inform applicants of the requirement to demonstrate compliance prior to proposal preparation instead of prior to award, thereby giving potential applicants advance notice of these requirements. Additionally, the methods for demonstrating compliance with certifications, disclosures, and assurances are clarified. The first method provides for each individual certification, disclosure, and assurance to be signed by the Authorizing Institutional Representative. The second method currently provides that ''Signature by the Authorizing Institutional Representative on the proposal Cover Page may confirm that all necessary certifications and assurances are met.'' This statement is only accurate when the Cover Page includes a notice that lists each certification and assurance, and states that signature by the Authorizing Institutional Representative confirms that these specific certifications and assurances are met. To clarify this requirement, the Handbook will be revised to state: ''Signature by the Authorizing Organizational Representative on the proposal Cover Page may confirm that all necessary certifications and assurances are met, provided that the Cover Page includes a notice to that effect.'' An administrative change is made to change the term ''Authorizing Institutional Representative'' to ''Authorizing Organizational Representative'' because the latter term is more commonly used by NASA recipients. Finally, this final rule corrects the list of NASA implementing regulations in paragraph (c) of the Provision at § 1260.32, ''Nondiscrimination'' by adding ''14 CFR 1253''.

This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

B. Regulatory Flexibility Act

NASA certifies that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* because the changes do not impose additional requirements. The changes only modify the timing of existing requirements.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because this final rule does not impose any new recordkeeping or information collection requirements, or collection of information from offerors, contractors, or members of the public that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

List of Subjects in 14 CFR Part 1260

Grant Programs—Science and Technology.

Tom Luedtke,

Assistant Administrator for Procurement.

■ Accordingly, 14 CFR part 1260 is amended as follows:

■ 1. The authority citation for 14 CFR part 1260 continues to read as follows:

Authority: 42 U.S.C. 2473(c)(1), Pub. L. 97–258, 96 Stat. 1003 (31 U.S.C. 6301, *et seq.*)

PART 1260—GRANTS AND COOPERATIVE AGREEMENTS

■ 2. Revise paragraph (c) in §1260.10 to read as follows:

§ 1260.10 Proposals.

* * * * *

(c)(1) All announcements for grant and cooperative agreement funding opportunities shall require the applicant to submit all required certifications, disclosures, and assurances as part of the proposal. The following certifications and assurance are required to be submitted as part of all proposals:

(i) A certification for debarment and suspension under the requirements of 14 CFR 1265.510.

(ii) A certification, and a disclosure form (SF LLL) if required, on Lobbying under the requirements of 14 CFR 1271.110 for awards exceeding $100,000.

(iii) An assurance of Compliance with NASA Regulations Concerning Nondiscrimination as required by 14 CFR parts 1250 through 1253 or incorporation by reference of a signed NASA Form 1206 that is on file, current, and accurate.

(2) Compliance with certifications, disclosures, and assurances must be demonstrated by one of the following two methods:

(i) Each individual certification, disclosure, and assurance may be signed by the Authorizing Organizational Representative; or

(ii) Signature by the Authorizing Organizational Representative on the proposal Cover Page may confirm that all necessary certifications and assurances are met, provided that the Cover Page includes a notice to that effect.

* * * * *

■ 3. Revise the undesignated headings and paragraph (c) in § 1260.32 to read as follows:

§ 1260.32 Nondiscrimination.

Nondiscrimination

April 2004.

* * * * *

(c) Work on NASA grants is subject to the provisions of Title VI of the Civil Rights Act of 1964 (Pub. L. 88–352; 42 U.S.C. 2000d–1), Title IX of the Education Amendments of 1972 (20 U.S.C. 1680 *et seq.*), section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794), the Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*), and the NASA implementing regulations (14 CFR parts 1250, 1251, 1252, and 1253).

* * * * *

[FR Doc. 04–9015 Filed 4–21–04; 8:45 am]

BILLING CODE 7510–01–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No.: 2003–P–029]

RIN 0651–AB71

Revision of Patent Term Extension and Patent Term Adjustment Provisions

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Final rule.

SUMMARY: The patent term extension provisions of the Uruguay Round Agreements Act (URAA) and the patent term adjustment provisions of the American Inventors Protection Act of 1999 (AIPA) each provide for the possibility of patent term extension or adjustment if the issuance of the patent was delayed due to review by the Board of Patent Appeals and Interferences (BPAI) or by a Federal court and the patent was issued pursuant to or under a decision in the review reversing an adverse determination of patentability. The United States Patent and Trademark Office (Office) is revising the rules of practice in patent cases to indicate that under certain circumstances a panel remand by the BPAI shall be considered a decision in the review reversing an adverse determination of patentability for purposes of patent term extension or patent term adjustment. The Office is also adopting other miscellaneous changes to the patent term adjustment provisions of the rules of practice.

DATES: *Effective Date:* May 24, 2004.

Any request for reconsideration of the patent term extension or adjustment indicated on a patent resulting from an application in which the notice of

allowance was mailed before May 24, 2004 on the basis of the changes to 37 CFR 1.701 or 1.702 in this final rule must be filed no later than July 21, 2004.

FOR FURTHER INFORMATION CONTACT: Kery A. Fries, Legal Advisor, Office of Patent Legal Administration, by telephone at (703) 305–1383, by mail addressed to: Box Comments—Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313–1450, or by facsimile to (703) 746–3240, marked to the attention of Kery A. Fries.

