Rules and interpretations in some instances are consonant with the clear meaning and wording of the statute defining *which* events are adjustment events.)

When GAB No. 3 (three-year pendency guarantee) events come into play, however, although the language of the statute seems quite clear and logical, and dictates a straightforward linear combination of all three GABs, the USPTO Rules require something entirely different; and the USPTO *interpretation* of its own Rules is in dramatic conflict with the clear wording of its own Rules. The author assures the readers that they will read in disbelief the illogic promulgated by the USPTO on this subject. But readers must understand what has

happened in order to protect their clients' interests. That understanding will be achieved by carefully considering subsections 2., 3., 4., and 5. that follow.

2. *How to Combine Adjustments for GAB No. 1 (14-4-4-4) and GAB No. 2 (Interferences, Successful Appeals, and Secrecy Orders) When GAB No. 3 (Three-Year Pendency Guarantee) Is Not Involved*

We start by assuming that examination prosecution has *not* extended more than three years from the filing date. Then we proceed according to the analytical sequence that follows.

(i) If there are any 14-4-4-4 delays (GAB No. 1), add all days of delay as adjustment days to the 20-years-from-filing term, except that any day that experiences a plurality of adjustment events counts only as one day of adjustment. Those delays postpone issuance of the patent but also add adjustment (extension) days to the term measured from issuance.

(ii) If there are any GAB No. 2 delays (secrecy orders, interferences, and *successful* patentability appeals), add all those fault-free delays to those of GAB No. 1 above as adjustment days to the 20-years-from-filing term, except that any day that experiences a plurality of GAB No. 1 and No. 2 adjustment events counts only as one day of adjustment. Those delays will postpone issuance of the patent but will also add adjustment days to the term measured from issuance. Thus, the adjustment is provided under GAB No. 2 independently of any GAB No. 1 adjustment, except that a day with both GAB No. 1 and GAB No. 2 events will count as only one adjustment day.

3. *How to Determine the Beginning of Delay Under GAB No. 3 (Three-Year Pendency Guarantee) When GAB No. 1 (14-4-4-4) Is Not Involved*

Now let us assume that examination/prosecution has lasted more than three years from the filing date and that an *exclusionary* event has occurred. We investigate, therefore, whether and when adjustments to term under GAB No. 3 are generated. We do so *initially, but only initially*, independently of the existence or absence of GAB No. 1 adjustments. But to set the stage let us examine 35 USC §154(b)(1)(B) (which *is* GAB No. 3).

(B) Guarantee of no more than 3-year application pendency.—Subject to the limitations under paragraph (2) [Overlap, Terminal Disclaimer, and Required Reduction Period], 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) [interference], any time consumed by the imposition of an order under section 181 [secrecy], 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) [reinstatement based upon "all due care"],

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.

Thus, the statute states that beginning on the filing date, each day counts toward the three years specified in the first clause, but "not including" any days that fall within the exclusions listed in (B)(i), (ii), and (iii). As a consequence, the counting of days (toward the three years) stops when an exclusionary event begins and does not resume until after it ends. Moreover, after counting resumes, it stops again if a second exclusionary period begins before three years are accumulated outside the first exclusionary period, and so on.

In short, to determine the end of the three-year period under 35 USC §154(b)(1)(B), at which time delay begins and adjustment days

begin to accrue, one should count up days from the filing date, skip all days during exclusionary events, and stop counting on finally reaching a total of three years' worth of *non*-exclusionary days. At *that* time the proscribed delay under the three-year pendency guarantee commences the count of the compensating adjustments. The GAB No. 3 section of the statute quoted above clearly so states. And the literal language of Rule 1.702(b) is in agreement.

4. *How to Combine the GAB No. 1 (14-4-4-4) and No. 3 (Three-Year Pendency) Adjustment Bases to Determine the Extension*

a. *According to the Clear Meaning of the Words of the Statute and Rule 1.702(b)*

versus

b. *According to the Nonstatutory, Non-Rules USPTO (Mis)Interpretation of the Statute and Its Own Rule 1.703(f)*

Delays for which adjustments accrue necessarily begin *after* the point in time that marks subsequent time periods as *late*. The USPTO accepts that self-evident definition when GAB Nos. 1, 2, and 3 delays exist *in isolation from each other* – but *not* for a GAB No. 3 three-year pendency guarantee delay that develops in the *same* application as does a GAB No. 1, 14-4-4-4, delay. For the latter situation, instead of the three-year pendency delay being marked as late from the day after three years from the filing date (excluding exclusions), the USPTO declared, on June 21, 2004, that the *delay* begins from the day the *application is filed*. 69 Fed. Reg. 34,283.

Can it really be the law that the entire pendency of an application from its filing date to its issue date constitutes a *delay* under the statute in the issuance of the patent? The USPTO insists that it is, but only for a three-year pendency delay, and only when there are also one or more 14-4-4-4 delays. When, however, the pendency exceeds three years (excluding exclusions) and *no* 14-4-4-4 delays occurred, then the *delay begins* at the *end* of the three years (excluding exclusions) and *not on the day the application was filed*. (Note: A three-year pendency *delay* that is held to occur beginning on the filing

date, and that extends to the date of issue, would result in an adjustment (extension) equal to the *entire length of the prosecution*. As a consequence, *every* patent whose pendency is *more* than three years (excluding exclusions) would *always* have a *full* 20-year term from the *date it issues* – not just from its filing day. Such a result is, of course, absurd under the statute and the law of common sense.)

Following the USPTO logic of 69 Fed. Reg. 34,283 (reproduced in Appendix B), all 14-4-4-4 (GAB No. 1) delays that occur during the first three years of *non-excluded prosecution*, and which, therefore, *could not possibly overlap* delays that are measured beginning *after* three-year pendency, will actually *always* overlap GAB No. 3 delays under the current USPTO definition that the three-year pendency *delay begins on the filing date*. The consequence is that it can never be possible to obtain adjustments for *both* those 14-4-4-4 delays and three-year pendency delays, *and the USPTO has expressly so stated*. The *one* adjustment that the USPTO *does* grant as between 14-4-4-4 and three-year pendency that occur in the same application is the *longer* of those two adjustments (*but not their sum*), contrary to the facial requirement of the statute. But under *these* circumstances the USPTO laughably, inconsistently measures the period of the three-year pendency delay as beginning *after* the three years of prosecution while having also insisted that the delay began on the *filing date* in holding that the 14-4-4-4 delay overlaps the three-year pendency delay.

The overall practical *adjustments* calculation consequences of this USPTO interpretation of the relationship between 14-4-4-4 and three-year pendency *delays* are captured in the following illustrative fact situations.

1. Assume X days of 14-4-4-4 delay events occur during a span of time, Y, that equals exactly three years of prosecution with no excluded events. Further assume the patent issues at the end of Y.

Total Resulting Adjustment = X days, due to 14-4-4-4. This is simple and obvious because there is no three-year pendency delay under any interpretation.

2. Same facts as 1., except that after the time period Y ends, the patent does *not* issue. Instead, prosecution continues for Z days of non-excluded prosecution to issuance, i.e., Z constitutes three-

year pendency adjustment days. Z (three-year pendency delay) and X (14-4-4-4 delays), therefore, *are spaced apart*.

Total Resulting Adjustment Is the Greater of Either X (14-4-4-4) or Z (Three-Year Pendency), But Not X + Z, Dependent Upon *Additional* Facts as Set Forth in a., b., and c., Below:

a. Assume Z, the actual three-year pendency delay, is *less* than X, the 14-4-4-4 delay, ($Z < X$). Then, the total adjustment is *still* only X days, *not* $Z + X$. Why? Because $Y + Z$, which is the *entire* prosecution period, necessarily includes the 14-4-4-4 delay, X, and the USPTO insists that the *entire* prosecution period, $Y + Z$, not Z alone, is the three-year pendency *delay*. Believe it or not! Because Z, the *real* three-year pendency delay, is less than X, the adjustment is *only* X under the *fictitious theory that X and Z are delays that overlap* in time even though X and Z are distinctly *spaced apart* periods! So sayeth the USPTO.

b. Assume Z, the actual three-year pendency delay, is *greater* than X, ($Z > X$), then the total adjustment is Z days, *not* $Z + X$, under the same fiat-based logic in a. above.

c. Assume Z and X are exactly equal, ($Z = X$), and that those periods continue to be spaced completely apart. Then the adjustment is Z days or X days, which are the same, but *not* $Z + X$ days.

The results of examples 2.a., b., and c. are based upon the USPTO's proposition that the three-year pendency *delay* is *not* Z, which is measured from the end of Y, but rather $Y + Z$, which is *the entire period of prosecution beginning with the day of filing*. Under this bizarre interpretation of the GAB No. 3 delay, the X delay (14-4-4-4) and the Z delay (three-year pendency) must *always* overlap each other (even though they may actually be spaced apart) because both are within the entire prosecution period of $Y + Z$.

