

# Developments in U.S. Patent Law



Prepared for

#### **2023 BIO Conference Attendees**

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June 2023

### Developments in U.S. Patent Law



tion of the invention are end ments of law have been compli has been determined that a patent vention shall be granted under the law

Therefore, this 5.860.492

#### United States Patent

Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America for the term set forth below, subject to the payment of maintenance fees as provided

If this application was filed prior to June 8, 1995, the term of this patent is the longer of seventeen years from the date of grant of this patent or twenty years from the earliest effective U.S. filing date of the application, subject to any statutory extension.

If this application was filed on or after June 8. 1995, the term of this patent is twenty years from the U.S. filing date, subject to any statutory ex tension. If the application contains a speci reference to an earlier filed application of plications under 35 U.S.C. 120, 121 or the term of the patent is twenty years date on which the earliest applicati subject to any statutory extens

# What's New?

- Patent Office Initiatives
- Legislative Proposals
- Judicial Developments



#### 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

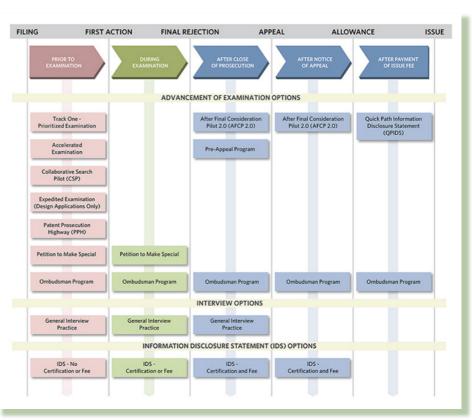
• Applicants having received a final rejection of claims may request further consideration in connection with a further amendment to at least one independent claim that the applicant believes will lead to allowance with only limited further searching and/or consideration by the examiner.



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





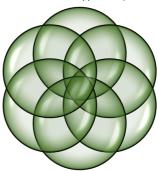
Cancer Moonshot **Expedited Examination** Pilot **Program** 

- Qualifying applications involving cancerrelated 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.

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

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

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 targeting specific aenetic markers or mutations using a specific pharmaceutical composition.

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



# 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 7, 2027, or until 4000 petitions are granted.
- Applications must contain one or more claims to a product or process that mitigates climate change by reducing, removing, or assessing 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.
- Additionally increasing by 5% application filing, search, and examination fees.

#### **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 Request for Continued Examination (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 <u>link</u>.



### **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 Addressed Enablement



#### Amgen v. Sanofi

- Court held invalid as non-enabled claims reciting a genus of antibodies by their function: binding particular amino acid residues on a protein and, thus, blocking that protein from interfering with the body's ability to remove cholesterol.
- Patents "claim[ing] an entire class" of inventions "must enable a [skilled person] to make and use the entire class."
- The patent need not always describe "how to make and use every single embodiment within a claimed class."
- A roadmap to each embodiment may be sufficient, but not when it requires "painstaking experimentation."

Court's decision is available at this link.



# 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?
- The Federal Circuit effectively answered "yes."
- Despite the government's recommendation for the Supreme Court's review ...
- Court issued an order in mid-May 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 recites a patent-ineligible concept, e.g., abstract idea, under 35 U.S.C. § 101?
- In both cases, the Federal Circuit summarily affirmed district court decisions that concluded the patents claimed abstract ideas without inventive concept and without technical improvement over prior art.
- The Federal Circuit has explicitly invited Supreme Court review and, despite the government's repeated recommendations—including here—for such review ...
- Court issued an order in mid-May, 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?
- Federal Circuit effectively answered "yes."
- The government recommended no Supreme Court review and ...
- Court issued an order in late April, declining to address this issue.



# Thank you

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