SUPPLEMENTARY INFORMATION: Section 532(a) of the URAA (Pub. L. 103–465, 108 Stat. 4809 (1994)) amended 35 U.S.C. 154 to provide that the term of a patent ends on the date that is twenty years from the filing date of the application, or the earliest filing date for which a benefit is claimed under 35 U.S.C. 120, 121, or 365(c). Public Law 103–465 also contained provisions, codified at 35 U.S.C. 154(b), for patent term extension due to certain examination delays. The Office implemented the patent term extension provisions of the URAA in a final rule published in April of 1995. *See Changes to Implement 20-Year Patent Term and Provisional Applications,* 60 FR 20195 (Apr. 25, 1995), 1174 *Off. Gaz. Pat. Office* 15 (May 2, 1995) (final rule).

The AIPA (Pub. L. 106–113, 113 Stat. 1501, 1501A–552 through 1501A–591 (1999)) further amended 35 U.S.C. 154(b) to include additional bases for patent term extension (characterized as ''patent term adjustment'' in the AIPA). Original utility and plant patents issuing from applications filed on or after May 29, 2000, may be eligible for patent term adjustment if issuance of the patent is delayed due to one or more of the enumerated administrative delays listed in 35 U.S.C. 154(b)(1). The Office implemented the patent term adjustment provisions of the AIPA in a final rule published in September of 2000. *See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term,* 65 FR 56365 (Sept. 18, 2000), 1239 *Off. Gaz. Pat. Office* 14 (Oct. 3, 2000) (final rule). The patent term adjustment provisions of the AIPA apply to original (*i.e.*, non-reissue) utility and plant applications filed on or after May 29, 2000. *See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term,* 65 FR at 56367, 1239 *Off. Gaz. Pat. Office* at 14–15. The patent term extension provisions of the URAA (for delays due to secrecy order, interference or successful appellate review) continue to apply to original utility and plant applications filed on or after June 8, 1995, and before May 29, 2000. *See id.*

The Office is amending the rules of practice in patent cases to indicate that certain remands by the BPAI shall be considered ''a decision in the review reversing an adverse determination of patentability'' for patent term adjustment and patent term extension purposes. Specifically, if an application is remanded by a panel of the BPAI and the remand is the last action by a BPAI panel prior to the mailing of a notice of allowance under 35 U.S.C. 151 in the application, the remand shall be considered a decision reversing an adverse determination of patentability for patent term adjustment and patent term extension purposes. However, a panel remand shall not be considered a decision in the review reversing an adverse determination of patentability if there is filed a request for continued examination under 35 U.S.C. 132(b) (§ 1.114) that was not first preceded by the mailing, after such remand, of at least one of an action under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151.

The term ''panel'' of the BPAI means a panel comprised of members of the BPAI as defined in 35 U.S.C. 6(a). The phrase ''remanded by a panel'' of the BPAI does not pertain to a remand or order returning an appeal to the examiner issued by a BPAI administrator. *See e.g., Revised Docketing Procedures for Appeals Arriving at the Board of Patent Appeals and Interferences,* 1260 *Off. Gaz. Pat. Office* 18 (July 2, 2002). The phrase ''remanded by a panel'' of the BPAI also does not pertain to a remand or order returning an appeal to the examiner that is issued by a BPAI administrator subsequent to the issuance of a docketing notice.

The Office initially took the position that a remand by a BPAI panel was not a ''decision'' within the meaning of 35 U.S.C. 154(b)(1)(A)(iii), much less ''a decision reversing an adverse determination of patentability'' as that phrase is used in 35 U.S.C. 154(b)(1)(C)(iii). *See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term,* 65 FR at 56369, 1239 *Off. Gaz. Pat. Office* at 16. The Office has subsequently determined that there are a number of BPAI panel remands that convey the weakness in the examiner's adverse patentability determination in a manner tantamount to a decision reversing the adverse patentability determination. Such a BPAI panel remand generally results in the examiner allowing the application (either with or without further action by applicant) without returning the application with a response to the issues raised in the remand to the BPAI for a decision on the appeal. The changes in this final rule address the situation in which an examiner responds to a remand by a BPAI panel by allowing the application (either with or without further action by applicant), rather than returning the application with a response to the issues raised in the remand to the BPAI for a decision on the appeal. In this situation, the BPAI panel remand shall be considered ''a decision in the review reversing an adverse determination of patentability'' for patent term extension and patent term adjustment purposes. The changes in this final rule, however, will not apply if, after the BPAI panel remand, there is filed a request for continued examination under 35 U.S.C. 132(b) (§ 1.114) that was not first preceded by the mailing, after such remand, of at least one of an action under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151.

If the patent issues after a remand that is considered ''a decision in the review reversing an adverse determination of patentability,'' the BPAI panel remand is deemed by the Office to be the ''final decision in favor of the applicant'' for purposes of a patent term extension or adjustment calculation under § 1.701(c)(3) or § 1.703(e) (as applicable). The period of extension or adjustment calculated under § 1.701(c)(3) or § 1.703(e) (as applicable) would equal the number of days in the period beginning on the date on which a notice of appeal to the BPAI was filed under 35 U.S.C. 134 and § 1.191 and ending on the mailing date of the BPAI panel remand.

The Office also proposed changes to §§ 1.704 and 1.705 in a rule making to implement portions of the Office's 21st Century Strategic Plan. *See Changes to Support Implementation of the United States Patent and Trademark Office 21st Century Strategic Plan,* 68 FR 53816, 53843, 53857–58 (Sept. 12, 2003), 1275 *Off. Gaz. Pat. Office* 23, 45–46, 60 (Oct. 7, 2003) (proposed rule) (hereinafter ''*21st Century Strategic Plan* notice of proposed rule making''). The Office is adopting changes to §§ 1.704 and 1.705 proposed in the *21st Century Strategic Plan* notice of proposed rule making in this final rule so that all changes to the patent term adjustment provisions of the rule of practice currently under consideration will be adopted in the same final rule.