In 2.a., b., and c., of course, the true adjustment dictated by *statute* should always be the sum of the two real, spaced apart, delays, X and Z. Needless to say, the applicant can never get the full term to which he or she is literally entitled by statute and Rule 1.703(f) under this bizarre interpretation by the USPTO of the statute and *its own Rule*.

c. How the Legislative History Confirms the Clear Meaning of the Statute and Refutes the USPTO Misinterpretation of Both the Statute and Its Own Rule 1.703(f)

Under Supreme Court precepts for statutory interpretation, when the meaning of a statute is clear on its face, resort to legislative history is both unnecessary and inapposite. When, however, the legislative history provides irrefutable reinforcement of the statute's clear meaning, any proffered contrary interpretation should be viewed as seriously jaundiced. Here follows the controlling section of the statute and two quoted pertinent explanations thereof from its legislative history. (Emphasis has been supplied by the author, as has bracketed text, which adds verbal description to section numbers.)

§154(b)(2)(A):

To the extent that *periods of delay* attributable to grounds specified in paragraph (1) [14-4-4-4; three-year issue; and appeal, interference, secrecy order] *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.

Legislative History (145 Cong. Rec. S14708, S14718 (daily ed. November 17, 1999):

To the extent that there are *multiple grounds* for extending the term of a patent that may *exist simultaneously* (e.g., delay due to a secrecy order under section 181 and administrative delay under section 154(b)(1)(A) [14-4-4-4]), the term should not be extended for each ground of delay but only for the actual number of days that the issuance of a patent was delayed.

Legislative History (145 Cong. Rec. S14708, S14718 (daily ed. November 17, 1999):

Accordingly, subtitle D [AIPA PTA] 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*, includes 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 the 17 years as provided under the pre-GATT standard; in fact, most will receive considerably more.*

The reader will note that the USPTO's dubious manner of combining (rather than adding) nonoverlapping GAB No. 1 and GAB No. 3 adjustments *ensures* that *many diligent* patent applicants will receive patents with a term *less* than what §154(b) was expressly designed to guarantee.

5. How to Combine All Three Adjustment Bases, When Exclusions Are Added to the Mix

Exclusions consist of two components: GAB No. 2 adjustment-meriting delays (interferences, secrecy orders, and successful appeals); and applicant-requested delays in prosecution. Irrespective of which element of which component is in effect during prosecution, it serves to interrupt the progress of the three years of prosecution pendency period after which days of adjustment begin to accrue. That exclusionary *interruption* in the three years of prosecution pendency has led the USPTO to hold that GAB No. 1 and GAB No. 2 adjustments accrue during that period (except for overlaps). Because during an exclusion period there is no progress in the prosecution to contribute to the three-year period, *all* GAB No. 1 and No. 2 adjustments are credited to the applicant during exclusion periods subject only to traditional overlap restrictions.

When, however, *no* exclusions are in effect, the only adjustments possible are GAB No. 1 (14-4-4-4) adjustments and three-year pendency adjustments. Under the USPTO spurious algorithm for combining 14-4-4-4 adjustments and three-year pendency adjustments (discussed above), therefore, when no exclusion is operational, only the *greater* of 14-4-4-4 extensions or three-year pendency guarantee extensions accrues. However, if at any time during prosecution there is *also an exclusionary period*, any and all non-overlapping GAB No. 1 (14-4-4-4) and No. 2 (interference, secrecy, successful appeal) extensions that occur during an exclusion are *independently* added to the *greater* of 14-4-4-4 or three-year pendency guarantee extensions.

This peculiar concept of combining adjustments when exclusions are introduced into the mix may be more readily understood visually. Thus:

$$\begin{array}{c}
 \text{Total Adjustments} = \\
 \text{[During Exclusionary Periods: All Non-Overlapping} \\
 \text{GAB No. 1 (14-4-4-4) and GAB No. 2 (Interferences,} \\
 \text{Successful Appeals, Secrecy Orders) Adjustments]} \\
 + \\
 \text{[During Non-Exclusionary Periods: The Greater of GAB} \\
 \text{No. 1 (14-4-4-4) or GAB No. 3 (Three-Year Pendency} \\
 \text{Guarantee) Adjustments]}.
 \end{array}$$

From the above, it can be seen that a 14-4-4-4 adjustment can conceivably be added to the three-year pendency adjustment, but *only* in the specific circumstance that the 14-4-4-4 credit was generated *during* a prosecution's *exclusionary* period.

E. Determining What Are the First and Last Adjustment Days for GAB Nos. 1, 2, and 3

The calculation of adjustment periods for all three Guaranteed Adjustments bases depends upon which day starts the period and which ends it. For GAB Nos. 1 and 3, i.e., 14-4-4-4 and three-year guaranteed pendency, the first and last days are determined in the same way. For GAB No. 2 (interferences, secrecy orders, and successful appeals) the determination depends upon when the proceeding, order or review begins and ends. The 14 months from filing notification required of the USPTO (GAB No. 1) is exemplary of all GAB Nos. 1 and 3 and is now demonstrated.

A USPTO notification pursuant to 35 USC §132 (or a notice of allowance or *Ex parte Quayle* action) must be "*not later* than 14 months *after*" the filing date or entry into the national stage; if it is later, then "the term of the patent shall be extended 1 day for each day *after* the end of the period specified." Therefore, the first day *after* "14 months *after*" the filing date is the first day of extension.

Thus, by way of example, for an original, non-design application filed on May 30, 2000, the USPTO must mail a §132 notification on or before July 30, 2001. If the USPTO does not, then July 31, 2001

becomes the *first* extension day for the applicant, i.e., extension day number 1.

When is the last day of the extension? Assume, further, that the USPTO mails its notification *on* July 31, 2001, which is the first day *after the last permissible day*. We know with certainty that July 31, 2001, is an extension day, and indeed it is the *first* extension day; but it also becomes the *last* extension day because the USPTO mailing of a notification on that first extension day prevents the accrual of any additional days of extension thereafter (for that particular delay).

An important generic rule of logic for determining the last extension day to which an applicant is entitled is now discernible through the imperative of the above example even though the statute contains no express language on the subject. The logic, in the form of *reductio ad absurdum*, follows. (1) Assume that when an act required of the USPTO is *late* under Patent Term Guarantee, then the day on which the required act takes place is *not an extension day*. (2) If this were so, then when the USPTO acts one day *after* the last permissible day to act under the statute, the applicant would get *no extension at all*.

In short, in the example above having a May 30, 2000 filing date, the mailing of the USPTO notification which took place one day *late* under the statute *must* result in an extension day because mailing it the preceding day would have been timely. For both a late act and a timely act to have the same consequence under the statute constitutes a logical impossibility, i.e., an absurdity.

We must now consider the common situation in which the last day permitted for taking some action in the USPTO falls on a Saturday, Sunday, or Federal holiday recognized in the District of Columbia. Usually such a problem is the applicant's problem, but under the Patent Term Guarantee Act it can be, and is, an issue the USPTO faces; however, its resolution is of importance primarily to the applicant.

When the last day of the 14-month period falls on a Saturday, Sunday, or Federal holiday, logic requires the conclusion, under the Patent Term Guarantee Act, that a USPTO notification mailed on the

next business day is too late. That is, the applicant is entitled to one or more days of extension.

Why is this a necessary logical conclusion when for every other prosecution situation under the patent statute and rules the next business day suffices?

First, because the statute states without ambiguity, equivocation, vagueness, or indefiniteness that by taking appropriate action on a day no later than the *last day* of the 14-month period, the USPTO avoids subsequent days of adjustment.

Second, the statute has no express or implied waiver for Saturdays, Sundays or Federal holidays; the statute is "clear on its face."

Third, by way of direct, precedential analogy, precisely such a situation applied to any 12-month anniversary date for a provisional application under URAA that fell on a Saturday, Sunday, or Federal holiday. The USPTO construction of the statute was that the provisional application went abandoned on the succeeding day. Any necessary action had to be taken *prior* to that anniversary date (unless by Express Mail *on* that date), *not* on the next day, whether business or not. A statutory amendment under AIPA itself was required to change that construction. 35 USC §119(e)(3). See Chapter 7, Foreign and Provisional Application Priority, *supra*.

Fourth, Tuesday is always the day of each week on which the USPTO issues patents. That is when their legal lives begin. U.S. patents issue even on Federal holidays when that holiday falls on a Tuesday. And this is so even though the USPTO is neither open nor operational on that day. 37 CFR §1.6(a)(1). For example, on Tuesday, July 4, 2000, Independence Day, unquestionably a Federal holiday in the District of Columbia, the USPTO issued U.S. utility patents 6,081,922 through 6,085,351. When the consideration is patent term, therefore, Saturdays, Sundays, and Federal holidays are irrelevant to the beginning of the term (from issue) and should logically also be irrelevant in a calculation fixing the end of that term, for example, when fixing the end of the four-month period from payment of the issue fee to the date of issue.

