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How The Patent System May Look After Trump's Return

By **Dani Kass**

Law360 (November 6, 2024, 5:28 AM EST) -- The U.S. Patent and Trademark Office during Donald Trump's first term as president focused on making the invalidation of patents more difficult, and attorneys say his second administration is likely to do the same following his projected reelection.

The Biden administration under USPTO Director Kathi Vidal has required flexibility on intellectual property to address drug pricing and access, and she empowered the Patent Trial and Appeal Board to look closely at patents. But those approaches probably won't continue based on how the agency operated under Trump's former director, Andrei Iancu.

"In the PTAB processes, Iancu said, 'I trust the panel. The panel is doing a good job. They're making the right decisions.' It's all about: 'Yes, the PTO is doing a good job, and they've got it,'" said Mayer Brown LLP partner Saqib Siddiqui. "Whereas with Kathi Vidal, we've seen a little bit of skepticism: 'Are they doing a good job? Can we add another layer of review? Should I be watching this?'"

While the Trump campaign did not substantially address patents, his more general beliefs are likely to show his plan, Siddiqui added. That includes focusing on pro-business policies, appointing as many judges as he can, lessening government interference in pharmaceuticals, and fighting competition from China.

However, Trump has proven himself nothing but unpredictable, Siddiqui added.

"You never know exactly what he would do," he said.

A Return to Pro-Business Patent Policies

Vidal and Iancu had very different approaches to the patent system, often characterized as the former being pro-patent quality — and therefore more open to invalidating them — and the latter being pro-business or pro-inventor.

It's unclear what exactly Trump's take is compared to those who he appoints to control his agency. While the USPTO works closely with the U.S. Department of Commerce and other government arms, Iancu told Law360 he wasn't having conversations about IP with Trump directly during the president-elect's first term.

Recently, patent office directors have tended to last for a single presidential term. Iancu, now a partner

at Sullivan & Cromwell LLP, declined to discuss whether he could be back in the office or if he had any desire to return.

Under Vidal's leadership, the USPTO has monitored decisions from the PTAB closely. Vidal has heavily used the new director review process — mandated by the U.S. Supreme Court in its June 2021 Arthrex decision — to review PTAB institution and merits decisions, along with overseeing sanctions proceedings. She also created the Delegated Rehearing Panel to expand the agency's bandwidth to hold director reviews.

Vidal has granted several petitions and has regularly used sua sponte authority to jump in when she disagrees with proceedings.

How a Trump administration might handle the new rehearing process is likely going to depend on the director rather than a policy position from high up, said Mintz Levin Cohn Ferris Glovsky and Popeo PC member Peter Snell.

"That's more of a personality issue in how an acting or sitting USPTO director views the most effective way to guide policy," he said.

But attorneys noted that during Iancu's tenure, he did whatever possible to streamline proceedings, and so an extra layer of review isn't likely to be favored under the Trump administration.

A major area where the difference between the administrations has played out is discretionary denials, or when a PTAB panel can decide to turn away a petition challenging a patent for a reason other than the merits. This can include repetitive or improperly stacked-up petitions, but the one that gets the most attention is allowing administrative patent judges to turn down petitions if related litigation is in its late stage.

The NHK-Fintiv precedent aims to stop the same patent validity challenge from being reviewed in two separate forums, lessening resources for courts and parties and lowering the risk of contradictory rulings. It was a landmark, controversial policy in Iancu's USPTO, but was reined in by Vidal, who tried to create more certainty on when Fintiv denials are used in proceedings like inter partes reviews.

"[Iancu] was really focused more on cutting regulation, cutting red tape and trying to bring efficiencies to the process," said Dechert LLP partner Noah Leibowitz, adding that he predicts "a hands-off approach to streamlining and cutting down on the regulatory process in favor of increased numbers and quantity of patents coming out of the patent office."

Vidal, a patent litigator who came to the USPTO from Winston & Strawn LLP, controversially proposed a rule over so-called terminal disclaimers. Applicants can file those disclaimers when getting a patent that might otherwise be rejected for obviousness-type double patenting by agreeing that both patents will expire at the same time, and can only be enforced when owned by one party.

The largely unpopular proposal would have made it so that when one patent was invalidated, those on the other end of a terminal disclaimer would be invalidated, too.

Iancu said that proposal won't last.

"I would expect a new Trump administration to forgo that approach," he told Law360. "It makes it

extremely difficult to obtain patents on your real innovation. Taken to its logical end, it makes it extremely costly to protect the full scope of your innovation. What's going to happen is, especially with smaller companies with fewer resources, which defines almost all startups, you would expect them to either forgo patent protection or obtain much more limited patent protection. Or spend a disproportionate amount of their limited resources on their patent portfolio."

The new administration also likely would support a pair of high-profile bipartisan bills in Congress, according to Leibowitz.

The Promoting and Respecting Economically Vital American Innovation Leadership Act, or PREVAIL, features several changes, including limiting the ability to bring validity challenges in multiple venues and creating a standing requirement at the PTAB.

The Patent Eligibility Restoration Act, or PERA, looks to clarify what is patentable under the Patent Act's Section 101, which has become muddled over the last decade when courts have tried to decide what counts as an invalid abstract idea or natural phenomena.