Discussion of Specific Rules

Section 1.701: Section 1.701(a)(3) is amended by adding the following sentence: If an application is remanded by a panel of the Board of Patent Appeals and Interferences and the

remand is the last action by a panel of the Board of Patent Appeals and Interferences prior to the mailing of a notice of allowance under 35 U.S.C. 151 in the application, the remand shall be considered a decision in the review reversing an adverse determination of patentability as that phrase is used in 35 U.S.C. 154(b)(2) as amended by section 532(a) of the Uruguay Round Agreements Act, Public Law 103–465, 108 Stat. 4809, 4983–85 (1994), and a final decision in favor of the applicant under § 1.701(c)(3). Section 1.701(a)(3) is also amended to provide that a panel remand shall not be considered a decision in the review reversing an adverse determination of patentability as provided in § 1.701(a)(3) if there is filed a request for continued examination under 35 U.S.C. 132(b) (§ 1.114) that was not first preceded by the mailing, after such remand, of at least one of an action under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151. Section 1.701(a)(3) is also amended to change ''decision reversing an adverse determination of patentability'' to ''decision in the review reversing an adverse determination of patentability'' for consistency with 35 U.S.C. 154(b)(2) as amended by section 532(a) of the URAA.

Section 1.702: Section 1.702(e) is amended by adding the following sentence: If an application is remanded by a panel of the Board of Patent Appeals and Interferences and the remand is the last action by a panel of the Board of Patent Appeals and Interferences prior to the mailing of a notice of allowance under 35 U.S.C. 151 in the application, the remand shall be considered a decision by the Board of Patent Appeals and Interferences as that phrase is used in 35 U.S.C. 154(b)(1)(A)(iii), a decision in the review reversing an adverse determination of patentability as that phrase is used in 35 U.S.C. 154(b)(1)(C)(iii), and a final decision in favor of the applicant under § 1.703(e). Section 1.702(e) is also amended to provide that a panel remand shall not be considered a decision in the review reversing an adverse determination of patentability as provided in § 1.702(e) if there is filed a request for continued examination under 35 U.S.C. 132(b) (§ 1.114) that was not first preceded by the mailing, after such remand, of at least one of an action under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151. Section 1.702(e) is also amended to change ''decision reversing an adverse determination of patentability'' to ''decision in the review reversing an adverse determination of patentability'' for consistency with 35 U.S.C. 154(b)(1)(C)(iii).

Section 1.703: Section 1.703(f) is amended to change ''[t]o the extent that periods of adjustment attributable to the grounds specified in § 1.702 overlap'' to ''[t]o the extent that periods of delay attributable to the grounds specified in § 1.702 overlap'' for consistency with 35 U.S.C. 154(b)(2)(A). The language of former § 1.703(f) misled applicants into believing that delays under 35 U.S.C. 154(b)(1)(A) (§§ 1.702(a) and 1.703(a)) and delays under 35 U.S.C. 154(b)(1)(B) (§§ 1.702(b) and 1.703(b)) were overlapping only if the period of delay under 35 U.S.C. 154(b)(1)(A) occurred more than three years after the actual filing date of the application. If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)–(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A).

Section 1.704: Section 1.704(d) is amended to change ''cited in a communication'' to ''first cited in any communication'' in order to clarify that the item must have been first cited in any communication from a foreign patent office in a counterpart application instead of merely being cited in such a communication. An applicant who fails to cite an item, within thirty days of receipt by an individual designated in § 1.56(c) of a first communication from a foreign patent office in a counterpart application citing the item, and instead files an information disclosure statement, within thirty days of a subsequent communication citing the item, cannot be considered to have acted with reasonable efforts to conclude prosecution of the application. The change to require that this thirty-day time period run from a first communication parallels the corresponding language in § 1.97(e)(1). The provisions of § 1.704(d) do not apply if the applicant does not submit the information disclosure statement within thirty days of a first communication including a citation of an item to a party designated in § 1.56(c). In such situations, the submission of an information disclosure statement may be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under § 1.704(c)(6), (c)(8), (c)(9), or (c)(10).

Section 1.705: Section 1.705(d) is amended to provide that a patentee may request reconsideration of the patent term adjustment within two months of the date the patent issued if the patent indicates a revised patent term adjustment relative to the patent term adjustment indicated on the notice of allowance. The Office currently includes the patent term adjustment information that will be printed on the face of the patent on the Issue Notification. *See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term*, 65 FR at 56388, 1239 *Off. Gaz. Pat. Office* at 33 (response to comment 49). The Office plans to discontinue the practice of including patent term adjustment information on the Issue Notification, but is changing the period for filing a request for reconsideration under § 1.705(d) of the patent term adjustment indicated in the patent from thirty days to two months. This two-month period in § 1.705(d) is non-extendable. *See* § 1.705(e).

The Patent Application Locating and Monitoring (PALM) system maintains computerized contents records of all patent applications and reexaminations. The Patent Application Information and Retrieval (PAIR) system provides public access to PALM for patents and applications that have been published (*i.e.*, applications no longer being maintained in confidence), which can be accessed over the Internet at *http://pair.uspto.gov*. The PAIR system also has a private side (*http://pair-direct.uspto.gov*) which may be used by an applicant to access confidential information about his or her pending application. *See Clarification of 37 CFR 1.704(c)(10)—Reduction of Patent Term Adjustment for Certain Types of Papers Filed After a Notice of Allowance has been Mailed*, 1247 *Off. Gaz. Pat. Office* 111, 112 (June 26, 2001). While the Office plans to discontinue the practice of including patent term adjustment information on the Issue Notification, applicants can check PAIR to see the Office's current patent term adjustment determination upon receipt of the Issue Notification to ascertain whether the patent term adjustment determination has been revised since the mailing of the notice of allowance.