By way of summary, MPEP §2731 provides that the end of the period *after* which the USPTO must act to avoid adjustments under GAB No. 1 (14-4-4-4) and GAB No. 3 (three-year pendency guarantee) is:

"day zero" (not "day one").

The following day is "day one."

Under GAB No. 2 (interferences, secrecy orders, and successful appeals), the *period of pendency* of the proceeding determines the period of adjustment as discussed in preceding sections. Thus:

the first day of the proceeding, order, or review ... is "day one" of the period of adjustment.

III. REQUIRED REDUCTION BASES (RRB) DIMINISH THE PERIOD OF ADJUSTMENT (EXTENSION) OF PATENT TERM, IF ANY

A. The Adjustment-Reduction Equation

The reader recognizes at this point that a patent's basic 20-years from filing term will be modified under AIPA/URAA by combining the adjustment days (credits), *if any*, generated after the filing of the application and up until issuance, as explained in text Section II. above, with the reduction offset days (debits), *if any*, also generated between filing and issuance, as explained below in this text Section III.

In short, the term variable T , is ascertained by solving the equation:

$T = (20 \text{ years from filing}) + [f(\text{GAB } 1,2,3) - f(\text{RRB})]$, where $[f(\text{GAB } 1,2,3) - f(\text{RRB})]$ is only permitted to be positive or zero, and all units in the equation are in days. Thus, if $f(\text{GAB } 1,2,3)$ is zero, then $f(\text{RRB})$ need not even be calculated because no value of $f(\text{RRB})$ is permitted to result in $[f(\text{GAB } 1,2,3) - f(\text{RRB})]$ being negative, i.e., if there is nothing in existence, i.e., no adjustment days, against which to apply an offset, then an offset cannot occur.

It is important to note, however, that the incapacity of $-f(\text{RRB})$ to reduce $[f(\text{GAB } 1,2,3) - f(\text{RRB})]$ below zero, i.e., to a negative number, is no gift to the applicant. This is so because, as explained earlier, those

f(RRB) delays in concluding processing and examination of an application inherently, by themselves, extend prosecution and, thereby, shorten the term of the resulting patent.

The calculation of f(GAB) defined by 35 USC §154(b)(1)(A) (GAB No. 1), and (C) (GAB No. 2), and (B) (GAB No. 3), is complex, as was seen in text Section II., above, because of the many variables specified not only by those subsections of the statute, but also by USPTO-generated rules *and commentaries* that appear in:

(1) *Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term; Final Rule*, 65 Fed. Reg. 56,366-394;

(2) *Changes to Implement the Patent Business Goals; Final Rule*, 65 Fed. Reg. 54,604-683;

(3) *Changes to Implement Eighteen-Month Publication of Patent Applications; Final Rule*, 65 Fed. Reg. 57,024-061; and

(4) *Explanation of 37 CFR §1.703(f) and of USPTO Interpretation of 35 USC §154(b)(2)(A)*. 69 Fed. Reg. 34,283.

Despite the complexities encompassed by f(GAB 1,2,3), the applicant should recognize that that function is actually the *carrot* part of the Term equation. The *stick* part of the equation is f(RRB). *Every act of, or failure to act by*, the applicant, from filing to issuance, must be individually gauged against the following statutory standard if reductions to adjustment extensions are to be avoided:

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

35 USC §154(b)(2)(C)(i).

If this generic statutory standard is *self-executing*, the applicant may not be free to *merely* look to the statutory and rules provisions that *expressly* set forth grounds for reduction of the adjustment period. Much more would have to be considered!

The USPTO asserts that much more does have to be considered! Rules 1.704(c)(1) through 1.704(c)(11) are those that merely address

situations that occur with sufficient frequency to warrant being, in the USPTO's view, specifically provided for in its rules of practice. However,

An attempt to provide an exhaustive listing of actions or inactions that interfere with the Office's ability to process or examine an application is impractical, since there are a *myriad* of actions or inactions that occur *infrequently* but will interfere with the Office's ability to process or examine an application. [Emphasis added.]

65 Fed. Reg. 56,371. On that same page, the USPTO presents exemplary fact patterns that constitute *unlisted* reduction-generating events, two of which are set forth in this section, at subsection B.2.b.ii., *infra*.

In text subsection B. immediately below, there is presented and explained those reduction bases that are:

(a) specifically denominated in the statute;

(b) specifically denominated in USPTO rules under specific authority from the statute (but some of which, the author suggests, are in direct conflict with statutory provisions); and

(c) a huge, amorphous category of non-specific reduction bases postulated, but not listed, by the USPTO for which the applicant, but not the USPTO, is responsible for including in the patent term adjustment calculation. However, the Office itself may "reduce a period of adjustment ... on the basis of [applicant's] conduct [or inaction] that interferes with the Office's ability to process or examine an application ... even if such conduct [or inaction] is not specifically addressed in 37 CFR 1.704(c) [or in the statute]." MPEP §2732.

B. Two Categories of Reduction Situations

1. *Structured – The Three-Month Grace Period for Applicant to Reply to a USPTO Notice or Action*

a. Under the Statute

The Patent Term Guarantee statute provides that a *reduction* shall apply to any adjustments generated under the very specific

guarantee of *no more than three-year application pendency* (§154(b)(1)(B)) (GAB No. 3):

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. [Emphasis added.]

35 USC §154(b)(2)(C)(ii).

The reader may recall that the USPTO "notice" of this subsection to which the applicant must reply within three months, *in order to escape a reduction of adjustment days*, are those very same notifications that arise after examination begins under application-reexamination §132. Thus, for example, the applicant has three months to respond, if a reduction is to be avoided, to a rejection, objection, or any requirement such as, for example, a restriction requirement, requirement for election of species or request for information under Rule 1.105. All of these are the *same* "notifications," the reader will recall, of which the USPTO must provide at least one within 14 months of the filing date *in order for the USPTO to avoid imposition of an adjustment*.

Most importantly, however, is that this three-month grace period for applicant to reply, in order to preclude reduction, is independent of the period of time by which the applicant is *otherwise* obliged to reply. As a first example, a one-month period to reply to a restriction requirement may be extended two months, with fee, and a reply anytime during that three-month period will *not* invoke a reduction. As a second example, a two-month period to reply to a USPTO *letter* requesting information under Rule 1.105 may be safely extended to three months, with fee, without invoking a reduction. (If the Rule 1.105 request is part of an *Office action*, the period to reply is a full three months as standard in Office actions.)

The period, or shortened statutory period, for reply that is set in the Office action or notice has no effect on the three-month period set forth in this paragraph.

37 CFR §1.704(b).

The plain language of this rule, and the statutory section it supports, therefore, results in the need for applicant to reply within three months even to an Office action that *permits* the full six-month statutory period for reply. Days following the three-month period to reply are reduction offsets to any adjustment extension even though the post-three-month reply does *not* result in abandonment of the application under 35 USC §133. USPTO Commentary, 65 Fed. Reg. 56,371; MPEP §2732.

b. Under the Rules and USPTO Commentary

The three-month grace period for reply to a USPTO notice, narrowly permitted under the three-year pendency guarantee of the *statute* (GAB No. 3), was broadly, indeed comprehensively, extended by Rule 1.704(b) to *all* situations wherein applicant must reply to a USPTO notice or notification in order to avoid failing "to conclude processing or examination of an application." AIPA gives the Director broad authority to draft such rules under 35 USC §154(b)(2)(C)(iii).

An important consequence of this broadly-applied, structured, three-month grace period rule is that it is applicable even to *pre-examination notices* which are themselves *excluded* from those USPTO acts that stop the calendar's 14-month progression to an *adjustment* (as discussed in text Section II.A.1.b., *supra*).

Thus, the following USPTO notices, which deal with pre-examination events that clearly delay conclusion of the processing and examination of applications from the moment they occur, can permissibly be replied to during the three-month grace period *without* generating a *reduction* of any adjustment. Of course, each of applicant's *failures* to process the application promptly, which the following notices capture, results in extending prosecution that *itself* necessarily shortens patent term.

(1) Notice of Incomplete Nonprovisional Application;

(2) Notice of Omitted Item(s) in a Nonprovisional Application; [Ed. Note: Prior to January 29, 2007, a Notice of Omitted Item(s) did not, and could not, generate a reduction because the USPTO did not require a reply to such a Notice, i.e., a reply was optional. Effective January 29, 2007, a reply is always required by: a petition either for the date of deposit or for a later filing date or by the filing of an amendment to the application, e.g., a substitute specification.]