"You might see a renewed focus on both of those bills, because in a larger sense, they both speak to cutting down on some of the regulation, trying to have a better, more well-defined landscape for patentees and [having] more clear understandings of what's patentable or not," Leibowitz said.

Filling Judgeships in Texas and the Federal Circuit

During Trump's first administration, getting as many judgeships filled as possible was a priority, and he was able to get three Supreme Court justices, 54 circuit judges and more than 170 district judges confirmed.

While the Biden administration has continued to fill up the courts at a rapid pace, there are still two openings in the popular patent district of the Western District of Texas, where U.S. District Judge Robert L. Pitman has been holding down the entire Austin division with only retired and visiting judges to help out. There are two openings in the Northern District of Texas and one in the Southern District of Texas, along with openings in the Southern and Central districts of California — all of which often receive patent cases.

In another division of the Western District of Texas, Trump had put U.S. District Judge Alan Albright on the bench, who has single-handedly changed the landscape of patent litigation in the last few years by luring a significant portion of the country's patent litigation to Waco.

But Trump wasn't given a chance to touch the Federal Circuit, despite adding judges to all the other circuit courts.

That's not likely to recur in Trump's next term. The court has three of the oldest active federal judges in the country, including 97-year-old U.S. Circuit Judge Pauline Newman, who has been suspended for refusing to undergo medical testing to refute doubts about her competency. U.S. Circuit Judge Alan Lourie is turning 90 in January, and U.S. Circuit Judge Timothy Dyk is 87. U.S. Circuit Judges Sharon Prost, 73, and Jimmie V. Reyna, 71, also are eligible to take senior status.

"While the judge he appoints to the Federal Circuit will have important ramifications to how the Federal Circuit will impact IP law, we don't know his decision-making process," Siddiqui said. "What we have to

do is just go to more broader ideas and broader philosophies. Someone younger and someone pro-business and someone who [has engaged in] less judicial activism — that's the kind of judge he will appoint."

The Biden administration took patent law heavily into account when naming two judges to the Federal Circuit: U.S. Circuit Judge Tiffany Cunningham was a patent litigation partner at Perkins Coie LLP when nominated, and U.S. Circuit Judge Leonard Stark was a district court judge in Delaware, overseeing one of the largest patent dockets in the country.

"The data point that we have that is somewhat analogous was the first Trump administration's appointing of [Iancu], who generally favored stronger protections for U.S. innovators," Snell said. "I think we can look to that as a proxy for general judicial attitudes that might be embodied within his proposed appointees."

Walking Back Controversial Drug Pricing Initiatives

Outgoing President Joe Biden had pursued a series of hotly contested initiatives aimed at lowering drug pricing, and attorneys said they'd be surprised if Trump followed through with them.

In late 2023, the Biden administration proposed a framework that would allow the federal government to invoke its march-in rights under the Bayh-Dole Act, which has never been done before. There, the government could force drugmakers to provide reasonably priced licenses if government funds were part of the underlying research.

The outstanding question is when the requirements for march-in rights can be met, where the law says "action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee or their licensees."

"We're certainly getting questions [from clients] about what that might look like, and similarly for a Trump administration, what might be policies for federal march-in," said Leibowitz. "At the very end of Trump's prior term, there was an initiative to affirmatively state a policy that drug pricing would not give rise to federal march-in rights under Bayh-Dole."

Iancu likewise said march-ins wouldn't happen in a Trump administration, claiming they would be "destructive of innovation in universities and federal labs, and the transfer of that innovation to the market, which is usually through startups and small businesses."

The Biden administration also had supported a World Trade Organization waiver of patents on COVID-19 vaccines, aiming to make the vaccines more accessible internationally and infuriating drugmakers and politicians on the other side of the aisle.

Additionally, the government tried to step in during patent litigation against Moderna, invoking a wartime law that would have the government assume full liability given that the company's actions were at the "express authorization" of the federal government.

The U.S. Department of Justice in February 2023 said the suit from Arbutus Biopharma against it belongs in the U.S. Court of Federal Claims, but the Delaware federal court quickly shot the DOJ down.

"That's something we would not see under a Trump administration," Siddiqui said. "We would not see

the DOJ intervene and say, 'I know you have patents, but this company was making these drugs for this reason, and so you can't sue them for it.'"

Continued Focus on International Competition

The Trump administration will likewise pursue the bipartisan agenda of keeping the U.S. as No. 1 in innovation internationally — particular fighting against China, which could show up through a variety of actions.

One such effort is to make more manufacturing domestic, such as by using tariffs on imported goods to discourage outsourcing, Snell said.

"Reduction of reliance on foreign-made technology, when coupled with a general sense of stronger patent rights and ability to enforce those rights, could have a synergistic effect," he said.

Iancu likewise stressed the need to bring manufacturing back to the U.S.

"The more we can onshore innovation and manufacturing, the better for the United States," he said. "It is really important to recognize that innovation doesn't happen in a vacuum. It's hard to be an innovation leader if you're not a manufacturing leader."

But the concern about China must focus on IP theft, too, the former director said. He called China "the most significant violator of intellectual property rights around the world."

"I would expect the next administration to continue its policies to pressure China to stop the widespread theft of intellectual property," Iancu said.

--Editing by Adam LoBelia.