Section 1.705(d) is also amended to permit a patentee to file the request for reconsideration if the patent indicates or should have indicated a revised patent term adjustment of a revision to patent term adjustment indicated in the notice of allowance. Section 1.705(d) formerly provided that a request for reconsideration under § 1.705(d) was limited to the situation where the patent issues on a date other than the projected

date of issue. There are a number of papers which if submitted by an applicant after the mailing of the notice of allowance will result in a reduction of any patent term adjustment, such as: (1) Request for refunds; (2) status letter; (3) amendments under § 1.312; (4) late priority claims; (5) a certified copy of a priority document; (6) drawings; (7) letters related to biological deposits; and (8) oaths or declarations. *See* § 1.704(c)(10). In addition, receipt of the payment of the issue fee more than three months after mailing of the notice of allowance will also result in a reduction of any patent term adjustment. *See* § 1.704(b) and § 1.703(f) (''[t]he date indicated on any certificate of mailing or transmission under § 1.8 shall not be taken into account in this calculation''). There are also Office delays that may occur after the mailing of the notice of allowance which may result in an increase in the amount of patent term adjustment, such as the failure to issue the patent within four months after the date the issue fee was paid under 35 U.S.C. 151 and all outstanding requirements were satisfied, or the failure to issue the patent within three years after the date on which an application was filed under 35 U.S.C. 111(a). *See* § 1.702(a)(4) and § 1.702(b).

Section 1.705(d) is also amended to provide that any request for reconsideration under § 1.705(d) that raises issues that were raised, or could have been raised, in an application for patent term adjustment under § 1.704(b) shall be dismissed as untimely as to those issues. The purpose of § 1.705(d) is to provide patentees with an avenue to obtain reconsideration of the patent term adjustment indicated in the patent when the patent term adjustment indicated in the patent differs or should have differed from the patent term adjustment indicated in the notice of allowance due to events occurring after the mailing of the notice of allowance. Section 1.705(d) is not an avenue for patentees to seek review of issues that were raised, or could have been raised, in an application for patent term adjustment under § 1.704(b). Any request for reconsideration of the patent term adjustment indicated in the patent on the basis of issues that were raised, or could have been raised, in an application for patent term adjustment under § 1.704(b) is considered untimely if not filed within the period specified in § 1.705(b).

Requests for reconsideration of patent term adjustment determinations indicated in notice of allowances and patents under 35 U.S.C. 154(b) and §§ 1.702 through 1.704 are provided for in § 1.705. Petitions under § 1.182 or 1.183, or requests for a certificate of correction under either 35 U.S.C. 254 and § 1.323 or 35 U.S.C. 255 and § 1.324, are not substitute *fora* to obtain reconsideration of a patent term adjustment determination indicated in a notice of allowance if an applicant fails to submit a request for reconsideration within the time period specified in § 1.705(b), or to obtain reconsideration of a patent term adjustment determination indicated in a patent if a patentee fails to submit a request for reconsideration within the time period specified in § 1.705(d).

Response to comments: The Office published a notice proposing changes to the rules of practice to provide that under certain circumstances a panel remand by the BPAI shall be considered a decision in the review reversing an adverse determination of patentability for purposes of patent term extension or patent term adjustment. *See Revision of Patent Term Extension and Patent Term Adjustment Provisions Related to Decisions by the Board of Patent Appeals and Interferences* 68 FR 67818 (Dec. 4, 2003), 1277 *Off. Gaz. Pat. Office* 227 (Dec. 30, 2003) (proposed rule). The Office received seven written comments (from an intellectual property organization, a law firm, a business, and patent practitioners) in response to this notice of proposed rule making. The Office also received five written comments concerning §§ 1.704 and 1.705 in response to the *21st Century Strategic Plan* notice of proposed rule making. Comments generally in support of a change are not discussed. The comments and the Office's responses to those comments follow:

Comment 1: One comment questioned whether the Office has the authority to interpret a remand from the BPAI as a decision by the BPAI reversing an adverse determination of patentability. The comment suggested that the Office should amend the rules of practice to permit the BPAI to designate a remand as a decision by the BPAI reversing an adverse determination of patentability.

Response: 35 U.S.C. 2(b)(2) provides that the Office may establish regulations, not inconsistent with law, which shall govern the conduct of proceedings in the Office, 35 U.S.C. 3(a)(2)(A) provides that the Director is responsible for providing policy direction and management supervision for the Office, and 35 U.S.C. 154(b)(3)(A) provides that the Director shall prescribe regulations establishing procedures for the application for and determination of patent term adjustments under 35 U.S.C. 154(b). Therefore, the Office has sufficient rule making authority to promulgate regulations to avoid situations in which an applicant is deprived of patent term extension or adjustment because a BPAI panel designates a decision as a remand rather than as a reversal coupled with a remand.

Comment 2: One comment suggested that the Office should amend the rules of practice to permit the BPAI to designate a remand as a decision by the BPAI reversing an adverse determination of patentability.

Response: It is unnecessary to amend the rules of practice to provide that a BPAI panel may designate a remand as a decision by the BPAI reversing an adverse determination of patentability. First, a BPAI panel may do so in essence by designating the decision as a reversal coupled with a remand. Second, a BPAI panel remand will be considered a ''decision in the review reversing an adverse determination of patentability'' under § 1.701(a)(3) or § 1.702(e) as amended in this final rule if the remand is the last action by a panel of the Board of Patent Appeals and Interferences prior to the mailing of a notice of allowance under 35 U.S.C. 151 in the application (except if there is filed a request for continued examination under 35 U.S.C. 132(b) (§ 1.114) that was not first preceded by the mailing, after such remand, of at least one of an action under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151.).

