

compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

#### C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

#### D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

#### E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531-1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of

\$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

#### F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023-01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321-4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting less than 30 days that will prohibit vessel traffic to transit between Columbia River Mile 142 and 143 during diving and vessel recovery operations. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023-01-001-01, Rev. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

#### G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

#### List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

#### **PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS**

- 1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05-1, 6.04-1, 6.04-6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

- 2. Add § 165.T13-0998 to read as follows:

#### **§ 165.T13-0998 Safety Zone; Columbia River, Cascade Locks, OR.**

(a) *Location.* The following area is designated safety zone: All navigable waters of the Columbia River, from

surface to bottom, between river mile 142 and 143.

(b) *Regulations.* In accordance with the general regulations in 33 CFR part 165, subpart C, no person may enter or remain in the safety zone created in this section or bring, cause to be brought, or allow to remain in the safety zone created in this section any vehicle, vessel, or object unless authorized by the Captain of the Port or his designated representative.

(2) To seek permission to enter, contact Derrick Barge DB 125 or tug RUTH via VHF-FM marine channel 14. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(c) *Enforcement period.* This safety zone is in effect from 7 a.m. until 5 p.m. on October 27, 2018 through November 16, 2018. It will be subject to enforcement this entire period unless the Captain of the Port, Columbia River (COTP) determines it is no longer needed. The Coast Guard will inform mariners of any change to this period of enforcement via Broadcast Notice to Mariners.

Dated: October 26, 2018.

**D.F. Berliner,**

*Captain, U.S. Coast Guard, Acting Captain of the Port Sector Columbia River.*

[FR Doc. 2018-23955 Filed 11-1-18; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF COMMERCE

### Patent and Trademark Office

#### 37 CFR Part 1

[Docket No. PTO-P-2018-0030]

#### **Interim Procedure for Requesting Recalculation of the Patent Term Adjustment With Respect to Information Disclosure Statements Accompanied by a Safe Harbor Statement**

**AGENCY:** United States Patent and Trademark Office, Commerce.

**ACTION:** Notification of interim procedure.

**SUMMARY:** The patent laws provide for patent term adjustment in the event that the issuance of the patent is delayed due to certain enumerated administrative delays. The USPTO makes the patent term adjustment determination included on the patent by a computer program that uses the information recorded in the USPTO's Patent Application Locating and Monitoring (PALM) system. The USPTO will be modifying

its computer program that calculates patent term adjustment to recognize when an applicant files an information disclosure statement concurrently with a safe harbor statement. In order to assist both applicants and the USPTO, the USPTO is providing a new form for applicants to use when making a safe harbor statement. The USPTO is also establishing an interim procedure and providing a form for patentees to request a recalculation of their patent term adjustment determination for alleged errors due to the USPTO's failure to recognize that an information disclosure statement was accompanied by a safe harbor statement.

**DATES:** *Effective Date:* This procedure is effective November 2, 2018.

**FOR FURTHER INFORMATION CONTACT:** Kery A. Fries, Senior Legal Advisor, Office of Patent Legal Administration, Office of Deputy Commissioner for Patent Examination Policy, by telephone at (571) 272-7757, or by mail addressed to: Mail Stop Comments-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

**SUPPLEMENTARY INFORMATION:** The American Inventors Protection Act of 1999 or AIPA (Pub. L. 106-113, 113 Stat. 1501, 1501A-552 through 1501A-591 (1999)) amended 35 U.S.C. 154(b) to provide for patent term adjustment in the event that the 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). Under the patent term adjustment provisions of the AIPA, a patentee generally is entitled to patent term adjustment for the following reasons: (1) If the USPTO fails to take certain actions during the examination and issue process within specified time frames (35 U.S.C. 154(b)(1)(A)); (2) if the USPTO fails to issue a patent within three years of the actual filing date of the application (35 U.S.C. 154(b)(1)(B)); and (3) for delays due to interference or derivation proceedings, secrecy orders, or successful appellate review (35 U.S.C. 154(b)(1)(C)). See 35 U.S.C. 154(b)(1). The AIPA, however, sets forth a number of conditions and limitations on any patent term adjustment accrued under 35 U.S.C. 154(b)(1). Specifically, 35 U.S.C. 154(b)(2)(C) provides, in part, that “[t]he period of adjustment of the term of a patent under [35 U.S.C. 154(b)(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” and 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.” 35 U.S.C. 154(b)(2)(C)(i) and (iii). The USPTO 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) (final rule).

The “regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application” (35 U.S.C. 154(b)(2)(C)(iii)) are set forth in 37 CFR 1.704. 37 CFR 1.704 provides for a reduction of any patent term adjustment if an information disclosure statement (1) is filed after a notice of allowance or after an initial reply by the applicant; or (2) is filed as a preliminary paper or paper after a decision by the Board or Federal court that requires the USPTO to issue a supplemental Office action. See 37 CFR 1.704(c)(6), 1.704(c)(8), 1.704(c)(9), and 1.704(c)(10). 37 CFR 1.704 also provides for a reduction of any patent term adjustment if a request for continued examination is filed after the mailing of a notice of allowance. See 37 CFR 1.704(c)(12).

