

What's New at the USPTO and How Will it Shape Life Sciences IP?

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PRACTICES Intellectual Property, Patents, Life Sciences, Patent Office Trials, AI and Deep Learning

The United States Patent and Trademark Office (USPTO) is undergoing significant changes as new leadership comes on board to implement policy directives from the new administration.

New Leadership

Howard Lutnick has been confirmed as U.S. Secretary of Commerce and will oversee the USPTO. Mr. Lutnick is well-acquainted with the IP system, being a named inventor on 800 patents and applications worldwide, and has pledged as one of his priorities to reduce the USPTO backlog. Along with the Acting Director and Acting Commissioner, they are certain to advance the new administration's focus on promoting U.S. technological dominance while awaiting Senate confirmation of newly announced Director John Squires.

Policies and Rules Which May Affect Drug Development and IP

USPTO Rules and Fees

Effective Jan. 18, 2025, higher fees are now charged across the board, including newly imposed fees such as those for utility patent applications filed at least six years and/or nine years after the earliest claimed benefit date. This is aimed at reducing extended continuation and other similar filings, also called "evergreening," which some would argue are a leading cause of high drug prices. This fee change will make it more costly for drug developers to obtain all the IP coverage that they might have previously pursued and could prejudice drug development by small and medium entities.

On the bright side, however, a proposed rule that would have restricted enforceability for patents with terminal disclaimers tied to any invalid or anticipated claims has been withdrawn. Enactment of that proposal could have been devastating for companies with portfolios of large patent families or even those with two patents.

America First Policy

The "America First Policy" seeks to "champion core American interests and always put America and American citizens first."¹ Integral to this policy is a directive to "assess the status of United States intellectual property rights such as patents, copyrights, and trademarks" conferred to non-US inventors and to "make recommendations to ensure reciprocal and balanced treatment of intellectual property rights..."²

Artificial Intelligence (AI) Policy

With respect to its policy on AI, which is increasingly being utilized in the life sciences for drug discovery and treatment, the administration's goal is to reduce government regulation and

encourage private-sector innovation in AI. To this end, Executive Order 14179 dated January 23, 2025, titled "Removing Barriers to American Leadership in Artificial Intelligence" revokes President Biden's Executive Order 14110 on the safe and trustworthy use of AI.

Limits on Drug Pricing

Executive Order 14148 dated January 20, 2025 and titled "Initial Rescissions of Harmful Executive Orders and Actions" rescinds Biden Executive Order 14087 titled "Lowering Prescription Drug Costs for Americans." Executive Order 14087 related to the Inflation Reduction Act, which in part, imposed caps on prescription drug costs and allowed for earlier price setting for small molecule medicines, which some believed discouraged drug research and development.

Legislative Developments

Several key legislative initiatives are being considered to strengthen patent rights, clarify statutory language and equitable relief rights, and adjust the balance in the patent system. These initiatives may be more likely to pass given the new administration's goal of strengthening patent rights:

- **PREVAIL Act:** This act promotes fair practices in patent trials and aims to protect the patent rights of small businesses and individual inventors by limiting serial petitions, applying estoppel earlier in the challenge process and preventing unfair influence on PTAB decisions.
- **Patent Eligibility Restoration Act (PERA):** This bill seeks to clarify patent eligibility under 35 USC §101, removing the "new" requirement and excluding certain subject matter, such as mathematical formulas and mental processes, from patentability. PERA would make it clear that proteins and nucleic acids that are altered from how they occur in nature would be eligible for patenting.
- **RESTORE Patent Rights Act:** This act would partially reverse the *eBay Inc. v. MercExchange* decision, restoring a presumption in favor of granting permanent injunctions for patent infringement cases and allowing patent holders to enjoy their IP rights with a higher likelihood of keeping infringers out of the market.

Future Outlook

We can be optimistic that the new administration's policies will revitalize U.S. innovation and strengthen patent protection. Looking ahead, we can expect additional efforts to reduce the patent backlog, foster technological leadership in AI and ensure that the U.S. remains at the forefront of innovation in emerging industries.

¹ America First Policy Directive to the Secretary of State, Executive Order 14150 dated January 20, 2025.

² America First Trade Policy, Presidential Memorandum dated January 20, 2025, specifically referring to rights conferred to those in the People's Republic of China (PRC).