Comment 3: One comment suggested that the Office should treat a remand by a BPAI administrator the same as a remand by a BPAI panel in determining whether the remand is considered a decision in the review reversing an adverse determination of patentability for patent term extension and adjustment purposes.

Response: The Office cannot treat a remand or other order by an administrator as a ''decision in the review reversing an adverse determination of patentability'' for patent term extension or adjustment purposes because an administrator is not a member of the BPAI as defined in 35 U.S.C. 6(a) and because 35 U.S.C. 6(b) requires that appeals be heard by at least three members of the BPAI. While the Office has proposed to define BPAI as including a BPAI member or employee acting with the authority of the BPAI for certain purposes (proposed § 41.2(2)), the Office has cautioned that this definition of ''BPAI'' is not applicable in a situation in which action by a BPAI panel is required by statute, and has also proposed to define BPAI member as a member of the BPAI as set forth in 35 U.S.C. 6(a) (proposed § 41.2(3)). *See Rules of Practice Before the Board of Patent Appeals and*

Interferences, 68 FR 66647, 66649 (Nov. 26, 2003), 1277 *Off. Gaz. Pat. Office* 157, 159 (Dec. 23, 2003) (proposed rule).

Comment 4: Several comments suggested that the filing of an information disclosure statement or certain amendments should not preclude a remand from being considered a decision in the review reversing an adverse determination of patentability for patent term extension or adjustment purposes. The comments provided the following examples of amendments that should not preclude a remand from being considered a decision in the review reversing an adverse determination of patentability for patent term extension or adjustment purposes: (1) Amendments which only correct formal matters (*e.g.*, update the address of a depository such as the American Type Culture Collection (ATCC); (2) amendments which improve the clarity of the claims; (3) amendments which rejoin claims that were withdrawn pending the allowance of a product claim; (4) amendments which only define the claims over newly cited prior art; (5) an examiner's amendment or examiner requested amendment; (6) amendments that do not address the merits of the claims; (7) amendments that change the title or abstracts to correspond to all of the allowed claims; (8) inconsistencies between reference characters used in the specification and those used in the drawings; (9) inconsistent case use of pronouns; (10) resubmission of documents that were lost by the Office; (11) amendments which incorporate limitations from a dependent claim into an independent claim; and (12) any amendment so long as at least one previously rejected claim is allowed in unamended form. One comment suggested that if an information disclosure statement contains a certification under § 1.704(d), the information disclosure statement should not preclude a remand from being considered a decision in the review reversing an adverse determination of patentability for patent term extension or adjustment purposes. One comment suggested that a remand should be treated as a decision by the BPAI reversing an adverse determination of patentability any time the examiner *sua sponte* withdraws all of the rejections against any one claim. Finally, one comment suggested that if the Office drops any issue raised upon appeal after the remand, the examiner's dropping of an issue raised upon appeal should be considered a decision in the review reversing an adverse determination of patentability.

Response: The suggestions are adopted in part as follows. If an application is remanded by a panel of the BPAI and the remand is the last action of a BPAI panel prior to the mailing of a notice of allowance under 35 U.S.C. 151 in the application, the Office will consider that remand to be a decision in the review reversing an adverse determination of patentability. Therefore, if the examiner allows the application (patent term extension or adjustment is not relevant if the application is not ultimately allowed) without returning the application to the BPAI for decision (and thus the BPAI panel remand is the last action by a BPAI panel in the application), the Office will consider that remand to be a decision in the review reversing an adverse determination of patentability. A panel remand, however, shall not be considered a decision in the review reversing an adverse determination of patentability if there is filed a request for continued examination under 35 U.S.C. 132(b) (§ 1.114) that was not first preceded by the mailing, after such remand, of at least one of an action under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151.

Comment 5: One comment also suggested that the Office should permit applicant to petition under § 1.705 for a case-by-case determination of whether the BPAI remand should be considered a decision in the review reversing an adverse determination of patentability for patent term extension or adjustment purposes.

Response: The statutory scheme of 35 U.S.C. 154(b) provides that patent term adjustment and reductions to patent term adjustment are determined by objective criteria rather than on the basis of *ad hoc* determinations. That is, 35 U.S.C. 154(b)(1) specifies certain objective conditions under which (subject to certain conditions and limitations) an applicant is entitled to patent term adjustment, and 35 U.S.C. 154(b)(2)(C) requires the Office to specify (by regulations) the conditions under which there will be a reduction of patent term adjustment under 35 U.S.C. 154(b)(1). Thus, it is more in line with the statutory scheme set forth in 35 U.S.C. 154(b) for the Office to specify objective criteria under which a BPAI panel remand will be considered a decision in the review reversing an adverse determination of patentability for patent term extension or adjustment purposes, than it would be to leave this to case-by-case determinations.

In addition, as discussed in the final rule to implement the patent term adjustment provisions of the AIPA: "the Office must make its patent term adjustment determinations by a computer program that uses the information recorded in the Office's automated patent application information system (the Patent Application Location and Monitoring system or PALM system). Thus, the Office must determine whether the Board of Patent Appeals and Interferences (or court) decision was of a nature such that 'the patent was issued under a decision in the review reversing an adverse determination of patentability' under 35 U.S.C. 154(b)(1)(C)(iii) from information concerning the decision susceptible of being recorded in the PALM system (rather than by a case-by-case review of each decision).'' *See Changes To Implement Patent Term Adjustment Under Twenty-Year Patent Term,* 65 FR at 56370, 1239 *Off. Gaz. Pat. Office* at 17 (quoting 35 U.S.C. 154(b)(1)(C)(iii)).