37 CFR 1.704(d), however, provides that a paper containing only an information disclosure statement in compliance with 37 CFR 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 37 CFR 1.704(c)(6), (c)(8), (c)(9), or (c)(10) if the information disclosure statement is accompanied by one of the statements set forth in 37 CFR 1.704(d)(1)(i) or (d)(1)(ii) (a “safe harbor statement”). Similarly, 37 CFR 1.704(d) also provides that a request for continued examination in compliance with 37 CFR 1.114 containing only an information disclosure statement in compliance with 37 CFR 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 37 CFR 1.704(c)(12) if the information disclosure statement included in request for continued examination is accompanied by a safe harbor statement. Thus, unless the information disclosure statement is accompanied by a safe harbor statement in compliance with 37 CFR 1.704(d), 37 CFR 1.704 provides for a reduction of any patent term adjustment if an information disclosure statement (1) is filed after a notice of allowance or after an initial reply by the applicant; or (2) is filed as a preliminary paper or paper after a decision by the

Board or Federal court that requires the USPTO to issue a supplemental Office action. See 37 CFR 1.704(c)(6), 1.704(c)(8), 1.704(c)(9), and (c)(10). Similarly, unless the submission for a request for continued examination after a notice of allowance has been mailed is solely an information disclosure statement and it is accompanied by a safe harbor statement in compliance with 37 CFR 1.704(d), 37 CFR 1.704 provides for a reduction of any patent term adjustment if a request for continued examination is filed after the mailing of a notice of allowance. See 37 CFR 1.704(c)(12).

A proper safe harbor statement under 37 CFR 1.704(d) must state that each item of information contained in the information disclosure statement: (1) Was first cited in any communication from a patent office in a counterpart foreign or international application or from the USPTO, and this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the information disclosure statement (37 CFR 1.704(d)(1)(i)); or (2) is a communication that was issued by a patent office in a counterpart foreign or international application or by the USPTO, and this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the information disclosure statement (37 CFR 1.704(d)(1)(ii)).

The USPTO performs an automated calculation of how much patent term adjustment, if any, is due to a patentee using the information recorded in the USPTO's PALM system, except when a patentee requests reconsideration pursuant to 37 CFR 1.705. See *Changes to Implement Patent Term Adjustment under Twenty-Year Patent Term*, 65 FR 56365, 56370, 56380-81 (Sept. 18, 2000) (final rule). Currently, the computer program used for this automated calculation cannot determine whether a compliant safe harbor statement under 37 CFR 1.704(d) accompanied an information disclosure statement. Thus, this computer program calculates the patent term adjustment total as if no compliant safe harbor statement under 37 CFR 1.704(d) was made. As the USPTO develops its next generation information technology (IT) systems that will address this problem, the USPTO is introducing an interim procedure for patentees to request a patent term adjustment recalculation when a safe harbor statement pursuant to 37 CFR 1.704(d) was filed, and a new form for applicants to use when making a safe harbor statement.

*Interim Procedure for Requesting Recalculation:* The USPTO has created the following interim procedure by which a patentee may request recalculation of patent term adjustment where the sole reason for contesting the patent term adjustment determination is the USPTO's failure to recognize a timely filed safe harbor statement accompanying an information disclosure statement. The USPTO's interim procedure waives the fee under 37 CFR 1.705(b)(1) as set forth in 37 CFR 1.18(e) to file the request for reconsideration. The interim procedure will remain in effect until the USPTO can update the patent term adjustment computer program and provide notice to the public that the computer program has been updated.

Under the interim procedure, recalculation of patent term adjustment is requested by submitting a form in lieu of the request and fee set forth in 37 CFR 1.705(b). This form, "Request for Reconsideration of Patent Term Adjustment in View of Safe Harbor Statement Under 37 CFR 1.704(d)" (PTO/SB/134) will be available on the USPTO website at <https://www.uspto.gov/patent/patents-forms>.

The Office of Management and Budget (OMB) has determined that, under 5 CFR 1320.3(h), Form PTO/SB/134 does not collect "information" within the meaning of the Paperwork Reduction Act of 1995. The form must be filed within the time period set forth in 37 CFR 1.705(b), and the USPTO will not grant any request for recalculation of the patent term adjustment that is not timely filed. The time period set forth in 37 CFR 1.705(b) may be extended under the provisions of 37 CFR 1.136(a).

