

Developments in U.S. Patent Law



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Developments in U.S. Patent Law



What's New?

- Patent Office Initiatives
- Legislative Proposals
- Judicial Developments

Administrative (Patent Office) Initiatives

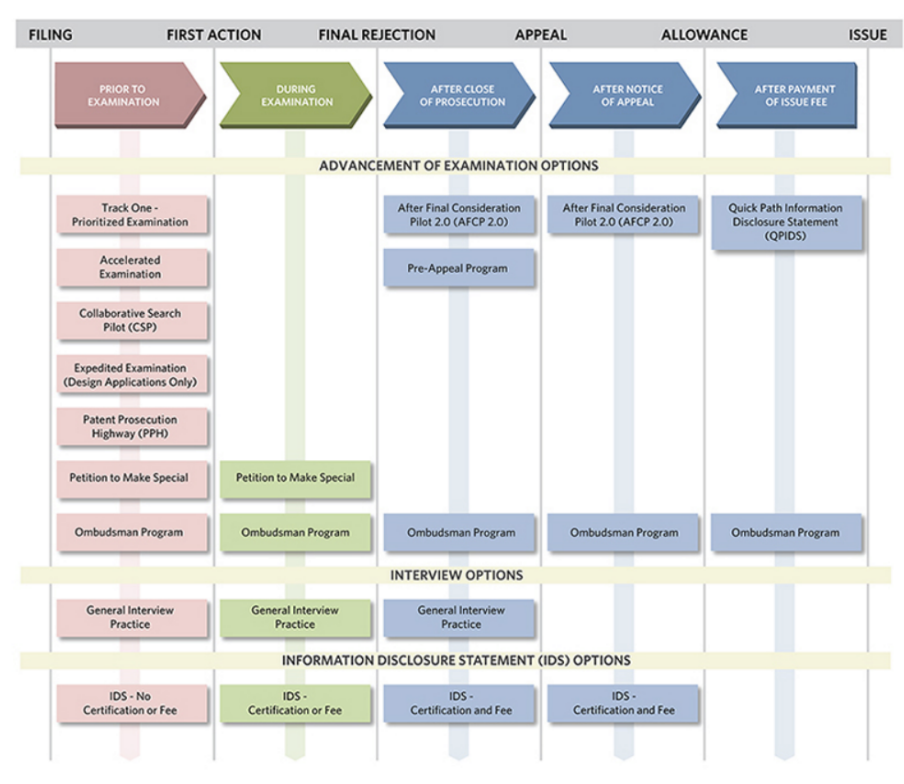
The Patent Office has several, popular on-going initiatives

- **Track One – Prioritized Examination**
 - Prioritized examination is available for a fee at the time of filing an original utility application.
 - Thousands of applicants have obtained patents within six months of filing.
- **Patent Prosecution Highway**
 - When an applicant receives a ruling from its national patent office that at least one claim is allowable, the applicant may request accelerated examination of the corresponding claim(s) in the counterpart U.S. application.
 - This allows applicants to reach final disposition of a patent application more quickly and efficiently than standard examination processing. More than 70,000 applications have used this program.
- **After Final (Action) Consideration**
 - Applicants having received a final rejection of claims may request further consideration in connection with a further amendment to at least one independent claim that the applicant believes will lead to allowance with only limited further searching and/or consideration by the examiner.
 - No official cost to participate (for now)

Administrative (Patent Office) Initiatives

The Patent Office has many more on-going initiatives, each designed to help applicants more efficiently obtain patents

All are explained at the Patent Office's dedicated website [link](#)



Patent Office Initiatives

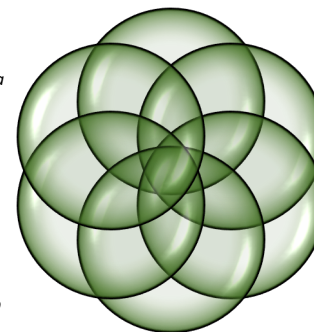
Cancer Moonshot Expedited Examination Pilot Program

- Qualifying applications involving cancer-related technologies are advanced out of turn for examination.
- Program is open until the earlier of January 31, 2025, or until 1000 petitions are granted.
- The application must be in the field of oncology or smoking cessation and must contain at least one **eligible method claim**.
- Details at this Patent Office website [link](#).

A method of treating a nicotine dependency and promoting smoking cessation by administering a specific pharmaceutical composition.

A method of treating a cancer by administering a specific pharmaceutical composition wherein the method comprises a step to diagnose the cancer.