Comment 6: One comment suggests that the rule be automatically retroactively applied or alternately set up a petition procedure where patentees would be allowed to petition for recalculation of the patent term extension or adjustment determination based upon the amended rule.

Response: The Office cannot "automatically'' apply revised §§ 1.701(a)(3) and 1.702(e) retroactively in applications in which the notice of allowance was mailed before May 24, 2004. However, a patentee who believes that the patent term extension or adjustment indicated on his or her patent would have been calculated differently under § 1.701(a)(3) or § 1.702(e) as amended in this final rule may file a request for reconsideration of the patent term extension or adjustment indicated on the patent. Any such request for reconsideration must be filed no later than July 21, 2004.

For applications in which the notice of allowance is mailed on or after May 24, 2004, any applicant who believes that the URAA patent term extension (§ 1.701) or AIPA patent term adjustment (§§ 1.702 through 1.705) indicated in the notice of allowance was not calculated correctly in view of the changes to § 1.701(a)(3) or § 1.702(e) in this final rule must file a timely petition under § 1.181 or timely request for reconsideration under § 1.705(b) (respectively) to have the patent term extension or adjustment determination corrected. Any applicant who believes that the URAA patent term extension (§ 1.701) or AIPA patent term adjustment (§§ 1.702 through 1.705) indicated in the notice of allowance was not calculated correctly on any basis other than the changes to § 1.701(a)(3) or § 1.702(e) in this final rule must file a

timely petition under § 1.181 or timely request for reconsideration under § 1.705(b) (respectively) to have the patent term extension or adjustment determination corrected.

Comment 7: One comment suggests that the period of adjustment for administrative delay should end on the date of the mailing of the notice of allowance, not on the mailing date of the remand.

Response: The suggestion is not adopted. If an application is allowed after a panel remand by the BPAI, the period of appellate review ended with the decision (remand) by the BPAI.

Comment 8: Several comments indicated that events such as the filing of a request for refund or the filing of a status letter are caused by an Office error or delay, and should not result in a reduction of patent term adjustment under § 1.704(c)(10).

Response: The patent term adjustment provisions of 35 U.S.C. 154(b) provide that "[t]he 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.'' *See* 35 U.S.C. 154(b)(2)(C)(iii). Section 1.704(c)(10) provides that circumstances that constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application also include "[s]ubmission of an amendment under § 1.312 or other paper after a notice of allowance has been given or mailed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the lesser of: (i) [t]he number of days, if any, beginning on the date the amendment under § 1.312 or other paper was filed and ending on the mailing date of the Office action or notice in response to the amendment under § 1.312 or such other paper; or (ii) [f]our months.'' The Office did not propose any change to the provisions of § 1.704(c). The *21st Century Strategic Plan* notice of proposed rule making, however, did include a previously published clarification of the provisions of § 1.704(c)(10). *See Clarification of 37 CFR 1.704(c)(10)—Reduction of Patent Term Adjustment for Certain Types of Papers Filed After a Notice of Allowance Has Been Mailed,* 1247 *Off. Gaz. Pat. Office* at 111–12.

The filing of certain papers, such as a request for refund or a status letter, after a notice of allowance has been mailed causes substantial interference with the patent issue process. See id. Therefore, pursuant to the authority to 35 U.S.C. 154(b)(2)(C)(iii), the Office has prescribed a regulation (§ 1.704(c)(1)) establishing the filing of such papers after a notice of allowance has been mailed as a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.

Section 1.26(b) provides a lengthy (two-year) period for filing any request for refund. Thus, applicants may avoid a reduction of any patent term adjustment by not filing a request for refund during the period between the mailing of a notice of allowance and the date the patent is issued. Applicants who choose to file a request for refund at a time when the filing of such a paper causes interference with the patent issue process must accept the negative impact on patent term adjustment that will result from such a course of action.

As discussed above, the PAIR system provides public access to PALM for patents and applications that have been published which can be accessed over the Internet (at http://pair.uspto.gov), and has a private side (*http://pair-direct.uspto.gov*) which may be used by an applicant to access confidential information about his or her pending application. *See id.* Thus, applicants who choose to file status letters rather than check the status of their applications via the PAIR system must accept the negative impact on patent term adjustment that will result from such a course of action.

Comment 9: Several comments indicated that the thirty-day period provided in § 1.704(d) was too short and should be changed to three months for consistency with § 1.97(e).

Response: Section 1.704(d) was adopted to permit applicants to submit information cited in a communication from a foreign patent office in a counterpart application to the Office without a reduction in patent term adjustment if an information disclosure statement is promptly (within thirty days of receipt of the communication) submitted to the Office.

See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 FR at 56373, 56385, 1239 *Off. Gaz. Pat. Office* at 20, 30–31. The Office did not propose to change the thirty-day period provided in § 1.704(d).

Section 1.704(d) does not provide that an information disclosure statement must be submitted within its thirty-day period to avoid a reduction of patent term adjustment (or to be considered by the Office), but rather provides a "safe-harbor'' against reductions to patent term adjustment under §§ 1.704(c)(6), (c)(8), (c)(9), or (c)(10) that may result from the filing of an information disclosure statement. The filing of an information disclosure statement during any of the periods set forth in §§ 1.704(c)(6), (c)(8), (c)(9), or (c)(10) will interfere with the patent examination or printing process. Therefore, the Office must limit the time period in § 1.704(d) to thirty days to avoid substantial interference with the Office's ability to meet the time frames specified in 35 U.S.C. 154(b)(1). *See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term,* 65 FR at 56385, 1239 *Off. Gaz. Pat. Office* at 30.

