## CHAPTER 2700

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| **2701** | Revised to update 35 U.S.C. 154, in view of the revisions from the AIA that deleted "of this title" after the citation to various sections of title 35.<br>Revised to indicate that design patents issued from applications filed on or after the date of entry into force of the Hague Treaty will have a term of 15 years from the grant date of the design patent. |
| **2710** | Revised text to clarify that the citation to 35 U.S.C. 154(b) is to the statute in effect on May 29, 2000 and amended thereafter.<br>Consistent with the existing guidance regarding which applications are eligible for patent term extension or adjustment, added a citation to *Thomas D. Sykes v. Jon W. Dudas*, 573 F.Supp2d 191, 89 USPQ2d 1423 (D.D.C. 2008). In this decision, the court held that amendments to 35 U.S.C. 154 by the 1999 American Inventors Protection Act (AIPA) do not apply to applications filed prior to May 29, 2000. |
| **2720** | Revised to update 37 CFR 1.701, as necessitated by the AIA revisions related to the new name of the patent appeal board and the addition of deviation proceedings, and the regulatory changes that moved appeal regulations to part 41 of title 37.<br>Revised text as necessitated by the AIA revisions related to the new name of the patent appeal board and to clarify that the citation to 35 U.S.C. 154(b) is to the statute in effect on May 29, 2000 and amended thereafter.<br>Revised to indicate that patent term extension (PTE) information under former 35 U.S.C. 154 will be printed on the front face of the patent. Text relating to publication of PTE on the Notice of Allowance and Fee(s) Due form and correction of such PTE determination was deleted. |
| **2730** | Revised to update 35 U.S.C. 154(b), as necessitated by the AIA revisions related to the new name of the patent appeal board, the change that patent term adjustment (PTA) will be printed no later than the issuance date of the patent (instead of on the notice of allowance), and the change that the exclusive remedy for an applicant dissatisfied with the Director's determination on the request for reconsideration of the patent term adjustment is a civil action filed in the U.S. District Court for the Eastern District of Virginia.<br>Revised to update 37 CFR 1.702, as necessitated by the AIA revisions related to the new name of the patent appeal board, the reference in subsection (a) to the date the national stage commenced under 35 U.S.C. 371(b) or (f) (instead of fulfilling the requirements of 35 U.S.C. 371) and the addition of deviation proceedings, and the changes to the subtitle in subsection (b).<br>Revised to update 37 CFR 1.703, as necessitated by the AIA revisions related to the new name of the patent appeal board, the reference in subsection (a) to the date the national stage commenced under 35 U.S.C. 371(b) or (f) (instead of fulfilling the requirements of 35 U.S.C. 371) and the addition of deviation proceedings, and the regulatory changes that moved appeal regulations to part 41 of title 37 and altered the language in subsection (b) to better reflect the period of appeal is from the time jurisdiction begins and ends at the Patent Trial and Appeal Board.<br>Revised to update 37 CFR 1.704, as necessitated by the AIA revisions related to the new name of the patent appeal board, and the regulatory changes that moved appeal regulations to part 41 of title 37 and altered the language in subsection (c) to avoid any PTA reduction if an IDS submission resulting from an Office communication is submitted within 30 days and if a compliant appeal brief is filed within 3 months from the notice of appeal.<br>Revised to update 37 CFR 1.705, as necessitated by the AIA revisions that patent term adjustment will be printed on the patent (instead of the notice of allowance), and the regulatory changes that requires any request for reconsideration of the PTA determination |

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| | be filed no later than two months from the issue date of the patent and that any requests for reinstatement of PTA reduction under 37 CFR 1.704(b) must be filed prior to issuance of the patent.<br>Revised text to discuss the above-mentioned statutory & regulatory changes and the effective date of the changes. |
| **2731** | Revised to update 37 CFR 1.703, as necessitated by the AIA revisions related to the new name of the patent appeal board, the reference in subsection (a) to the date the national stage commenced under 35 U.S.C. 371(b) or (f) (instead of fulfilling the requirements of 35 U.S.C. 371) and the addition of deviation proceedings, and the regulatory changes that moved appeal regulations to part 41 of title 37 and altered the language in subsection (b) to better reflect the period of appeal is from the time jurisdiction begins and ends at the Patent Trial and Appeal Board.<br>Revised text to discuss the above-mentioned statutory & regulatory changes and the effective date of the changes.<br>Added text to discuss that written restriction requirements are notifications under 35 U.S.C. 132, and therefore, would toll any PTA time period running under 37 CFR 1.703(a).