- (3) Notice to File Missing Parts of an Application;
- (4) Notice of Informal Application;
- (5) Notice to File Corrected Application Papers, With Filing Date Granted; or
- (6) Notice to Comply With Requirements for Patent Applications Containing Nucleotide Sequences or Amino Acid Sequence Disclosures.

2. *Unstructured – Varied Circumstances That Generate Reductions (No Uniform Grace Periods), If Any*

a. *Rules-Defined Reduction Situations Caused by Applicant's "Failure to Conclude," Independent of Failure to Reply*

We turn now to the balance of the *Rules-defined* exemplary "[c]ircumstances that constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application." They are set forth in §1.704(c)(1) through (11). (The "myriad of actions or inactions" by applicant that arise *infrequently*, and for that reason are not listed in the rules, but that can result in reductions of adjustment extensions, according to the USPTO, will be addressed below in the next "Unstructured" subsection, "b. Infrequently Arising Reduction Circumstances Not Specifically Listed in the Rules".) 65 Fed. Reg. 56,371.

The 11 "circumstances" of Rule 1.704(c) reductions are termed "Unstructured" by the author because their natures are varied, they occur scattered over the patent prosecution procedural landscape, and the nature of their days of reduction offset vary considerably, and may be in the form of the lesser of two periods. [The author has restructured and paraphrased (c)(1)-(11) in what he believes are accurate and more assimilable forms for the reader than the Rules themselves.]

(c)(1) Circumstance. "Suspension of action under §1.103 [Suspension of Action] at the applicant's request."

Reduction. Number of days *beginning* on filing date of request; ending on day suspension is terminated. (Thus, even the day of the request is a reduction (offset) day as is the day the suspension ends.)

Note Well: Rule 1.103(a) provides for granting up to six months suspension when requested by applicant "for good and sufficient cause."

Query: How can such a request for suspension result in a reduction for "failure" to **reasonably** conclude prosecution" when it can only be granted "for good and sufficient cause"?

(c)(2) *Circumstance.* "Deferral of issuance of a patent under §1.314" at applicant's request.

Reduction. Number of days *beginning* on day of applicant's *request*; ending on day the patent *issues*.

(c)(3) *Circumstance.* "Abandonment of the application or late payment of the issue fee."

Reduction. Number of days *beginning* on date of abandonment or the day *after* issue fee was due; ending on the *earlier* of:

(i) the date that is four months *after* the filing date of the *grantable* petition to revive the application or to accept payment of the issue fee; or

(ii) mailing date of the decision reviving the application or accepting late payment of the issue fee.

(c)(4) *Circumstance.* "Failure to file a petition to withdraw the holding of abandonment or to revive an application within two months from the mailing date of a notice of abandonment."

Reduction. Number of days "beginning on the day *after* the date two months from the mailing date of a notice of abandonment and ending" on the filing date of "a petition to withdraw the holding of abandonment or to revive the application."

(c)(5) *Circumstance.* "Conversion" of a provisional application to a nonprovisional application.

Reduction. Number of days *beginning on* provisional filing date and ending on date of request for conversion. [Thus, both the day of filing the provisional and the day of filing the conversion request are days of reduction. "Conversion" of a provisional application must be distinguished from relying on a provisional's filing date for priority when filing a nonprovisional application. The latter does *not* generate a reduction. §1.53(c)(3).]

(c)(6) *Circumstance.* "Submission of a preliminary amendment or other preliminary paper less than one month before the mailing" of either an "Office action under 35 U.S.C. 132 or notice of allowance under 35 U.S.C. 151" if that submission requires the USPTO to mail either a supplemental Office action or notice of allowance.

Reduction. The lesser of:

- (i) Four months.
- (ii) Number of days beginning on the day *after* the mailing date of the original Office action or the notice of allowance, and ending *on* the mailing date of the subsequent Office action or notice of allowance.

(c)(7) *Circumstance.* Submission of a substantially complete reply having an inadvertent omission (§1.135(c)).

Reduction. Number of days beginning the day *after* the filing date of the incomplete reply and ending on the filing date of the correcting paper.

(c)(8) *Circumstance.* Submission of a post-reply supplemental reply or paper not requested by the examiner.

Reduction. Number of days "beginning on the day *after* the date the original reply was filed and ending" on the filing date of the supplemental reply or paper.

(c)(9) *Circumstance.* Submission of an amendment or other paper:

- (i) *after* a decision (certain decisions under §41.50(b) and (c) are excepted) by the Board of Patent Appeals and Interferences, *or* a Federal court; *but*
- (ii) less than one month before the USPTO mails a §132 Office action or notice of allowance; *if* as a consequence,
- (iii) the USPTO is required to mail a supplemental Office action or supplemental notice of allowance.

Reduction. The lesser of:

- (i) Four months.

(ii) Number of days beginning on the day *after* the mailing date of the original Office action or notice of allowance and ending on the mailing date of the supplemental Office action or notice of allowance.

(c)(10) *Circumstance.* Submission of Rule 1.312 amendment *or other paper* after a notice of allowance is mailed or given.

Reduction. The lesser of:

(i) Four months.

(ii) Number of days beginning *on* the filing date of the Rule 1.312 amendment *or other paper* and ending *on* the mailing date of the Office action or notice in response.

Examples of an "other paper" other than a Rule 1.312 amendment after allowance that **do** generate reductions set forth in MPEP §2732 are:

- a request for a refund,
- a status letter,
- late priority claims,
- a certified copy of a priority document,
- drawings,
- letters related to biological deposits, and
- oaths or declarations

However, the following are examples of papers set forth in MPEP §2732 that are **not** considered to be failures to reasonably conclude prosecution even when filed after a notice of allowance.

- Issue Fee Transmittal,
- Power of Attorney,
- Power to Inspect,
- Change of Address,
- Change of Status (small/not small entity status),

- A response to the examiner's reasons for allowance or a request to correct an error or omission in a notice of allowance (or allowability), and
- Letters related to government interests (e.g., those between NASA and the USPTO).

(c)(11) Circumstance. "Further prosecution via a continuing application." [The reader should note the use of the generic term "continuing application" in this instance of failing to conclude prosecution; it comprehends continuations, divisions, and continuations-in-part.]

Reduction. All days of ancestral application prosecution prior "to the actual filing date of the application" that results in the patent.

Finally, *none* of the Rules 1.704(c)(6) [preliminary amendment], (8) [supplemental reply], (9) [amendment after Board decision], or (10) [Rule 1.312 amendment or other paper after allowance] circumstances are intended to include, by virtue of Rule 1.704(d): "An information disclosure statement" if accompanied by a statement that each listed item was cited in a paper from a foreign patent office in a counterpart application that was received no more "than thirty days prior to the filing of the information disclosure statement."

b. Infrequently Arising Reduction Circumstances Not Specifically Listed in the Rules

i. The Myriad Potential Reductions

The USPTO has represented that "there are a myriad of actions or inactions [by applicant] that occur infrequently but which interfere with the Office's ability to process or examine an application." Consequently, "an attempt to provide an exhaustive listing" of such actions and inactions is "impractical." 65 Fed. Reg. 56,371.

Although the impracticality may be correct, the representation that there is a myriad of *unspecified* events that may reduce patent term extension to which the applicant is otherwise entitled will no doubt widely result in a high degree of free-floating anxiety among both applicants and their patent practitioners. **Although each act or**

inaction in a myriad may occur only infrequently, a myriad is so huge a quantity that one or more of them may well occur in the prosecution of most applications.

Let us first inspect some examples believed by the USPTO to be denizens of that myriad; second, examine how the USPTO proposes to deal with the problems posed by the unidentified members of this unstructured galaxy; and third, the practical consequences to every applicant of the USPTO's handling of those problems.

ii. Examples of the Myriad, Individually Infrequent, Unstructured Reduction Circumstances

By way of example, the USPTO sets forth, in its commentary at 65 Fed. Reg. 56,371:

(1) "applicant files and persists in requesting reconsideration of a meritless [in the USPTO's view] petition under §1.10 [petition because of disagreement about date entitlement for paper filed by Express Mail]";

(2) "parties to an interference obtain an extension for purposes of settlement negotiations which do not result in settlement ... when the scope of the broadest claim in the application at the time an application is placed in condition for allowance is substantially the same as suggested or allowed by the examiner *more than six months earlier.*" (Emphasis added.)

The reader will note the subjectivity within each of the two examples. In (1), the petition is "meritless" according to the USPTO, but petitions, it should be borne in mind, may properly be brought for consideration by higher levels of authority in the USPTO (which are often granted) when rejected at a lower level. In (2), the arbitrary six-month cut-off establishes a binary dilatory/non-dilatory point in time by non-rule USPTO fiat.

