

Sequence Listing Errors Can Rob You Of Patent Term Adjustment

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Under current USPTO Patent Term Adjustment (PTA) rules, an Applicant can be charged a Patent Term Adjustment (PTA) deduction for “applicant delay” before examination commences if the application is not “ready for examination” within eight months of its filing date (or national stage commencement date). While that rule first came into effect with the December 18, 2013 [Patent Law Treaty rule changes](#), we have been seeing more pre-examination PTA deductions since the USPTO implemented the [Supernus-related PTA changes](#) July 16, 2020. While those changes expressly altered the PTA rules surrounding Preliminary Amendments, Applicants may be surprised to be charged PTA deductions for correcting Sequence Listing errors.

The “Ready for Examination” Rule

The eight month “ready for examination” rule currently is set forth in 37 CFR 1.704(c)(13):

(13) Failure to provide an application in condition for examination as defined in paragraph (f) of this section **within eight months** from either the date on which the application was filed under 35 U.S.C. 111(a) or the date of commencement of the national stage under 35 U.S.C. 371(b) or (f) in an international application, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date that is eight months from either the date on which the application was filed under 35 U.S.C. 111(a) or the date of commencement of the national stage under 35 U.S.C. 371(b) or (f) in an international application and ending on the date the application is in condition for examination as defined in paragraph (f) of this section; and

This rule is loosely based on the PTA rule that **awards** PTA if the USPTO takes more than 14 months to issue the first Office Action under 35 USC § 132 or Notice of Allowance. While there is a large gap between 8 months and 14 months, the USPTO is always trying to reduce the time to the first Office Action, and does not want those efforts hindered by applications not being ready for examination.

According to the [USPTO's dashboard](#), the current average time to a first Office Action (“First Office Action Pendency”) is 16.9 months.

The “Ready for Examination” Requirements

The “ready for examination” requirements currently are set forth in 37 CFR 1.704(f):

(f) An application filed under 35 U.S.C. 111(a) is in condition for examination when the application includes a specification, including at least one claim and an abstract (§ 1.72(b)), and has papers in compliance with § 1.52, drawings (if any) in compliance with § 1.84, any English translation required by § 1.52(d) or § 1.57(a), **a sequence listing in compliance with § 1.821 through § 1.825 (if applicable)**, the inventor's oath or declaration or an application data sheet containing the information specified in § 1.63(b), the basic filing fee (§ 1.16(a) or § 1.16(c)), the search fee (§ 1.16(k) or § 1.16(m)), the examination fee (§ 1.16(o) or § 1.16(q)), any certified copy of the previously filed application required by § 1.57(a), and any application size fee required by the Office under § 1.16(s). An international application is in condition for examination when the application has entered the national stage as defined in § 1.491(b), and includes a specification, including at least one claim and an abstract (§ 1.72(b)), and has papers in compliance with § 1.52, drawings (if any) in compliance with § 1.84, **a sequence listing in compliance with § 1.821 through § 1.825 (if applicable)**, the inventor's oath or declaration or an application data sheet containing the information specified in § 1.63(b), the search fee (§ 1.492(b)), the examination fee (§ 1.492(c)), and any application size fee required by the Office under § 1.492(j).

As indicated by the highlighted language, a fully compliant Sequence Listing is one of the “ready for examination” requirements.

The “ready for examination” rule has a stopgap if an Office Action (or Notice of Allowance) is issued before any of the requirements are met:

An application shall be considered as having papers in compliance with § 1.52, drawings (if any) in compliance with § 1.84, and a sequence listing in compliance with § 1.821 through § 1.825 (if applicable) for purposes of this paragraph on the filing date of the latest reply (if any) correcting the papers, drawings, or sequence listing that is prior to the date of mailing of either an action under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151, whichever occurs first.

This means that if the USPTO does not notice any deficiencies before the first Office Action (or Notice of Allowance) is issued, the Applicant will **not** be charged a PTA deduction for correcting any deficiencies identified by the Examiner within the initial time period set in the Office Action.

On the other hand, if the USPTO (or Applicant) notices any deficiencies, correcting them after the 8 month window has passed could lead to a PTA deduction for “applicant delay.”

Sequence Listing Errors May Rob You Of PTA

While the USPTO usually issues early notice of any deficiencies in the fees (for example), it can take some time for the USPTO to issue notice of any errors in a Sequence Listing (e.g., a “Notice to Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures”). The current PTA rules do not offer any PTA safeguards for Applicants who believed they had complied with the Sequence Listing rules, but a technical error in the submission is identified sometime close to or after the eight month window has passed but before the first Office Action (or Notice of Allowance) is issued. Even if the Applicant submits a timely and complete response to a Notice to Comply, the Applicant may be charged a PTA deduction running from the eight month date to the date the response is filed.

Applicants concerned with maximizing patent term and minimizing PTA deductions should consider taking steps to ensure that any required Sequence Listing is filed well-before the eight month date, and that all Sequence Listing rules are complied with. The USPTO offers “[Helpful Hints](#)” for complying with the rules, and a “[Sequence Listing Checker](#)” Microsoft Windows-based software application for checking the computer readable forms of Sequence Listings for compliance with format and content rules. However, the USPTO may still find errors in a Sequence Listings that has “passed” the Sequence Listing Checker test. Thus, even taking advantage of these resources may not prevent all Sequence Listing errors; nevertheless, they could reduce the chances of Sequence Listing-related PTA robbery.

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