<br>Added text to clarify that a reply that is not in compliance with 37 CFR 1.113(c) will not start the four month requirement under 37 CFR 1.703(a)(3) for the Office to act on the reply.<br>Added text to discuss the regulatory change that no fee is required to file an appeal brief if it was filed on or after March 19, 2013 and that 37 CFR 1.703(a)(4) no longer requires payment of the appeal brief fee.<br>Added text to discuss when a remand by the Patent Trial and Appeal Board (Board) is deemed to be a decision under 35 U.S.C. 134 or 135 as stated in 35 U.S.C. 154(b)(1)(A)(iii) or a final decision as stated in 37 CFR 1.703(a)(5). Specifically, the remand must include a decision on the patentability of the claims, derivation, or priority of invention in order to be deemed a decision by the Board. The text explains that if the remand is not deemed a final decision by the Board, then the filing of a request for continued examination may impact the amount of PTA for the patent.<br>Added text to define a “final decision” by the Board or a Federal court as a last decision that does not require further action by the applicant to prevent termination of the proceedings. A decision containing a new ground of rejection is not a final decision. A final decision does not require that the decision is ready for judicial review.<br>Added text to explain that if prosecution is reopened after a notice of allowance, the PTA determination under 37 CFR 1.703(a)(6) would be based on when all outstanding requirements in response to the latest notice of allowance were satisfied.<br>Added text to discuss *Wyeth v. Kappos*, 591 F. 3d 1364, 93 USPQ2d 1257 (Fed. Cir. 2010), which found that different periods of delay overlap under 35 U.S.C. 154(b)(2)(A) only if the periods of PTA under 35 U.S.C. 154(b)(1) occur on the same calendar day. |
| **2732** | Revised to update 37 CFR 1.704, as necessitated by the AIA revisions related to the new name of the patent appeal board, and the regulatory changes that moved appeal regulations to part 41 of title 37 and altered the language in subsection (c) to avoid any patent term adjustment reduction if an IDS submission resulting from an Office communication is submitted within 30 days and if a compliant appeal brief is filed within 3 months from the notice of appeal.<br>Revised text to discuss the above-mentioned statutory & regulatory changes and the effective date of the changes. For example, it is explained that the filing of a non-compliant appeal brief will not be treated as an omission under 37 CFR 1.704(c)(7) if the notice of appeal was filed on or after September 17, 2012 because it would be treated under 37 CFR 1.702(c)(11). Text is also added to explain that the filing of an appeal brief that fails to |

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| | meet the requirements of 37 CFR 41.37 more than three months from the notice of appeal will delay the appeal and may result in a reduction in any earned PTA.<br>Text is added to fully explain that a submission of an information disclosure statement (IDS) within 30 days of receipt from a foreign counterpart office or the USPTO will not result in a reduction of any earned PTA. Three examples are added to demonstrate what individuals are included in 37 CFR 1.56(c) and how the 30 days may be calculated.<br>Added text to clarify that the submission of an IDS or an amendment after a notice of appeal but prior to jurisdiction passing to the Board will be deemed applicant delay under 37 CFR 1.704(c)(8) because treatment of such papers may cause delays in the appeal process.<br>Added text to explain that if the last day of the three month time period in 37 CFR 1.704(b) falls on a Saturday, Sunday, or Federal holiday within the District of Columbia, then any reply can be filed on the next succeeding business day without any reduction to earned PTA. Added a citation to *ArQule v. Kappos*, 793 F. Supp. 2d 214 (D.D.C. 2011), which held that the 35 U.S.C. 21(b) (a.k.a. the holiday/weekend exception) applies to the determination of PTA reductions under 35 U.S.C. 154(b)(2)(C)(ii) and 37 CFR 1.704(b).<br>Added text to reflect the establishment of the new micro-entity status.<br>Modified text to clarify that a submission of a request under 37 CFR 1.705(c) for reinstatement of reduced PTA will not be counted as a further reduction under 37 CFR 1.704(c)(10). |
| **2733** | Revised to update 37 CFR 1.705(a), as necessitated by the AIA Technical Corrections Act that patent term adjustment will be printed on the patent (instead of the notice of allowance).<br>Revised text to discuss the above-mentioned statutory changes and the effective date of the changes. Specifically, the text explains that the official notification of PTA will be published on the patent but the Office will still provide a preliminary PTA calculation on the notice of allowance, although it is not required to do so by statute. Patentee should not request reconsideration of the preliminary PTA determination but should wait until receipt of the official PTA determination on the patent.<br>Modified text to clarify existing policies that if the PTA determination on the patent is longer than expected, a registered practitioner may disclose the Office's error in a letter. The Office will place the letter in the patent file but will not otherwise act on the letter. If patentee wants the Office to reconsider the PTA determination, patentee must follow the procedures set forth in 37 CFR 1.705. Patentee can also file a terminal disclaimer to disclaim any portion of the PTA that is considered excessive. |
