

How a Second Trump Presidency Could Shape IP

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President-elect Donald Trump did not make intellectual property (IP) policy a major focus of his 2024 election campaign, but his policy priorities are nearly certain to have a profound effect on the IP landscape when he takes office in January. From leadership changes at the U.S. Patent and Trademark Office (USPTO) to shifts in biopharmaceutical patent policy to regulation of rapidly evolving fields like artificial intelligence (AI), here's what the IP community can expect from a second Trump presidency.

A New Director at the USPTO?

The director of the USPTO has enormous influence on IP policy, and Trump's appointee for that role is the most direct way he can impact it. President Joe Biden's appointee, Kathi Vidal, was instrumental in establishing guidelines for director review and providing increased clarity surrounding discretionary denials at the Patent Trial and Appeal Board (PTAB), among other accomplishments. Vidal announced her resignation on Nov. 12, tapping Deputy Director Derrick Brent to assume her duties when she departs the office in December. While Trump has not yet floated a candidate for Vidal's replacement, we can glean clues about the type of director he might choose



(Clockwise, from top left) W. Karl Renner, Kristi Sawert, Megan Chacon, and Michael Portnov of Fish & Richardson.

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from his first-term appointee, Andrei Iancu.

Iancu generally focused on reducing regulations, enhancing operational efficiency, implementing pro-inventor policies, and relaxing Section 101 requirements. He wanted to increase the number of patents being issued and wanted issued patents to be of high quality. Early in his tenure, the PTAB replaced the "broadest reasonable interpretation" standard for interpreting patent claims with the *Phillips* standard, aligning the board's claim construction standard with the district courts' standard. The Motion to Amend Pilot Program, launched in 2019, allowed pat-

ent owners an easier pathway to preserve their claims in America Invents Act (AIA) proceedings. Consistent with Iancu's belief that it was appropriate for the PTAB to exercise more discretion when considering whether to institute AIA proceedings, the PTAB's Precedential Opinion Panel issued several decisions that clarified the board's authority in such matters during his tenure.

We can expect Trump's second appointee for USPTO director to continue these policies, or at least proceed in a similar pro-patent owner vein. Trump generally disfavors government regulation of AI, so his USPTO director may relax Section 101 requirements in patent prosecution, making it easier for applicants to obtain patents on AI and other software-related innovations. At the PTAB, a Trump appointee likely will expand the board's discretion to deny institution in AIA proceedings, largely reversing Vidal's efforts to limit the practice. A Trump appointee likely will withdraw the USPTO's pending rule on terminal disclaimer practice, but the fate of other pending rules is unclear.

A New Chair at the FTC?

The Federal Trade Commission (FTC) under incumbent Chair Lina Khan has undertaken a number of IP-related enforcement actions in recent years. In 2023 and 2024, it challenged over 400 patents as improperly or inaccurately listed in the Food and Drug Administration (FDA) Orange Book, arguing that such listings may constitute unfair methods of competition. Earlier this year, the commission issued a rule banning noncompete agreements, which could eliminate a tool many companies use to protect their trade secrets. That rule is currently blocked pending an appeal in the U.S. Court of Appeals for the Fifth Circuit. Khan's commission has also expressed its support for the Biden administration's proposed march-in rights framework for biopharmaceuti-

cal patents (more on that proposal below).

Given the FTC's progressive tilt under Khan, many expect Trump to replace her with a more pro-business appointee. However, in remarks to the New York Post, Vice President-elect J.D. Vance suggested that there could be a place for Khan in a Trump administration, as he generally supports her efforts to crack down on perceived abuses in the tech sector. Several Republican officials, including Sen. Josh Hawley of Missouri and Rep. Matt Gaetz of Florida, have been dubbed "Khanservatives" for their support of some of Khan's actions as FTC chair, reflecting the Republican Party's increasing skepticism of big tech.

Sporadic Republican support notwithstanding, it is more likely than not that Trump will replace Khan as FTC chair, making it less likely that the FTC under her successor will continue the legal fight for its noncompete ban or aggressively pursue further challenges to Orange Book-listed patents.

Relief for Biopharmaceutical Patents

The Inflation Reduction Act (IRA), arguably the Biden administration's signature legislative achievement, authorizes the U.S. Department of Health and Human Services through the Centers for Medicare & Medicaid Services (CMS) to negotiate drug prices directly with biopharmaceutical companies. Only one round of products has been selected for negotiations under the IRA to date, so data on its effectiveness is limited. However, the act's drug price negotiation provisions could have significant ramifications for drug companies' ability to monetize their biopharmaceutical patents. While Trump has stated that he would push for rollbacks to the IRA's climate-related provisions and redirect unspent funds elsewhere, it is unclear how a second Trump administration would handle drug price negotiations.