Non-enumerated circumstances that may prove to be bases for reductions that offset adjustments will continue inevitably to surface with time. Subsequent to the USPTO's Federal Register Commentaries promulgated with its initial *Patent Term Guarantee* rules, the USPTO published one such non-enumerated circumstance

on its website, *Guidelines Setting Forth a Modified Policy Concerning the Evidence of Common Ownership, ... as Required by 35 USC 103(c)*. And it is an important one!

When an application and §103(a) prior art are commonly owned at the time the invention was made (or subject to an obligation of assignment to the same person), then §103(c)(1) provides for a prior art exclusion to a §103(a) rejection if the prior art is based only on §102(e), (f) or (g). A simple *statement* by the applicant or practitioner of the exclusionary facts vitiates the rejection. And this is so even if the statement is submitted after final rejection, i.e., even though it could have been submitted earlier.

The *Guidelines* properly specify that the rejection *must* be withdrawn because whenever "the exclusion is established, the propriety of the rejection is obviated as a matter of law." However, "the failure to submit evidence of entitlement to exclude ... following the *first* Office action ... may be considered by the Office ... to be a failure to engage in reasonable efforts to conclude prosecution." (Emphasis added.)

This theretofore non-enumerated circumstance, albeit now enunciated, carries a potential error factor in a patent term adjustment (PTA) calculation. And then on December 10, 2004, as if to further demonstrate that non-enumerated circumstances can grow like Topsy, 35 USC §103(c) was amended (to include paragraph (c)(2)) so that inventions under a joint research agreement enjoy the same prior art exclusion as those enjoyed by a common assignee.

Even after such a circumstance is recognized generally as a basis for reduction, its existence in any given prosecution cannot be *recognized* merely by *knowing that a reply to an Office action was filed* on a given date. The *content* of the reply must be known as well as that of the earlier reply that failed to include the exclusionary statement. A bare listing of the reply documents in the USPTO's computerized PAIR system (which is the instrumentality through which the USPTO calculates patent term adjustment) cannot provide the needed information even when the listed titles of the documents are specific and accurate. But the patent practitioner knows the controlling information and the applicant is charged with knowing it.

iii. Computer Algorithm the USPTO Uses Does Not Process the Myriad, Infrequent, Unlisted Reduction Circumstances

[T]he Office plans to calculate patent term adjustment with a computer program that uses the PALM [Patent Application Location and Monitoring] system records of the dates of receipt and nature of applicant correspondence and of the dates of mailing and nature of Office actions or notices. This automated approach will *not* lend itself to basing a *reduction* of patent term adjustment on circumstances *not* enumerated in §1.704(c) except in the most peculiar situations (e.g., unsuccessfully seeking reconsideration or judicial review of a petition decision designated as final agency action). [Emphasis added.]

65 Fed. Reg. 56,380.

iv. Consequences of USPTO Failure to Specify the Infrequent, Potential Reductions

Admittedly the USPTO:

(1) does not list all the circumstances that it views *could be* reduction basis events (let alone promulgate them as Rules in 37 CFR); and

(2) could not *recognize* them, even if it *could list* them, because of the limitations of the only computer program that the USPTO has for calculating PTA.

It appears, therefore, that virtually none of the "myriad" can be used by the USPTO during prosecution, from a practical point of view, as a reduction basis to offset an adjustment.

It should be remembered that 35 USC §154(b)(2)(C), *Reduction of Period of Adjustment*, provides in its totality that:

(i) *conceptually*, the adjustment will be reduced for failure "to engage in *reasonable* efforts to conclude prosecution";

(ii) *specifically*, the USPTO must provide no less than a three-month grace period for applicant to reply before a reduction is applied against a three-year pendency period adjustment; and

(iii) *specifically*, the Director shall issue "regulations" to implement the conceptual directive of (i).

Well, the Director *has* issued regulations establishing reductions in Rule 1.704(a)-(e). None of them include the myriad of events that the USPTO explicitly stated are outside its enumerated Rules. It may prove to be, therefore, that the USPTO view that the myriad of unenumerated events are *reduction* events has no basis in law simply because no regulations enumerating and governing them have been promulgated.

v. A Plurality of Reduction Events on One Day Generates Only One Day of Offset

The statute does not specify directly whether an overlap of *reduction* events generates one, or more than one, day of offset. Rule 1.704(c) *does* do so with respect to its 11 specified bases for reduction, in its statement that they are reductions "to the extent that the periods are not overlapping." There is no direction, however, on this subject for the unspecified myriad of actions and inactions. Nevertheless, it is reasonable, and would be prudent, to assume that reduction events from that myriad which overlap each other and/or with Rules reduction events count as only one offset event. That precept is based, albeit inferentially, upon the language of the statute. Section 154(b)(2)(C)(i) specifies, in pertinent part:

The *period* of adjustment ... shall be reduced by a *period*
... *during* which the applicant failed to engage
[Emphasis added.]

Thus, the *statute* references a "period" during which applicant caused delay; it does not reference delaying events. Necessarily, a period of time that begins on the first day of the earliest delaying event and ends on the last day of the last delaying event reduces the adjustment by that *period*; and that *period* necessarily has the same *duration* irrespective of whether it consists of "n" temporally

contiguous delaying events in tandem, or "n" overlapping delaying events. Moreover, "n" temporally sequential delaying events in unspaced tandem comprise a *period* of delay equal to their sum. The use of the statutory phrase "period during which" dictates that construction as a matter of logic imposed by the clear meaning of those words.

IV. PATENT TERM CALCULATION DISPUTE RESOLUTION

A. Calculation Dispute Resolution Initially Within the USPTO

There are two points in time when the USPTO notifies the applicant of the number of days of the PTA, if any.

The first is in the notice of allowance and issue fee due. Rule 1.705(a). It is shortly before that notice is mailed that the initial PTA is calculated by the Office's computer. 65 Fed. Reg. 56,388. For that reason, the USPTO will not entertain, *before* the mailing of that notice, any anticipatory request for correction of a prospective PTA. 37 CFR §1.705(b).

However, correction of a USPTO error recorded in PAIR for a prosecution document submission date or the title or nature of that document may properly, and should, be requested by the applicant *prior* to receiving the notice of allowance. Because the PTA calculation is based exclusively on the PAIR data, any PAIR data entry error will necessarily result in an incorrect calculation. Consequently, PAIR entries should be monitored closely throughout prosecution prior to receiving the notice of allowance and should be corrected promptly (as a cost-free process). PAIR data corrections may be sought in writing or by phone from the examiner or the appropriate USPTO Technology Center Customer Service Representative.

After the mail date of the notice of allowance, an applicant must apply for reconsideration of the PTA *no later than the payment of the issue fee*, and may do so only once. 35 USC §154(b)(3)(B)(ii) and 37 CFR §1.705(b). That procedure, which entails a fee, is discussed below. Seeking correction at that late date of a PAIR entry is subject to that fee (Rule 1.18(e)), but would have been fee-free prior to the notice of allowance.

The initial PTA set forth in the notice of allowance is based upon the USPTO *assumption* that the patent will issue on a date certain. Although the USPTO must issue the patent within four months after the issue fee is paid in order for the USPTO to avoid any additional adjustment days, it is not possible for the USPTO to know on what day the applicant will pay the issue fee or whether the USPTO will succeed in issuing the patent within four months thereafter.

As a consequence, the second point in time of PTA notification is reached when the patent actually issues. By then applicant's requested corrections, if any, will probably have been evaluated and the issue date, which had been problematic in the notice of allowance, will be a date certain. The PTA printed on the patent that issues may nonetheless still be in error. Any request for reconsideration of this second PTA must be filed in the USPTO no later than two months from the date the patent issues. 37 CFR §1.705(d). However, only a correction based upon an incorrect PTA related to the issue date estimate will be considered. Reconsideration or initial consideration of correction requests that were, or could have been, submitted earlier will not be entertained. If the PTA is corrected after the patent issues, a certificate of correction will so demonstrate.

It is noteworthy that the time for filing an application or request for revision of a PTA in *either* the first or second instance is *not* extendable. In the first instance, the requirement for expedition on applicant's part is justified because the USPTO has expressed an obligation (not binding) to render a *decision* on the applicant's request for correction of PTA *prior* to the issuance of the patent because the USPTO's calculation of the number of adjustment days is printed in the patent. In the second instance, because the statute requires any *judicial* remedy for the patentee to be by civil action in the U.S. District Court for the District of Columbia within only 180 days of issue (35 USC §154(b)(4)(A)), the USPTO considers expedition necessary in resolving a PTA dispute based upon the issue date printed on the patent.

1. *Prior to Issue*

The USPTO's PTA announced in the notice of allowance can be shown to be incorrect because of:

- (1) errors in date and document identification entries in its PALM and PAIR computer systems;
- (2) errors in calculating any event requiring adjustment under any of the three Guaranteed Adjustment Bases (GABs) discussed at length in Section II. of this chapter, *supra*; and
- (3) errors in calculating Required Reduction Bases (RRBs), discussed in Section III. of this chapter, *supra*, that offset or reduce GABs in the PTA.