| **2734** | Revised to update 37 CFR 1.705(b) and (c), as necessitated by the regulatory changes that require any request for reconsideration of the PTA determination be filed no later than two months from the issue date of the patent and that any requests for reinstatement of PTA reduction under 37 CFR 1.704(b) be filed prior to issuance of the patent.<br>Revised text to discuss the above-mentioned regulatory changes and the effective date of the changes.<br>Modified text to now allow the two month time period of 37 CFR 1.705(b) to be extended up to 5 additional months. In other words, patentee may have up to 7 months to file a request for reconsideration of the PTA on the patent after the patent is granted.<br>Added text to explain that if the Office agrees with patentee's request for reconsideration or finds that a correction to the PTA determination is needed, the Office will issue a certificate of correction to correct the PTA determination on the patent. If the Office denies patentee's request for reconsideration, patentee may appeal to the District Court for the Eastern District of Virginia within 180 days of the Office's decision on the reconsideration request. This is the exclusive remedy as provided in the amendments to 35 U.S.C. 154(b)(4) |

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| | by AIA Technical Corrections Act, which is effective for any patent granted on or after January 14, 2013.<br>Added text to discuss that 37 CFR 1.705(c) requires that any request for reinstatement of PTA reductions be filed prior to the issuance of the patent and the Office will not consider such a request if filed after the patent issues. Applicants do not need to know the PTA determination in order to make the due care showing under 37 CFR 1.705(b) so that there is no reason to delay filing a request for reinstatement. The Office will not delay issuance of the patent in order to address a request for reinstatement but instead will issue, as appropriate, a certificate of correction to change the PTA determination on the patent.<br>Added text to explain that if the last day of the three month time period in 37 CFR 1.704(b) falls on a Saturday, Sunday, or Federal holiday within the District of Columbia, then any reply can be filed on the next succeeding business day without any reduction to earned PTA.<br>Added a citation to *ArQule v. Kappos*, 793 F. Supp. 2d 214 (D.D.C. 2011), which held that the 35 U.S.C. 21(b) (a.k.a. the holiday/weekend exception) applies to the determination of PTA reductions under 35 U.S.C. 154(b)(2)(C)(ii) and 37 CFR 1.704(b). It is further explained that a request for reinstatement is not necessary if applicant utilizes the holiday/weekend exception. |
| **2735** | Entire subsection is deleted. The subject matter is now covered in MPEP 2734. Former 37 CFR 1.705(d) and (e) were removed in light of regulatory changes to 37 CFR 1.705(b). |
| **2736** | Revised to update 37 CFR 1.705, as necessitated by the regulatory changes that redesignated former 37 CFR 1.705(f) as 37 CFR 1.705(d). |
| **2750** | Revised text to clarify that the rights from PTE under 35 U.S.C. 156 are not limited to a claim-by-claim basis but extend to the patent. However, if the patent claims other products in addition to the approved product, any PTE will not be applied to the claims covering the other products. Added a citation to *Genetics Institute LLC v. Novartis Vaccines and Diagnostics Inc*., 655 F.3d 1291, 99 USPQ2d 1713 (Fed. Cir. 2011), which found that PTE under 35 U.S.C. 156 does not apply on a claim-by-claim basis.<br>Modified text to clarify that the FDA will grant a marketing applicant 5 years of data exclusivity for any active ingredient or salt or ester of the active ingredient which has not been previously approved.<br>Added text to explain that the AIA clarified that the sixty-day period of 35 U.S.C. 156 will not start until the next business day if the permission was transmitted after 4:30 pm on a business day or on a day that is not a business day. |
| **2751** | Consistent with the existing guidance that patents subject to a terminal disclaimer may receive PTE under 35 U.S.C. 156, added a citation to *Merck & Co., Inc. v. Hi-Tech Pharmacal, Co., Inc*., 482 F.3d 1317, 82 USPQ2d 1203 (Fed. Cir. 2007). The court found that PTE under 35 U.S.C. 156 applies even if the patent is subject to a terminal disclaimer, which was filed to overcome an obviousness-type double patenting rejection.<br>Modified text to clarify that eligibility for PTE for a product subject to regulatory review under 35 U.S.C. 156(g) depends on whether the active ingredient present in the final dosage form that was previously approved by the FDA. In support, added a citation to *PhotoCure ASA v. Kappos*, 603 F.3d 1372, 95 USPQ2d 1250 (Fed. Cir. 2010), which held that the reference in 35 U.S.C. 156(f) to active ingredient means the ingredient actually present in the approved drug and not merely an active moiety responsible for pharmacological properties.<br>Added text to further discuss applying the active ingredient language from 35 U.S.C. 156 to an approved product having more than one active ingredient. Added a citation to *Arnold Partnership v. Dudas*, 362 F.3d 1338, 70 USPQ2d 1311 (Fed. Cir. 2004) to support the already stated policy that an approved product that has two active ingredients is not |

