

Publications

November 5, 2025 • Updates

USPTO Launches Streamlined Claim Set Pilot to Accelerate Patent Examination

Key Takeaways:

- The U.S. Patent and Trademark Office (USPTO) introduced a new pilot program offering expedited examination for certain pending, unexamined applications with narrowly tailored claim sets.
- The program imposes strict eligibility and claim requirements but may reduce pendency, especially relevant for biotech and life sciences applicants facing long examination timelines.
- Biotech and life sciences companies should review the application criteria and downstream restrictions carefully before opting in — particularly if pursuing broader patent protection or follow-on filings.

A series of procedural changes at the USPTO is influencing the strategy for biotech and life sciences applicants. Over the past year, the agency introduced two new fees and launched a streamlined examination pilot, each with implications for how and when applications are filed. This alert focuses on the new Streamlined Claim Set Pilot Program, which aims to reduce pendency by accelerating examination of narrowly tailored applications.

This alert breaks down the USPTO’s new pilot program requirements and related guidance, with a look at potential implications for biotech and life sciences applicants.

Eligibility Criteria at a Glance

Announced on Oct. 24, 2025, the USPTO’s “Streamlined Claim Set Pilot Program” offers expedited examination for certain pending, unexamined applications with narrow claim sets. With this program, the USPTO “anticipates that focusing examination resources on already filed, unexamined applications that have a streamlined claim set will enhance efforts to reduce the USPTO’s inventory and pendency.” The program will run through Oct. 27, 2026, or until each technology center accepts at least approximately 200 applications.

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Related Capabilities

- Intellectual Property
- Biotechnology & Life Sciences Patent Prosecution
- Patent Preparation & Prosecution
- Life Sciences

The USPTO has established a whopping nine requirements for applications to be accepted in the program:

1. **Application Type:** Applications must be non-continuing, non-national stage and non-reissue applications. While applications that claim priority to one or more provisional applications (35 U.S.C. § 119(e)) or to one or more foreign applications (35 U.S.C. §§ 119(a)-(d) or (f)) are eligible, applications that claim priority to either a U.S. nonprovisional application, or an international application designating the U.S., are excluded.

2. **Claim Limits:** Applications must have a single independent claim, 10 or fewer total claims and no multiple dependent claims. Here, the USPTO specified that claims must be in proper dependent form under 35 U.S.C. § 112(d), in that they must (i) refer to a previous claim, (ii) include every limitation of that prior claim and (iii) recite an additional limitation of the subject matter of that prior claim.

The reference to the prior claim must also appear in the preamble and the dependent claim must be directed to the same statutory class of invention as the independent claim. To comply with these claim requirements, applicants can file a preliminary amendment to amend the claims. But, if an examiner issues a written restriction requirement, then the USPTO treats the restriction requirement as the “first office action” and terminates the “special status” previously afforded to the application.

3. **Filing Date:** Applications must have been filed *before* Oct. 27, 2025.

4. **Examination Status:** Applications must not be docketed to an examiner and must not have received a first office action.

5. **Electronic Filing:** Applications must have been filed electronically using the USPTO’s Patent Center. Petitions must also be filed through Patent Center.

6. **Format:** Applications must have been filed in DOCX format.

7. **Nonpublication:** With or prior to filing their petitions, applicants must rescind any nonpublication request.

8. **Inventor Petition Cap:** Applications are not eligible if they name an inventor or joint inventor who has also been named on more than three other applications that have also petitioned for consideration in the program. In other words, there is a limit of four petitions under the program per inventor or joint inventor.

9. **Petition and Fee:** Applicants must file their petition with USPTO on Form PTO/SB/472, certifying that all program requirements have been satisfied. If accepted, PTO/SB/472 requires applicants to agree not to (i) present more than one independent claim, (ii) more than ten total claims or (iii) a multiple dependent claim. Finally, PTO/SB/472 requires applicants to certify that the correct non-refundable fee accompanies their petition (37 C.F.R. § 1.17(h)). Currently, the fee for filing a petition for the program is \$60 for a small entity and \$150 for a non-small entity. Lastly, PTO/SB/472 provides an admonition: if the USPTO dismisses an applicant’s petition, there is no opportunity to correct deficiencies.

If the petition is instead granted, applications receive “special status” and are placed on an examiner’s special docket until the first office action is issued.

Once the first office action is issued, applications are removed from the examiners’ special docket and return to the regular examination track. Standard reply periods apply from that point forward.

Restrictions Don't End with Special Status

Even after special status ends, an examiner can treat as unresponsive any response that (i) adds claims that would result in more than one independent claim and/or more than 10 total claims pending in the application; (ii) adds a multiple dependent claim; or (iii) presents a claim, other than the independent claim, that does not comply with the dependency format. If an examiner believes that a response was a bona fide attempt to advance the application to a final action, then the examiner has discretion to provide a shortened statutory period of two months for applicants to provide a compliant response.

Stated differently, although applications are no longer treated as “special” following a first office action, USPTO *still* requires applicants to comply with program claim requirements for the entire duration of examination.

Additional USPTO Guidance

The USPTO provides a few other points of guidance. After the USPTO issues a final office action, applicants can submit an amendment, an affidavit or other evidence in compliance with 37 C.F.R. § 1.116. Applications under appeal follow the normal appeal procedure.

If applications become involved in proceedings outside of the normal examination process — like a secrecy order, a derivation proceeding, or a petition filed under 37 C.F.R. §§ 1.181 – 1.183 — then the applications will not have special status during that proceeding. Notably, the USPTO does not provide a provision for withdrawing applications from the program. Rather, it advises that applicants can abandon an application in the program in favor of a continuing application.

Considerations for Biotech and Life Sciences Applicants

While the pilot is officially framed as a study on how limited claim sets affect pendency and examination quality, the USPTO is also using it as a testing ground for broader examination reforms. Applicants in biotech and life sciences should view this as both a procedural opportunity and a strategic data point.

With an average first action pendency of 28.5 months for applications in Art Unit 1600, this new program offers a low-cost option for prioritized examination for a specific subset of nonprovisional applications. Applicants eager to quickly secure a patent on a discrete invention may find this program appealing — especially if they are cost-conscious. But, considering the number of certifications and agreements required to participate in this program, applicants should consider both their short- and long-term objectives before opting in.

For guidance on evaluating eligibility or developing a filing strategy under the USPTO's Streamlined Claim Set Pilot Program, please contact Michelle McMullen, Rebecca McFadyen or a member of Polsinelli's Intellectual Property team.