Rule Making Considerations

Administrative Procedure Act

The change to § 1.703 in this final rule simply amends its provisions for consistency with 35 U.S.C. 154(b)(2)(A), and the change to § 1.705 concerns only the procedures for requesting reconsideration of the patent term adjustment determination printed on the patent. Therefore, these rule changes involve interpretive rules, or rules of agency practice and procedure under 5 U.S.C. 553(b)(A), and prior notice and an opportunity for public comment were not required pursuant to 5 U.S.C. 553(b)(A) (or any other law). *See Bachow Communications Inc.* v. *FCC,* 237 F.3d 683, 690 (D.C. Cir. 2001) (rules governing an application process are "rules of agency organization, procedure, or practice'' and exempt from the Administrative Procedure Act's notice and comment requirement).

Regulatory Flexibility Act

As discussed previously, the changes to §§ 1.703 and 1.705 involve interpretive rules, or rules of agency practice and procedure under 5 U.S.C. 553(b)(A), for which prior notice and an opportunity for public comment were not required pursuant to 5 U.S.C. 553(b)(A) (or any other law).

The Deputy General Counsel for General Law of the United States Patent and Trademark Office has certified to the Chief Counsel for Advocacy of the Small Business Administration that changes in this final rule will not have a significant economic impact on a substantial number of small entities (Regulatory Flexibility Act, 5 U.S.C. 605(b)). The provisions of the Regulatory Flexibility Act relating to the preparation of a flexibility analysis are not applicable to this rule making because the changes in this final rule will not have a significant economic impact on a substantial number of small entities.

The primary change in this final rule (§§ 1.701 and 1.702) is to set forth the circumstances under which the Office

will consider a remand by the BPAI to be a decision in the review reversing an adverse determination of patentability for purposes of patent term extension and patent term adjustment. Of the 3,843 decisions in *ex parte* appeals in fiscal year 2003, 454 of these decisions remanded the application without affirming or reversing any of the rejections on appeal. Since approximately 25% of the patents granted in fiscal year 2003 were to small entities, the Office estimates that approximately 114 small entity applicants may be affected by the change to §§ 1.701 and 1.702 in this final rule. Since the Office received over 350,000 nonprovisional applications in fiscal year 2003, the change to §§ 1.701 and 1.702 in this final rule would impact relatively few (fewer than 0.1% of) patent applicants.

The change to § 1.704 merely clarifies that the thirty-day time period in § 1.704(d) runs from the first citation of the information by a foreign patent office, and that a subsequent citation of the same information by another foreign patent office would not start a new thirty-day period. Thus, the change to § 1.704 in this final rule will not have a significant economic impact on any entity.

In any event, the changes in this final rule merely concern the Office's manner of calculating patent term extension or patent term adjustment determination in certain situations, and revise the time period (from thirty days to two months) for requesting reconsideration of the patent term adjustment determination printed on the patent. The changes in this final rule would not impose any additional fees or requirements on any patent applicant. The Office published a notice of proposed rule making and certified that an initial Regulatory Act Analysis was not required. No comment on the changes being adopted in this final rule made reference to any impact of the changes on small entities.

Executive Order 13132

This rule making does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

Executive Order 12866

This rule making has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).

Paperwork Reduction Act

This final rule involves information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The collection of information involved in this final rule has been reviewed and previously approved by OMB under OMB control number 0651–0020. The United States Patent and Trademark Office is not resubmitting an information collection package to OMB for its review and approval because the changes in this final rule do not affect the information collection requirements associated with the information collection under OMB control number 0651–0020.

The title, description and respondent description of this information collection is shown below with an estimate of the annual reporting burdens. Included in the estimate is the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information. The primary change in this final rule is to set forth the circumstances under which the Office will consider a remand by the BPAI to be a decision in the review reversing an adverse determination of patentability for purposes of patent term extension and patent term adjustment.

OMB Number: 0651–0020.

Title: Patent Term Extension.

Form Numbers: None.

Type of Review: Approved through October of 2004.

Affected Public: Individuals or households, business or other for-profit institutions, not-for-profit institutions, farms, Federal Government and State, Local and Tribal Governments.

Estimated Number of Respondents: 26,859.

Estimated Time Per Response: Between 1 and 25 hours.

Estimated Total Annual Burden Hours: 30,905 hours.

Needs and Uses: The information supplied to the United States Patent and Trademark Office by an applicant requesting reconsideration of a patent term adjustment determination under 35 U.S.C. 154(b) (§ 1.702 *et seq.*) is used by the United States Patent and Trademark Office to determine whether its determination of patent term adjustment under 35 U.S.C. 154(b) is correct, and whether the applicant is entitled to reinstatement of reduced patent term adjustment. The information supplied to the United States Patent and Trademark Office by an applicant seeking a patent term extension under 35 U.S.C. 156 (§ 1.710 *et seq.*) is used by the United States Patent and Trademark Office, the Department of Health and Human Services, and the Department of Agriculture to determine the eligibility of a patent for extension and to determine the period of any such extension. The applicant can apply for patent term and interim extensions, petition the Office to review final eligibility decisions, withdraw patent term applications, and declare his or her eligibility to apply for a patent term extension.

Comments are invited on: (1) whether the collection of information is necessary for proper performance of the functions of the agency; (2) the accuracy of the agency's estimate of the burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information to respondents.