In one instance, however, the USPTO's RRB calculation may include a *prima facie* correct reduction that may be shown, nonetheless, to be *unjustified* (albeit correctly calculated) under Rule 1.705(c). This can happen when the PTA comprehends a reduction for applicant's failure "to reply to a rejection, objection, argument, or other request within three months of the date of mailing of the Office Communication." (Rule 1.705(c), which implements 35 USC §154(b)(2)(C)(ii).) Both the statute and rule permit the applicant to overcome that proper *prima facie* calculation for the reduction with "a showing to the satisfaction of the Director that, in spite of all due care," the applicant was unable to reply within the three-month time period. (See Section I. of this chapter.)

An application requesting PTA revision under Rule 1.705(c) by way of *reinstating* adjustment that had been reduced because the USPTO was unaware of applicant's "all due care," requires, *inter alia*: (1) two fees (37 CFR §1.18(e) and (f)); and, of course, (2) the showing that applicant *did* exercise "all due care" even though having failed to meet the three-month deadline for reply.

The fees and showings required under subsection (c) are largely derivative from subsection (b). Thus, the fee required when reconsideration is requested solely under subsection (b) is stated in §1.18(e). When, however, the request is for *either* solely reinstating term under subsection (c) *or* for both reconsidering and reinstating under (b) and (c), *two* fees are required as set forth in §1.18(e) and (f). Thus, seeking no more than *reinstatement* of an adjustment that was reduced *prima facie* properly, under subsection (c), requires considerably larger fee payments than the single fee for requesting no more than *correction* of an incorrect reduction.

The showings required that are *common* to both subsection (b) and subsection (c) justify careful consideration because *certain of them may require admissions against the applicant's interests*. (When relief under both subsections (b) and (c) is sought, only a single submission is necessary.) Rule 1.705(b) (and (c) derivatively) require:

A statement of the facts involved, specifying:

(i) The correct patent term adjustment and the basis or bases under §1.702 for the adjustment;

(ii) The relevant dates as specified in §§1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in §1.703(f) to which the patent is entitled;

(iii) Whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer; and

(iv) (A) *Any circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in §1.704; or*

(B) *That there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in §1.704. [Emphasis added.]*

37 CFR §1.705(b)(2)(i)-(iv).

Of course, the terminal disclaimer clause (iii) overrides all PTA considerations. But, aside from that, clauses (iv)(A) and (iv)(B) require close and careful attention from the patent practitioner and the applicant. They constitute the horns of a dilemma, one of which almost necessarily will impale the applicant, and neither clause has anything to do with whether or not the PTA as calculated by the USPTO is correct.

Clause (A) seeks to require the applicant to be responsible for finding all of the prosecution events that may be encompassed by the "myriad" of possible undefined and undetermined term reduction events for which the USPTO has abdicated responsibility for incorporating in its patent term computer algorithm. Yet the USPTO demands that the applicant either ascertain them in the prosecution history in issue and *declare* them or *declare that no such events exist* under clause (B)! This is so even though those events, if any, have no bearing on the specific PTA events about which the applicant is claiming the USPTO is in error!

The consequences to the applicant and the practitioner, no matter what is said in a statement under (A) or (B), are potentially horrendous with respect to prospective charges of inequitable and unethical conduct under Rules 1.56 and 10.23 in any future litigation (to be discussed further in text Section V., *infra*).

Irrespective of what may happen in future litigation with respect to the PTA of any patent, third parties are not permitted to submit any petition or paper to the USPTO on the subject of PTA under 35 USC §154(b). 37 CFR §1.705(f). If there is such a submission, it "will be returned to the third party, or otherwise disposed of, at the convenience of the Office."

Finally, when challenging a USPTO adjustment determination, it should bring some comfort to the patent practitioner to know that Rule 1.704(e) provides in pertinent part:

Submission of an application for patent term adjustment under §1.705(b) (with or without request under §1.705(c) ["all due care"] for reinstatement of reduced patent term adjustment) will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under paragraph (c)(10) of this section.

Presumably, however, seeking a waiver of part or all of up to a three-month reduction under Rule 1.705(c) *without also* seeking a waiver under Rule 1.705(b) *may* "be considered a failure to engage in reasonable efforts to conclude prosecution" and probably *will be* so considered if the waiver is not granted.

2. *After Issue*

If the actual issue date of a patent turns out to be other than the date that was projected in the notice of allowance because the projected date proves to have been erroneously estimated, the USPTO will itself revise the PTA that was set forth in the notice of allowance. 37 CFR §1.705(d). The revised PTA will be printed in the patent. If the applicant views that revised PTA based upon the erroneous estimate to still be in error, the applicant may file a request for reconsideration of the PTA *but only within two months after the patent issue date*. If successful, the USPTO will issue a certificate of correction stating the correct PTA.

Once again, however, the very same horns of the inequitable conduct dilemma generated by clauses (iv)(A) and (iv)(B) of Rule 1.705(b)(2) are thrust into Rule 1.705(d) which states in pertinent part that the "request for reconsideration ... must comply with ... (b)(2) of this section." It is (b)(2) that includes horn (iv)(A) and horn (iv)(B). Therefore, if an applicant is unfortunate enough to be obliged to seek reconsideration of the USPTO's PTA under subsections (b) or (c) or both, and under subsection (d), of Rule 1.705, the applicant and the practitioner will experience the danger of being gored twice.

B. Then in the U.S. District Court for the District of Columbia (After Pursuing Administrative Remedies)

Although the statute provides "the applicant *one* opportunity to request reconsideration of any patent term adjustment" made by the USPTO (35 USC §154(b)(3)(B)(ii)), in reality, as discussed immediately above in Section IV.A., there are two such opportunities. Indeed, the first such opportunity may itself be parsed into two parts. Thus, the first request for reconsideration, which can only be made by way of an "application for patent term adjustment" filed between the mailing date of the notice of allowance and payment of the issue fee, permits both challenging the PTA (Rule 1.705(b)), and also seeking dispensation for a reply that was late (after three months) "in spite of all due care" (Rule 1.705(c)). They must both, however, be parts, albeit independent parts, of the unitary "application for patent term adjustment."

The second opportunity to request reconsideration occurs when there is a difference between the actual issue date and the estimated

issue date used in the notice of allowance. The PTA that is printed in the issued patent will then be erroneous (unless the USPTO itself becomes aware of the error and corrects the PTA prior to its appearance in the patent). Rule 1.705(d). But it is impermissible in this second opportunity for reconsideration to raise consideration of issues that could have previously been raised, but were not, when the first opportunity had been available under Rule 1.705(b) and (c).

What must the patentee do if the USPTO *fails* either to render decisions responsive to any Rule 1.705(b), (c) or (d) requests or renders them *incorrectly* in the patentee's view? The answer is to bring a civil action against the Director of the USPTO seeking review of the USPTO's PTA printed in the patent. That action must be in the U.S. District Court for the District of Columbia and brought *within 180 days of the patent's issue date*. 35 USC §154(b)(4)(A). (That civil action is commonly and popularly called an appeal under the judicial review provisions of the Administrative Procedure Act, which are properly cited as 5 USC Chapter 7.) The same remedy applies when the USPTO *does* render responsive decisions but which are viewed to be incorrect by the patentee.

The 180-day time period to bring the action is absolute; it is a statute of limitations.

The nature and details of review under the Administrative Procedure Act are outside the scope of this treatise. It is noteworthy, however, that the district court has no jurisdiction to take the appeal unless the appellant perfected its administrative remedies before the USPTO, i.e., the applicant must have attempted to seek PTA correction unsuccessfully from the USPTO under Rule 1.705(b), (c), and/or (d).

C. Third Party Attack of USPTO's PTA Determination in Federal Court

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

35 USC §154(b)(4)(B). So sayeth the statute, and with good reason. Were it otherwise, a phalanx of competitors could prevent issuance of

the patent almost indefinitely (and past its period of commercial value) by each challenging the PTA based upon one or more of the potentially myriad "unstructured" bases for adjustment reduction that the prosecution history may suggest, as discussed in Section III.B.2. of this chapter. Disputes about the many "structured" but ambiguous bases for adjustment reduction, as well as conflicting rule and statute language discussed *supra*, could also serve a competitor's interest in delaying issuance.

But once the patent issues, none of a third party's regular *judicial* remedies is barred. Certainly in patent infringement litigation, whether brought by the patentee or by a competitor's declaratory judgment action, PTA is subject to being litigated. This may occur because of a faulty, overstated, PTA contributing to an affirmative defense of inequitable conduct (see text Section V., *infra*) or by rebutting an allegation of infringement on the ground that the patent, also because of an overstated PTA, has expired. Moreover, a third party could properly gain declaratory judgment jurisdiction in isolation from infringement litigation. The third party need simply allege an intention to engage in activity that would constitute infringement of an unexpired patent, but will not do so until the patent expires. A declaratory judgment action to resolve a disputed date of patent expiration would be classically proper.