If the request for recalculation is not based solely on the USPTO's failure to recognize a timely filed, compliant safe harbor statement under 37 CFR 1.704(d), the patentee must file a request for reconsideration of the patent term adjustment indicated on the patent under 37 CFR 1.705(b) with the fee set forth in 37 CFR 1.18(e). If a patentee files both form PTO/SB/134 and a request under 37 CFR 1.705(b) prior to the USPTO's recalculation of patent term adjustment, the USPTO will treat the papers as a request for reconsideration of the patent term adjustment indicated on the patent under 37 CFR 1.705(b) and charge the fee set forth in 37 CFR 1.18(e).

While the USPTO's interim procedure waives the fee under 37 CFR 1.705(b)(1) as set forth in 37 CFR 1.18(e) to file the PTO/SB/134, it does not waive any extensions of time fees due under 37 CFR 1.705(b) and 1.136. In addition, it

is noted that the fee specified in 37 CFR 1.18(e) is required for a request for reconsideration under 37 CFR 1.705, and the USPTO may only refund fees paid by mistake or in excess of that required (35 U.S.C. 42(d)). Thus, the interim procedure set forth in this document is not a basis for requesting a refund of the fee specified in 37 CFR 1.18(e) for any request for reconsideration under 37 CFR 1.705, including any previously filed request that was solely based on the USPTO's error in assessing a reduction to the amount of patent term adjustment under 37 CFR 1.704(c)(6), (c)(8), (c)(9), (c)(10), or (c)(12) for the submission of an information disclosure statement that was accompanied by the statement under 37 CFR 1.704(d).

The Office of Petitions will manually review the request for recalculation of patent term adjustment filed under the interim procedure. Specifically, the Office of Petitions will review the accuracy of the patent term adjustment calculation in view of regulations 37 CFR 1.702 through 1.704 as part of the recalculation. Upon review by the Office of Petitions, the patentee will be given one opportunity to respond to the recalculation. The response must be filed by patentee within two months of the mail date of the recalculation. No extensions of time will be granted. If patentee responds to the recalculation by requesting changes to the recalculation not related to the safe harbor statement, patentee must comply with the requirements of 37 CFR 1.705(b)(1) and (2).

If patentee fails to respond to the recalculation and the USPTO's determination of the amount of recalculated patent term adjustment is different from that printed on the front of the patent, the USPTO will *sua sponte* issue a certificate of correction that reflects the recalculated patent term adjustment. If patentee files a timely response after the USPTO's recalculation and the USPTO maintains its recalculation, the USPTO will issue its decision confirming its recalculation pursuant to 35 U.S.C. 154(b)(3)(B)(ii), and this decision is the Director's decision under 35 U.S.C. 154(b)(4). The USPTO's initial recalculation of patent term adjustment under the procedure outlined in this document is *not* the Director's decision under 35 U.S.C. 154(b)(4).

*New Form for Applicants to Use when Making a Statement Pursuant to 37 CFR 1.704(d):* In order to aid in recognizing when a compliant safe harbor statement under 37 CFR 1.704(d) has been filed with an information disclosure statement, the USPTO has created a

form titled, "Patent Term Adjustment Statement under 37 CFR 1.704(d)" (PTO/SB/133) for applicant's use when submitting the information disclosure statement. The USPTO is planning to update the patent term adjustment computer program to recognize when form PTO/SB/133 has been filed. Once updated, the patent term adjustment computer program will perform the patent term calculation by taking into account that applicant filed a compliant safe harbor statement under 37 CFR 1.704(d) when it performs the patent term adjustment calculation. When applicant provides the safe harbor statement with the information disclosure statement, use of form PTO/SB/133 is not required, but it is very strongly recommended as the failure to use this form may result in the patent term adjustment calculation not taking into account that such a statement was filed. The form will be available on the USPTO's website at <https://www.uspto.gov/patent/patents-forms>. The Office of Management and Budget (OMB) has determined that, under 5 CFR 1320.3(h), form PTO/SB/133 does not collect "information" within the meaning of the Paperwork Reduction Act of 1995.

Applicants who submit form PTO/SB/133 with an information disclosure statement will be considered to be making a proper safe harbor statement, and the filing will be reflected in the file record. Applicants may not alter the pre-printed text of form PTO/SB/133. The presentation to the USPTO (whether by signing, filing, submitting, or later advocating) of any USPTO form with text identifying the form as a USPTO-generated form by a party, whether a practitioner or non-practitioner, constitutes a certification under 37 CFR 11.18(b) that the existing text and any certifications or statements on the form have not been altered other than permitted by EFS-Web customization. See 37 CFR 1.4(d)(3). As a result of using the form, the USPTO's computer program, once updated, will take the safe harbor statement into account when patent term adjustment is calculated, thereby eliminating the need to file a request for reconsideration of patent term adjustment under 37 CFR 1.705(b) for this matter.

Dated: October 30, 2018.

**Andrei Iancu,**

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

[FR Doc. 2018-24004 Filed 11-1-18; 8:45 am]

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