LAW360

Portfolio Media. Inc. | 230 Park Avenue, 7th Floor | New York, NY 10011 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Patent Policy To Watch In 2024

By **Dani Kass**

Law360 (January 1, 2024, 8:02 AM EST) -- Both the U.S. Patent and Trademark Office and Congress are looking at a busy year for patent policy in 2024, with the agency set to provide guidance on artificial intelligence to the Biden administration and lawmakers working through two high-profile patent reform bills. Here's a breakdown of what patent attorneys should keep on their radar.

Guidance on Artificial Intelligence

The Biden administration has given the USPTO until the end of February to create guidance about the role of AI in inventorship, part of the White House's wide-ranging executive order on AI from late October.

"From an industry perspective, it is so important to understand what could potentially happen," said Paul Hastings LLP partner Preston Ratliff. "It's going to shape industries. Whether it's the high-tech industries, life sciences — all shapes and forms of technologies are now being influenced by AI."

The Federal Circuit held in August 2022 that AI cannot be named as an inventor on patents, and that decision has stayed in place with the U.S. Supreme Court refusing to reconsider it.

Ratliff said he wants to know where the line is between what's allowed and what is going too far. Likewise, Mayer Brown LLP partner Manuel Velez wants to know what role AI can play in co-inventorship rather than sole inventorship.

"Right now there's no requirement for inventors to disclose whether they've used AI as part of their research [or] as part of coming up with their inventions, so that may be something the patent office talks about," Ratliff said.

The USPTO will have to provide another set of guidance by the end of July on patent eligibility and AI.

The intersection of eligibility and AI is being closely watched, including in the life sciences industry, where the technology is being used in drug discovery to narrow down targets used to develop treatments, according to Velez.

The PREVAIL Act

The Senate's most active intellectual property duo, Delaware Democrat Chris Coons and North Carolina

Republican Thom Tillis, introduced a massive pair of bills in June aiming to reform policy.

The Promoting and Respecting Economically Vital American Innovation Leadership Act, or PREVAIL Act, has several facets. Its long list of changes includes reining in patent validity challengers from bringing the same challenges in multiple venues; creating a standing requirement at the Patent Trial and Appeal Board; requiring the creation of a code of conduct for the PTAB; and changing the standard used in invalidity challenges to match the stricter standard used in district courts.

Mayer Brown's Velez said this bill "seems to have some momentum," while noting that parts of it have been raised in other legislation that didn't go anywhere.

"I think we have to be cautious," Velez said. "It would certainly be the biggest change to [inter partes reviews] since they were instituted. The changes they proposed are important. The bottom line is they would make it harder for petitioners to successfully challenge patents at the PTAB, [and it's] also likely to reduce costs and uncertainties in the process."

Sterne Kessler Goldstein & Fox PLLC director Carla Kim said she's keeping her eyes on PREVAIL, citing concern about how it's "generally the trend to limit patent owners' rights."

The bill is co-sponsored by Sens. Dick Durbin, D-Ill., and Mazie Hirono, D-Hawaii.

The Patent Eligibility Restoration Act

The second bill introduced by Sens. Coons and Tillis — respectively chair and ranking member on the Senate Judiciary Committee's IP subcommittee — aims to reform patent eligibility.

The aptly named Patent Eligibility Restoration Act looks to start over on more than a decade of judicial decisions about what can be patented under Section 101 of the Patent Act. The bill would ensure eligibility for "useful process, machine, manufacture, or composition of matter, or any useful improvement."

Courts have been interpreting eligibility based on a series of decisions from the Supreme Court, the last in 2014, which say patents directed to abstract ideas and natural phenomena can't be patented without an added incentive concept. Attorneys have said for years that there is little predictability on how judges apply Section 101, and the Supreme Court has denied **countless attempts** for clarity.

The bill would throw out all that precedent and rely on a specific set of exceptions, like "process claims drawn solely to the steps undertaken by human beings in methods of doing business, performing dance moves, offering marriage proposals, and the like," even if done on a computer.

Crowell & Moring LLP partner Anne Li said PERA's limited scope may work in its favor.