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| | considered to have a single active ingredient made of two active ingredients. In addition, added a citation to *Ortho-McNeil Pharmaceutical, Inc. v. Lupin Pharmaceuticals, Inc.*, 603 F.3d 1377, 95 USPQ2d 1246, (Fed. Cir. 2010), in which the court found an enantiomer is a different drug product from its racemate and is eligible for PTE under 35 U.S.C. 156(f) even if the racemate itself had been previously marketed. |
| **2752** | Added text to explain that the AIA clarified that the sixty-day period of 35 U.S.C. 156 will not start until the next business day if the permission for commercial marketing or use for a product was transmitted after 4:30 pm on a business day or on a day that is not a business day. |
| **2753** | Modify text to clarify that any PTE will be granted based upon review of the product as either a medical device or a drug product.<br>Added text to explain that the AIA clarified that the sixty-day period of 35 U.S.C. 156 will not start until the next business day if the permission for commercial marketing or use for a product was transmitted after 4:30 pm on a business day or on a day that is not a business day.<br>Added text to refer to 35 U.S.C. 112(f) for applications subject to the first inventor to file provisions of the AIA as an alternative to the citation to 35 U.S.C. 112, paragraph 6, when discussing means plus function claims.<br>Modified the citation from 35 U.S.C. 156(g)(6)(C) to 35 U.S.C. 156(g)(6)(A) and changed "two or three" to "five-year" in discussing the limit under this subsection.<br>Changed from Mail Stop "Patent Extension" to "Hatch-Waxman PTE."<br>Added text to state that the original copy and the patent file will be scanned into the Image File Wrapper (IFW) system so that all documents will be viewable in PUBLIC PAIR. One copy of the application is forwarded to the regulatory agency and a second copy is used by a legal advisor in the Office of Patent Legal Administration (OPLA). |
| **2754** | Changed from Mail Stop "Patent Extension" to "Hatch-Waxman PTE."<br>Added text to state that PTE applications must not be filed via the Office's electronic filing system (EFS-Web). |
| **2754.012754.01** | Added text to explain that the AIA clarified that the sixty-day period of 35 U.S.C. 156 will not start until the next business day if the permission for commercial marketing or use for a product was transmitted after 4:30 pm on a business day or on a day that is not a business day. |
| **2755.01** | Deleted text that stated that notification of the issuance of interim extension will be published in the Official Gazette. |
| **2755.02** | Deleted text in the header of the sample of an order granting interim extension. |
| **2756** | Deleted text that stated a certified copy of the application for PTE is sent to the regulatory agency along with a second letter.<br>Clarified text by changing "restoration" to "extension" in reference to 35 U.S.C. 156. |
| **2757** | Added text that in the determination of the regulatory review period for an animal drug where components were submitted to the FDA in a phased review, the approval phase defined in 35 U.S.C. 156(g0(4)(B)(ii) begins on the date of the submission of the administrative New Animal Drug Application. To support the added text, a citation to *Wyeth Holdings Corp. v. Sebelius*, 603 F.3d 1291, 1299-1300, 95 USPQ2d 1233, 1240 (Fed. Cir. 2010) was added. |
| **2757.01** | No substantive changes – minor grammatical correction(s). |
| **2758** | Modified text to state that the determination which finds the patent ineligible for PTE "dismisses" (instead of denies) the application.<br>Modified the text of the sample Notice of Final Determination. In particular, the presentation of the formula for PTE is changed. |

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| | Deleted text pertaining to the restoration extensions not being applicable to patents in force on June 8, 1996 only because of a Hatch Waxman extension.<br>Clarified text that "original expiration date" in 35 U.S.C. 154 includes patent term extension under former 35 U.S.C. 154(b) for applications filed between June 8, 1995 and May 28, 2000 and PTA under current 35 U.S.C. 154(b) for applications filed on or after May 29, 2000.<br>Corrected the volume citation in F.2d for *Hoechst Aktiengesellschaft v. Quigg*, 917 F2d 522, 525, 16 USPQ2d 1549, 1551 (Fed. Cir. 1990) |
| **2759** | Clarified and updated the proper name and location of the electronic FOIA Reading Room on the USPTO website.<br>Deleted text that stated that a public file is available at the Public Search Room and the Office of Patent Legal Administration. |