Trump supported allowing CMS to negotiate drug prices during his 2016 campaign, but later dropped that proposal, and his 2024 campaign did not mention drug price negotiation. Thus, while it is unlikely that a second Trump administration would push to rescind CMS' drug price negotiation authority, it is equally unlikely that it would seek to expand it or expedite negotiations. Under the current IRA framework, innovator biopharmaceutical companies generally have two possible options:

1. Reach a settlement agreement with a limited number of generic or biosimilar drugmakers to maintain the broader price of their drugs.
2. Decline to negotiate with generics or biosimilars directly and risk being selected for negotiation by CMS.

Trump's approach to march-in rights is likely to be a major point of departure from the Biden administration's policies. In December 2023, the Biden administration proposed a new march-in rights framework that would allow agencies to consider the price of a patented product when determining whether to exercise its march-in authority under the Bayh-Dole Act. While the framework is not limited to biopharmaceutical patents, the Biden administration touted it as a strategy for lowering the cost of drugs. Trump has a history of opposing the exercise of march-in-rights based on price. In January 2021, in the final days of his term, the National Institute of Standards and Technology issued a proposed rule that would preclude federal agencies from exercising march-in rights based on pricing alone. That provision was dropped from a final rule implemented in March 2023. As such, a second Trump administration is unlikely to pursue a final version of the December 2023 rule or exercise march-in rights based on drug prices.

An Aggressive Stance Toward International IP Theft

Over the course of his political career, Trump has taken an aggressive stance on international IP and trade issues. In 2017, Trump directed the U.S. Trade Representative (USTR) to conduct a Section 301 investigation into potential unfair trade practices by China, including IP theft. The USTR's report found that China had engaged in several unreasonable or discriminatory trade practices, which led the first Trump administration to impose an initial round of tariffs on about \$50 billion worth of Chinese goods, followed by further rounds of Section 301-based tariffs. In 2018, the Jeff Sessions-led Department of Justice launched the China Initiative to prosecute alleged economic espionage, including trade secret theft. (That program ceased operations in February 2022.) Although his 2024 platform does not specifically mention alleged IP theft as a basis for tariffs, Trump has proposed even more significant tariffs in a second term, including a universal 10-20% tariff on most foreign products and a 60% tariff on Chinese products. We can expect a second Trump administration to continue robust investigations into alleged IP theft and, if appropriate, apply sanctions.

Fewer Guardrails on AI

Trump embraced AI enthusiastically during his first term, issuing the first executive order on AI in 2019 and an executive order creating guidelines for AI adoption by federal agencies in 2020. The Biden administration has also addressed AI, issuing a lengthy executive order in October 2023 focused on increasing safety, security, and trustworthiness in the development and use of AI. Trump's 2024 platform states that he will rescind the Biden executive order, which it claims hinders the development of AI technology and imposes progressive ideals upon it. Instead,

the platform states that Republicans support AI development “rooted in Free Speech and Human Flourishing.” This indicates that a second Trump administration will be far less inclined to place guardrails around the development of AI technology, in addition to being likely to loosen Section 101 requirements for AI inventions at the USPTO. Trump also has indicated that he views the AI race as a competition with China, which could provide further incentive for deregulation and pro-inventor policies.

Higher Chance of Legislative Patent Reform

With Republicans in control of the White House and both houses of Congress, the prospects of legislative patent reform becoming a reality have increased. The bipartisan Promoting and Respecting Economically Vital American Innovation Leadership (PREVAIL) Act, introduced by Sen. Chris Coons, D-Delaware, would strengthen protections for patent owners in PTAB proceedings by requiring standing for patent challengers, imposing a presumption of validity, requiring a showing of invalidity by clear and convincing evidence, and attaching estoppel as soon as a petition is filed, among other reforms. The bipartisan Patent Eligibility Restoration Act, introduced by Sen. Thom Tillis, R-North Carolina, would make it easier to obtain patents by abrogating the Supreme Court’s *Mayo/Alice* framework and limiting patent eligibility exclusions to a small number of categories. Given that Republicans generally support the policy aims of both bills, it seems

likely that a second Trump administration will push for their passage.

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