Interested persons are requested to send comments regarding these information collections, including suggestions for reducing this burden, to Robert J. Spar, Director, Office of Patent Legal Administration, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313–1450, or to the Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Officer for the United States Patent and Trademark Office.

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Courts, Freedom of Information, Inventions and patents, Reporting and record keeping requirements, Small Businesses.

■ For the reasons set forth in the preamble, 37 CFR Part 1 is amended as follows:

PART 1—RULES OF PRACTICE IN PATENT CASES

■ 1. The authority citation for 37 CFR Part 1 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2).

■ 2. Section 1.701 is amended by revising paragraph (a)(3) to read as follows:

§ 1.701 Extension of patent term due to examination delay under the Uruguay Round Agreements Act (original applications, other than designs, filed on or after June 8, 1995, and before May 29, 2000).

(a) * * *

(3) Appellate review by the Board of Patent Appeals and Interferences or by a Federal court under 35 U.S.C. 141 or 145, if the patent was issued pursuant to a decision in the review reversing an adverse determination of patentability and if the patent is not subject to a terminal disclaimer due to the issuance of another patent claiming subject matter that is not patentably distinct from that under appellate review. If an application is remanded by a panel of the Board of Patent Appeals and Interferences and the remand is the last action by a panel of the Board of Patent Appeals and Interferences prior to the mailing of a notice of allowance under 35 U.S.C. 151 in the application, the remand shall be considered a decision in the review reversing an adverse determination of patentability as that phrase is used in 35 U.S.C. 154(b)(2) as amended by section 532(a) of the Uruguay Round Agreements Act, Public Law 103–465, 108 Stat. 4809, 4983–85 (1994), and a final decision in favor of the applicant under paragraph (c)(3) of this section. A remand by a panel of the Board of Patent Appeals and Interferences shall not be considered a decision in the review reversing an adverse determination of patentability as provided in this paragraph if there is filed a request for continued examination under 35 U.S.C. 132(b) that was not first preceded by the mailing, after such remand, of at least one of an action under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151.

* * * * *

■ 3. Section 1.702 is amended by revising paragraph (e) to read as follows:

§ 1.702 Grounds for adjustment of patent term due to examination delay under the Patent Term Guarantee Act of 1999 (original applications, other than designs, filed on or after May 29, 2000).

* * * * *

(e) *Delays caused by successful appellate review.* Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to review by the Board of Patent Appeals and Interferences under 35 U.S.C. 134 or by a Federal court under 35 U.S.C. 141 or 145, if the patent was issued under a decision in the review reversing an adverse determination of patentability. If an application is remanded by a panel of the Board of Patent Appeals and Interferences and the remand is the last action by a panel of the Board of Patent Appeals and Interferences prior to the mailing of a notice of allowance under 35 U.S.C. 151 in the application, the remand shall be considered a decision by the Board of Patent Appeals and Interferences as that phrase is used in 35 U.S.C. 154(b)(1)(A)(iii), a decision in the review reversing an adverse determination of patentability as that phrase is used in 35 U.S.C. 154(b)(1)(C)(iii), and a final decision in favor of the applicant under § 1.703(e). A remand by a panel of the Board of Patent Appeals and Interferences shall not be considered a decision in the review reversing an adverse determination of patentability as provided in this paragraph if there is filed a request for continued examination under 35 U.S.C. 132(b) that was not first preceded by the mailing, after such remand, of at least one of an action under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151.

* * * * *

■ 4. Section 1.703 is amended by revising paragraph (f) to read as follows.

§ 1.703 Period of adjustment of patent term due to examination delay.

* * * * *

(f) The adjustment will run from the expiration date of the patent as set forth in 35 U.S.C. 154(a)(2). To the extent that periods of 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 term of a patent entitled to adjustment under § 1.702 and this section shall be adjusted for the sum of the periods calculated under paragraphs (a) through (e) of this section, to the extent that such periods are not overlapping, less the sum of the periods calculated under § 1.704. The date indicated on any certificate of mailing or transmission under § 1.8 shall not be taken into account in this calculation.

* * * * *

■ 5. Section 1.704 is amended by revising paragraph (d) to read as follows.

§ 1.704 Reduction of period of adjustment of patent term.

* * * * *

(d) A paper containing only an information disclosure statement in compliance with §§ 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under paragraphs (c)(6), (c)(8), (c)(9), or (c)(10) of this section if it is accompanied by a statement that each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement. This thirty-day period is not extendable.

* * * * *

■ 6. Section 1.705 is amended by revising paragraph (d) to read as follows:

§ 1.705 Patent term adjustment determination.

* * * * *

(d) If there is a revision to the patent term adjustment indicated in the notice of allowance, the patent will indicate the revised patent term adjustment. If the patent indicates or should have indicated a revised patent term adjustment, any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued and must comply with the requirements of paragraphs (b)(1) and (b)(2) of this section. Any request for reconsideration under this section that raises issues that were raised, or could have been raised, in an application for patent term adjustment under paragraph (b) of this section shall be dismissed as untimely as to those issues.

* * * * *

Dated: April 16, 2004.

Jon W. Dudas,

Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the United States Patent and Trademark Office.

[FR Doc. 04–9144 Filed 4–21–04; 8:45 am]

BILLING CODE 3510–16–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[AZ 126–0074b; FRL–7650–3]

Interim Final Determination That State Has Corrected a Deficiency in the Arizona State Implementation Plan, Arizona Department of Environmental Quality

AGENCY: Environmental Protection Agency (EPA).

ACTION: Interim final determination.

SUMMARY: EPA is making an interim final determination to stay and/or defer imposition of sanctions based on a proposed approval of revisions to the Arizona Department of Environmental Quality (ADEQ) portion of the Arizona