A method of treating or reducing the incidence of a cancer using an immunotherapeutic compound or composition (cancer immunotherapy method).



A method of treating a cancer by targeting specific genetic markers or mutations using a specific pharmaceutical composition.

A method of treating a rare or childhood cancer using a specific pharmaceutical composition.

A method of detecting or treating a cancer using a medical device specifically adapted to detect or treat the cancer.

Patent Office Initiatives

Climate Change Mitigation Program

- Qualifying applications involving technologies that reduce, remove, prevent, and/or monitor greenhouse gas emissions are advanced out of turn for examination.
- Program is open until the earlier of June 7, 2027, or until 4,000 petitions are granted.
- Applications **must contain one or more claims to a product or process that mitigates climate change by removing, reducing, preventing, or monitoring/tracking/verifying greenhouse gas emissions.**
- Details at this Patent Office website [link](#).



Patent Office Initiatives

Semiconductor Technology Pilot Program

- Qualifying applications involving technologies that increase semiconductor device production, reduce semiconductor manufacturing costs, and strengthen the semiconductor supply chain are advanced out of turn for examination.
- Program is open until the earlier of December 2, 2024, or until 1,000 petitions are granted.
- Applications **must contain at least one claim covering a processing/apparatus for manufacturing a semiconductor device and that corresponds to one or more of the technical concepts within CPC Class H10 or H01L.**
- Details at this Patent Office website [link](#).



Patent Office Initiatives: Proposed Fee Increases

5% Increases

- An across-the-board 5% fee increase to most patent-related fees.
- Increase by 5% filing, search, and examination fees above the 5% across-the-board proposal.

Information Disclosure Statement

- Three surcharges (\$200, \$500, \$800) due upon the first filing of any information disclosure statement (IDS) that results in a cumulative number of applicant-provided citations exceeding 50, 100, and 200 references, respectively.

Tiered fees for Continuation Applications

- New tiered fee for filing continuing applications more than 5 and 8 years after the earliest benefit date (\$2,200 and \$3,500, respectively).
- Intended to encourage more efficient filing and prosecution behavior and offset future lost maintenance fee collections that eventually recover the examination costs incurred

Patent Office Initiatives: Proposed Fee Increases

Tiered RCE fees

- The Office proposes to pass more of the costs associated with RCEs to applicants.
- Increasing fee amounts for first and second RCEs (\$1,500 and \$2,500, respectively), and adding an additional tier with a higher fee (\$3,600) for third and subsequent RCEs.

Tiered Terminal Disclaimer Fees

- The Office proposes to change the flat fee for filing a terminal disclaimer to a sliding fee scale where fees increase after certain milestones, e.g., a final action or appeal.
- Proposed fees (ranging from \$200 to \$1400) encourage applicants to file terminal disclaimers as early as possible during the examination process, enabling more efficient examination.

Excess Claims Fees

- The Office proposes to increase excess claims fees for total claims in excess of twenty and independent claims in excess of 3 to \$200 and \$600, respectively.

Details at this Patent Office website [link](#).



Promoting and Respecting Economically Vital American Innovation Leadership (PREVAIL)

- Bipartisan legislation that would overhaul the rules and procedures of the Patent Trial and Appeal Board (“PTAB”), the administrative body that conducts IPRs and PGRs, generally making those procedures more pro-patent owner
- Legislation would:
 - Require anyone challenging a patent in an IPR to have been sued or threatened with a lawsuit
 - Require the PTAB to utilize the “clear and convincing” evidence utilized by district courts for determining patent validity
 - Force patent challengers to select a single forum (district court or IPR/PGR)



Patent Eligibility Restoration Act of 2023

- Bipartisan legislation that proposes to eliminate judicially created exceptions to patent subject matter eligibility in favor of clearer statutory exclusions
- Would overrule the Supreme Court's decisions in *Bilski*, *Mayo*, and *Alice*, which have significantly narrowed the scope of subject matter eligible for patenting under 35 U.S.C. 101
- Proposed new statutory exclusions include mathematical concepts, mental processes, certain methods of organizing human activity (i.e., a process that is substantially economic, financial, business, social, cultural, or artistic), unmodified human genes and natural material.

Judicial Developments: Enablement of Genus Claims



Amgen v. Sanofi

- Supreme Court held that 35 U.S.C. § 112 requires specification to enable those skilled in the art to cumulatively identify and make all or nearly all embodiments of the invention without substantial time and effort.
- Courts and PTAB extending “stricter” analysis beyond biotechnology and functional claims

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Thank you

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