Pharmaceutical patentees have a strong economic interest in having patent terms of long duration. Generic drug manufacturers, on the other hand, have a strong economic interest in making sure that patents protecting prescription and over-the-counter drug products that have already proven to be commercially valuable, are restricted to the very shortest patent term to which they are entitled. Food and Drug Administration approved drug products and the patents covering them are listed in the Prescription and OTC Drug Product, Patent and Exclusivity Data section of the book, *Approved Drug Products With Therapeutic Equivalence Evaluations* (popularly known as the "Orange Book"). The generic manufacturer could file an Abbreviated New Drug Application (ANDA), which then permits the patentee to sue for infringement (which frequently is done). The generic is then free to defend with a challenge to the patent's expiration date, as provided for in 21 CFR §314.53(f). That challenge could be used either to establish noninfringement because the patent actually expired (its erroneously

lengthy printed PTA to the contrary notwithstanding) or is unenforceable because the patentee knew or should have known that the length of the USPTO-granted PTA was erroneously overstated and not revealed as such to the USPTO by the patentee.

**V. INCORRECTLY OVERSTATED PTA BY THE USPTO THAT
IS NOT REJECTED BY THE APPLICANT CAN
ESTABLISH INEQUITABLE CONDUCT (RULE 1.56)
AND UNENFORCEABILITY**

At this point in this chapter, *Patent Term Duration and Its Calculation*, the reader probably considers his or her independent calculation of PTA, to determine whether or not the USPTO's asserted PTA is correct for a given application or patent, to be a daunting task. Obviously that is a correct evaluation when the comparative calculation is carried out by hand with printed calendars, pencil, paper, and a hand calculator. Such a calculation would take many hours, sometimes days, except for an extremely brief and uncomplicated prosecution. Moreover, when in the midst of the calculation an earlier error is recognized or the need to evaluate whether a variant of an ambiguous rule will produce a significantly different term, the calculation must be redone or a parallel calculation undertaken.

In consequence, most practitioners have hitherto abhorred the prospect of having to serve their clients' needs through undertaking such calculations.

That calculation prospect was even more daunting to the USPTO than to applicants and their patent practitioners because by law the USPTO is required to perform the calculation (as in fiscal 2004) for each of the approximately 170,000 utility patent applications that issue, relentlessly, every year (a number that increases annually by 6% to 10%). Consequently, the USPTO developed, and is using for PTA calculations, a computer-algorithm based upon its previously in-place PAIR (patent application information retrieval) and PALM (patent application locating monitoring) computer platforms – neither of which was designed to implement PTA calculations. As a result, many PTA calculations by the USPTO have been in error, as the research sponsored by the author has evidenced, and as the USPTO admitted could occur. ***To be absolutely clear, the computer***

algorithmic calculation errors of the USPTO here discussed result from the computer generated PTA being violative of the USPTO's own Rules and its own stated interpretations of those Rules and the statute.

Moreover, for a random sample of 50 commercially valuable pharmaceutical/chemical patents with lengthy prosecutions, i.e., *longer* than three years, it was shown by the author and his research colleague that 26% had incorrect PTAs that were either erroneously too long (16%) or too short (10%). Each type of term adjustment error can have serious negative consequences for the patentee and the practitioner as will be seen below. In further independent confirmation of the author's statistical demonstration of the USPTO's algorithmic infirmities, the USPTO itself stated, in response to the author's Freedom of Information (FOIA) Request, that as of July 29, 2004, the USPTO computer has *never* given or recognized a three-year pendency guarantee (GAB No. 3) adjustment – despite the fact that many thousands of patents had issued by then under §154(b) with greater than three-year pendencies. This FOIA response by the USPTO suggests that the author's error data are possibly the tip of the iceberg.

Most importantly, the USPTO has stated that no examiner or other human being inspects the annual USPTO's 170,000 automatically computer-calculated PTAs to determine whether they are correctly calculated.

While neither the USPTO nor its examiners can be penalized for its PTA calculation errors, the practitioner and the client *will* be penalized for failing to recognize and correct them for a commercially lucrative patent. For the practitioner, disciplinary and malpractice proceedings may be in the offing, irrespective of whether the uncontested PTA is overstated or understated. For the client, the penalty could be a commercially valuable, validated and infringed patent becoming worthless.

Faced with these difficult realities, is it safe for a patentee or practitioner to simply accept the USPTO's submitted PTA calculation at face value? It would be dangerous to do so in the instances of erroneously understated as well as overstated PTAs based upon the following applicable facts and propositions.

1. *The practitioner is the one who created the prosecution history of the patent.* As such, he or she is *uniquely* knowledgeable about, and competent to determine, when the PAIR-based calculation is in error because of failure to properly apply the actual prosecution facts, e.g., dates, titles of documents, recognition that certain documents begin the clock for response while others do not, and the like. It should be borne in mind that the USPTO's calculation will always be wrong when pertinent PAIR data entries are incorrect for any of the dates and titles of documents listed; and the term extension upon which its calculation is based will be wrong, except in the fortuitous instances of an exact balancing of positive and negative errors.

2. The client and practitioner cannot shield themselves from their knowledge that: (a) the USPTO makes errors in its PTA calculations; and (b) the practitioner under Federal Circuit law "knew or should have known" of those aspects of errors based upon the USPTO's improper application of its computer algorithm to the practitioner-generated prosecution history. *Actual ignorance of any material aspects in the process of obtaining a patent about which a practitioner should not have been ignorant does not avoid culpable intent*, i.e., "studied ignorance" is no defense. *Brasseler, U.S.A. v. Stryker Sales Corp.*, 267 F.3d 1370, 60 USPQ2d 1482 (Fed. Cir. 2001); *FMC Corp. v. Hennessy Industries, Inc.*, 836 F.2d 521, 526 n.6, 5 USPQ2d 1272, 1275 n.6 (Fed. Cir. 1987). (See Chapter 25, *infra*.)

3. *The practitioner practices patent law as an agent or attorney, and as such is legally capable of, and responsible for, understanding and applying the Patent Term Guarantee statute and the USPTO's implementing rules.* Moreover, this chapter has set forth in detail, and comprehensively, a verbal flow chart that informs the reader in carrying out a PTA calculation, without any simplifying assumptions, and unbiased by earlier algorithmic designs for other purposes. (Actually, this chapter is the verbalized form of a flow chart underlying a newly commercially available online system that performs any PTA calculation in a matter of minutes; see patentterm.com.)

Let us now turn to the *USPTO stated view*, with illustrative examples, *that failure by a practitioner or applicant to report an overstated adjustment error in the USPTO's calculation can constitute inequitable conduct.*

Example 1. "For example, if a registered practitioner receives a determination that the application is eligible for a 1,500 day adjustment and the practitioner is not sure exactly what the adjustment should be, but believes that the adjustment should be 1,000 days, the practitioner does have a duty to disclose the error to the Office ... [in] a letter ... indicating that the term adjustment is thought to be longer than appropriate."

65 Fed. Reg. 56,387.

The Example No. 1 statement, combined with "studied ignorance" as a *non*-defense to culpable intent under *Brasseler v. Stryker, supra*, will be treated by competitor infringers and prospective infringers as a roadmap to litigation success. Moreover, underlying the entire duty of candor consideration in the overstated patent term adjustment context is the established proposition that "[i]ntent need not, and rarely can, be proven by direct evidence." *Merck & Co. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1422 (Fed. Cir. 1989). Quoting *Brasseler* on the subject of intent, the Federal Circuit once again observed that, "[w]hen balanced against high materiality, the showing of intent can be proportionately less." *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs.*, 394 F.3d 1348, 1354, 73 USPQ2d 1593, 1597 (Fed. Cir. 2005). The court again referenced *Brasseler* in its observation:

[I]nventors, patent owners, and attorneys associated with the filing or prosecution of a patent application have an *affirmative and continuing duty* to disclose material information to the PTO. See 37 C.F.R. §1.56(c); see also *Brasseler*, 267 F.3d at 1383. [Emphasis added.]

Evident Corp. v. Church & Dwight Co., 399 F.3d 1310, 1316, 73 USPQ2d 1910, 1914 (Fed. Cir. 2005). Prudence suggests, *perhaps dictates*, therefore, that a prospectively lucrative patent be safeguarded by its practitioner's *independent* PTA calculation prior to or promptly after issuance to avoid subsequent unenforceability.

