Developments in U.S. Patent Law

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What’s New?

• Patent Office Initiatives
• Legislative Proposals
• Judicial Developments
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.
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](marshallip.com).
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 detecting 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 detecting or treating a cancer using a medical device specifically adapted to detect or treat the cancer.

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).
Climate Change Mitigation Program

- Qualifying applications involving greenhouse gas reduction technologies are advanced out of turn for examination.
- Program is open until the earlier of June 5, 2023, or until 1000 petitions are granted.
- Applications must contain one or more claims to a product or process that mitigates climate change by reducing greenhouse gas emissions.
- 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, $300, $300) due upon the first filing of any information disclosure statement (IDS) that results in a cumulative number of applicant-provided citations exceeding 50, 100, or 200 references, respectively.

### Tiered fees for Continuation Applications

- New tiered fee for filing continuing applications more than 3 or 7 years after the earliest benefit date ($1500 and $3000, 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 ($1500 and $2500, respectively), and adding an additional tier with a higher fee ($3600) for third and subsequent RCEs.

Tiered Terminal Disclaimer Fees

• The Office proposes to change the flat fee for filing a terminal disclaimer.
• 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.

Details at this Patent Office website link.
Legislative Proposals

Protecting American Intellectual Property Act of 2022

• Impose sanctions on foreign entities/persons involved in “significant” theft of U.S.-owned trade secrets.

• Annual Presidential report to Congress, identifying “foreign persons” who have “knowingly engaged in, or benefited from, significant theft” of trade secrets, if the activity is “likely to result in . . . a significant threat to the national security, foreign policy, or economic health” of the U.S.

• Applies to foreign persons who provide “significant” financial or technical support to, or act on behalf of, the direct offender, including an entity’s CEO or board members.
Judicial Developments: Supreme Court Is Expected to Address

**Amgen v. Sanofi**

- Whether enablement is governed by the statutory requirement that the specification teach those skilled in the art to “make and use” the claimed invention, or whether it must instead enable those skilled in the art to cumulatively identify and make all or nearly all embodiments of the invention without substantial time and effort.

- Court’s decision expected by end of June 2023.
Judicial Developments: Supreme Court Will Not Address

**Teva Pharms. USA v. GlaxoSmithKline**

- If a generic drug’s FDA-approved label carves out all language that the brand manufacturer has identified as covering its patented uses, can the generic manufacturer be held liable on a theory that its label still intentionally encourages infringement of those carved-out uses?
- Court issued an order on May 15, 2023, declining to address this issue.
Judicial Developments: Supreme Court Will Not Address

U.S. Government Recommended Review

- *Interactive Wearables, LLC v. Polar Electro Oy*
- *Tropp v. Travel Sentry, Inc.*

- What is the appropriate standard for determining whether a patent claim is directed to a patent-ineligible concept, e.g., abstract idea, under 35 U.S.C. § 101?
- Court issued an order on May 15, 2023, declining to address this issue.
Judicial Developments: Supreme Court Will Not Address

**Thaler v. Vidal (PTO)**

- Patenting of artificial intelligence.
- Does the Patent Act categorically restrict the statutory term “inventor” to human beings alone?
- Court issued an order on April 24, 2023, declining to address this issue.
Marshall, Gerstein Team Attending 2023 INTA Conference

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Thank you