"Tillis and Coons are really just focusing on patent eligibility, not trying to overhaul the system," she said. "It's bipartisan, and in this political climate, having something sponsored in a bipartisan way is atypical."

Advance Notice of Proposed Rulemaking

USPTO Director Kathi Vidal in April issued an expansive advance notice of proposed rulemaking laying out a series of policy changes being considered by the agency. She provided two months for comments,

and the follow-up is being closely watched by the patent community.

One key area Vidal has focused on is discretionary denials at the PTAB, such as having the board deny petitions due to related litigation being in an advanced stage or the use of multiple petitions. The agency is aiming to make decisions on such denials more predictable and clarify rules, said Fish & Richardson PC principal Andrew Patrick.

"The office has not yet indicated which of the proposed changes will come into effect," he said.

Some of the proposals are not particularly controversial, like allowing parties to brief discretionary denials without cutting into the word limit on their merits challenges. But others are already causing frustration, such as the director's use of a "compelling merits" standard to decide when a challenge should be instituted regardless of discretionary denials.

"I think everyone involved is just very curious as to the direction this might take, and if the current analyses [on these topics] will be included or drop by the wayside," Patrick said.

Vidal has also faced allegations that she went too far with her proposals and is stepping on lawmaking territory belonging to Congress.

Drug Pricing Initiatives

The debate over whether and how patent practices impact drug pricing will continue into 2024, with a series of tangible efforts from various government arms.

The White House on Dec. 7 announced a big step in policy, proposing a rule to exercise so-called march-in rights. Under those rights, the government can force companies to license their patents for unreasonably priced drugs at a lower rate, so long as the patents were developed with some government funds.

The U.S. Federal Trade Commission in November challenged more than 100 pharmaceutical patents listed in the U.S. Food and Drug Administration's Orange Book, a database listing the patents covering a drug, along with their expiration dates. Generic competition cannot join the market — without the branded company's permission — until that expiration, but the FTC says branded-drug makers are listing patents that don't belong in the hopes of extending their exclusivity period.

The FDA doesn't have any effective power to decide if patent listings are improper, but the FTC may be able to sue in district court if the challenges to patents owned by AbbVie, AstraZeneca, Teva and other major drugmakers fall flat. Since the letters went out, recipients GlaxoSmithKline, Impax and Kaleo have **delisted** their patents.

Patents listed by the FDA are in a rough enforcement place: the FDA has made clear that it doesn't have patent expertise needed to intervene, and the USPTO is not involved in the drug regulatory process.

With a push from Congress, the FDA and USPTO in 2022 said they were working together on drug pricing.

"I'm worried about the sentiment toward patents by Congress and the general public that biotech or pharma companies are abusing patents, and patents are the cause of increased healthcare costs," said

Sterne Kessler's Kim. "That's been going on for a long time."

Attorneys are also keeping an eye on the Inflation Reduction Act of 2022, which allows Medicare to negotiate drug prices. In turn, the law impacts how companies are approaching research and development, and their subsequent IP protection needs.

"It's not necessarily affecting patent law itself, but it indirectly affects us," Kim said.

State Patent Assignment Laws

Lastly, attorneys should be focusing on a trend involving state laws limiting when an employee's patents can automatically be assigned to an employer, according to Crowell's Li.

Invention assignment laws give workers the right to their inventions if they are developed outside of work, and don't involve the company's resources, be it physical supplies or trade secrets.

The laws have been on the rise for several years, with existing provisions in effect in Minnesota, California, Delaware and six other states. In October, attorneys again took notice when one such law went into effect in New York.

Employers can still require their employees to assign IP rights to them if the inventor is at work or using work resources. Li said that distinction used to be clear-cut, but it's becoming fuzzier as work and personal life are blurring in a more remote world.

"When am I on the job? If I go to pick up my kids, and I'm thinking about my employer's problem, am I on the job?" Li said. "It would have been easier when the employee was at the office. [A contract] says 'all inventions,' so that's what all the employers think it all says. But the state law changed, so it doesn't matter what the contract says — it's against the law."

--Additional reporting by Ryan Davis. Editing by Emily Kokoll.