The protective measure of disclosing the USPTO error in a letter "indicating that the term adjustment is thought to be longer than appropriate," suggested by the USPTO in Example No. 1, can be safely done prior to issuance of the patent or for a reasonable period thereafter (perhaps up to 60 days by analogy to the review period

allowed under Rule 1.705(b)). If implemented after issuance, a certificate of correction should be requested. MPEP §2733. A delay beyond 60 days from issue courts litigation dangers and the potential for unenforceability of the patent.

If before issuance, the disclosure should be done with care. The correcting letter necessarily will be submitted after the notice of allowance is mailed, and the USPTO suggests that it be filed with the issue fee payment. MPEP §2733. The letter therefore has the potential for itself initiating a reduction period under Rule 1.704(c)(10). That rule provides for a *reduction* beginning with the filing of a *Rule 1.312* amendment or "other paper" *after a notice of allowance*. (In one of the prosecution histories the author researched, that letter was denominated by the examiner, albeit improperly, to be a Rule 1.312 amendment.) The practitioner, therefore, should clearly and gratuitously state that the letter is *not* a Rule 1.312 amendment, but rather is an "other paper" *required* by the USPTO and *should be* recognized as one that *should* be included in the USPTO "examples of papers that are *not* considered to be failures to reasonably conclude prosecution even when filed after a notice of allowance" as listed in MPEP §2731 (which discusses Rule 1.704(c)(10)).

Example 2. An applicant's "application for patent term adjustment" or a "request for reconsideration" of the PTA (because of change in issue date) must, in each and both those proceedings, include a statement:

that there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in §1.704.

37 CFR §1.705(b)(2)(iv)(B) and (d).

With respect to Example No. 2, the applicant or assignee is required to state that no Rule 1.704 events took place. And that written statement is effectively under *oath* as Rule 10.18(b)(1) makes clear (set forth in pertinent part):

(b) By presenting to the Office ... any paper, ...
a practitioner or non-practitioner, is *certifying* that –

(1) All statements made therein of the
party's own knowledge are true. [Emphasis added.]

The practitioner and applicant are unique in their complete knowledge of the facts of their prosecution history, and the practitioner is presumed by law to know the law. *Brasseler, U.S.A. v. Stryker Sales, supra*. The statement required to be made under Rule 1.704 would appear to be, therefore, made of the "party's own knowledge."

It would seem self-evident that such a certifying statement, which is effectively an affidavit or declaration, made in the context of gaining an advantage in the prosecution of an application, is subject to the duty of candor of Rule 1.56. It should be made, therefore, only with the practitioner having undertaken an independent PTA calculation to ensure its correctness. At bottom, a statement made to the USPTO under oath for the purpose of gaining a prosecution advantage is *always material* and will *not be considered cumulative* to any other provided information (such as, for example, the USPTO's own PTA calculation). See *Refac Int'l, Ltd. v. Lotus Development Corp.*, 81 F.3d 1576, 1583, 38 USPQ2d 1665, 1671 (Fed. Cir. 1996).

VI. TACKING EXTENSIONS FOR FDA REGULATORY DELAYS (35 USC §156) TO PTA UNDER AIPA (35 USC §154)

A. The Extension Tacking Calculation

The Hatch-Waxman Act of 1984 (Pub. L. No. 98-417, 98 Stat. 1585 (1984)) provided pharmaceutical patentees the right to obtain a patent term extension of up to five years when marketing time is lost during the normal patent term while conducting safety and efficacy chemical tests required by the Food and Drug Administration (FDA) and awaiting FDA approval of the drug's safety and efficacy. The length of the term extension is calculated by the FDA, not the USPTO. It is equal to *half* the time clinical testing was conducted plus the entire period the FDA took to review the tests and approve the patented invention for commercial use (up to a maximum of 5 years). However, using the FDA term extension calculation, it is the USPTO that grants the extension under 35 USC §156. This section provides, however, that the extension granted to offset the regulatory delay cannot result in a term that extends beyond 14 years from the date of FDA approval.

35 USC §155, strategically located between §154 and §156, provides that the §156 extension is applicable "[n]otwithstanding the

provisions of section 154." In short, tacking of the extensions is permitted but no matter what the correct patent term extension proves to be under §154, and even if up to 5 years is calculated under §156 – the total of the tacked extensions cannot carry the term beyond 14 years from FDA approval. The following examples are worth considering.

Example 1. A patent issues with an 18-year term from issue under §154 (an infrequent but possible event). FDA marketing approval is given 4 years after issuance. What extension can properly be added because of the 4 years of regulatory delay under §156? Answer: None, because the term that remains after market approval is $18 - 4 = 14$ years, which is the maximum allowed under §156.

Example 2. PTA results in a 17-year term from issuance. FDA grants market approval 5 years after issuance. This results in only 12 years of marketing that remains during the life of the patent unless an extension under §156 kicks in, which it does. But only 2 years (not 5) of that 5-year delay can properly be tacked on to the 17-year term under §154, to provide the maximum of 14 years after FDA approval. Nonetheless, that patent has a term of $17 + 2 = 19$ years from issuance during which the patented product can be marketed only during the final 14 years.

Example 3. PTA results in a 17-year term from issuance. FDA grants market approval 8 years after issuance. This results in only 9 years of marketing that remains during the life of the patent unless an extension under §156 kicks in, which it does. The 8-year delay, however, can provide only a maximum of 5 years of extension under §156. But it *can* be the *full* 5 years, because when added to the 9 years that remained, the maximum of 14 years from FDA approval is not exceeded. Note, however, that this patent has a term of 17 plus 5 years – 22 years from issuance.

B. The Terminal Disclaimer Issue Under §156 Extensions (as Distinguished From §154)

The reader is well aware that a §154 patent term adjustment cannot extend a patent's life beyond the date fixed in a terminal disclaimer. 35 USC §154(b)(2)(B). Extensions under §156, however,

are quite to the contrary. The MPEP, which treats §156 states:

patents may receive a patent term extension ... beyond an expiration date set by a terminal disclaimer.

MPEP §2751 (TERMINALLY DISCLAIMED PATENTS ARE ELIGIBLE).

Moreover, the USPTO has invariably issued such §156 extensions when terminal disclaimers would otherwise truncate them. The rationale for this practice appears as follows, in pertinent part, in MPEP § 2751:

Although 35 U.S.C. 154(b)(2) (June 8, 1995) precludes a patent from being extended under 35 U.S.C. 154(b) if the patent has been terminally disclaimed due to an obviousness-type double patenting rejection (see MPEP §2720), there is no such exclusion in 35 U.S.C. 156. Additionally, 35 U.S.C. 154(b)(2)(B) (May 29, 2000) provides that a patent cannot be adjusted beyond the date set by the disclaimer (see MPEP §2730), *but there is no similar provision in 35 U.S.C. 156.* [Emphasis added.]

Most importantly, the Federal Circuit has expressly affirmed the MPEP interpretation of §156 on this subject. *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 Fed.3d 1317, 82 USPQ2d 1203 (Fed. Cir. 2007).

Justice may well be served by such an interpretation. The patentee's faultless delay for which a §156 extension is designed to offset occurs *after* the patent issues (as distinguished from *prior* to issuance delays for adjustments under §154). Whatever the term otherwise would be, as when terminally disclaimed during prosecution, should not the §156 extension add to that term?

[Editor's Note: The next page of text is page 17.63.]

APPENDIX A

PATENT TERM GUARANTEE ACT (Text)

"Patent Term Guarantee Act of 1999".

(a) ADJUSTMENT OF PATENT TERM. — Section 154(b) of title 35, United States Code, is amended to read as follows:

"(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, United States Code, 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."

APPENDIX B

RULE 1.703(f) BEFORE JUNE 21, 2004, AND AFTER

BEFORE

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.

AFTER

To the extent that periods of *delay* 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 After version differs from Before *only* in that the word "*adjustment*" in the phrase "To the extent that periods of *adjustment*" was changed to "*delay*."

The reader will recognize that the change in that one word made no change whatsoever in the meaning and applicability of the rule – except that the USPTO interpreted its one word substitution so as to turn the rule on its head, as recorded at fn. 1, 69 Fed. Reg. 34,283:

¹Another way of explaining this is: Based upon the contentions presented in a number of patent term adjustment petitions under 37 CFR 1.705, it has become apparent to the Office that some applicants did not fully appreciate that delays under 35 U.S.C. 154(b)(1)(A) (§§1.702(a) and 1.703(a)) [GAB No. 1 (14-4-4-4)] and delays under 35 U.S.C. 154(b)(1)(B) (§§1.702(b) and 1.703(b)) [GAB No. 3 (three-year pendency)] *may still be overlapping delays* under 35 U.S.C. 154(b)(2)(A), *even if the period of delay* under 35 U.S.C. 154(b)(1)(A) [GAB No. 1 (14-4-4-4)] *did not occur more than three years after the actual filing date of the application.* [Emphasis added.]