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Outlook for 2025: how Trump and the USPTO will affect life sciences IP

Key developments for the industry this year include a more pro-patent administration and USPTO changes, say Carla Ji-Eun Kim and Deborah Sterling of Sterne Kessler.

The life sciences intellectual property landscape is poised for significant developments in 2025. Changes at the US Patent and Trademark Office (USPTO) and a new administration will influence innovation and protection strategies for the industry. This article covers some of the most impactful developments that we are watching for 2025.

Trump administration

This year ushers in a new administration and while IP was not a hot topic on the campaign trail, the new administration's priorities are likely to reshape the IP landscape in a number of ways, including:

- **USPTO director:** The Trump administration is expected to be more pro-patent than the Biden administration. While President-elect Trump has not yet announced his candidate for director, his first-term director, Andrei Iancu, instituted a number of reforms that favoured patent owners. Trump's second appointee is expected to also be more pro-patent than the outgoing director, Kathi Vidal.
- **Inflation Reduction Act (IRA):** Among other provisions, the IRA allows the government to negotiate drug prices directly with pharmaceutical companies under limited conditions. This could significantly impact a drug company's ability to recoup money spent on R&D and clinical trials, which, in turn, affects patent strategy.

  The 2024 Trump campaign touted rollbacks on climate provisions in the IRA, but took no stance on price negotiation provisions. It seems unlikely that Trump would roll back the drug pricing provisions. That said, if the IRA is struck down by the US court system, the Trump administration is equally unlikely to revive it.
- **March-in rights:** The Biden administration proposed a new march-in rights framework, allowing government agencies to consider a patented product's price to exercise its march-in rights under the Bayh-Dole Act. Trump has historically opposed price-based march-in rights and there is no reason to conclude that he would take a different stance now.
- **Section 101 reform:** In addition to the Promoting and Respecting Economically Vital American Innovation Leadership (PREVAIL) Act, with Republicans controlling the House and the Senate, the Patent Eligibility Restoration Act is likely to pass under the new administration. The bill seeks to abrogate the US Supreme Court's *Mayo/Alice* framework for patent eligibility analysis and reduce the current restraints on eligible subject matter.
- **Artificial intelligence (AI) push:** As a fan of AI technology, Trump has claimed that he will rescind Biden's 2023 AI executive order that focused on safety and security, which he thinks hampers AI development. A push for AI development will likely result in a relaxation of Section 101 requirements for AI inventions.

USPTO changes

- **USPTO fee increases:** The USPTO's fee increases, set to take effect in January 2025, will raise many patent-related fees by approximately 7%. These increases will likely influence prosecution strategy, particularly for smaller companies that have smaller patent budgets.
- **Obviousness-type double patenting (ODP):** Although the USPTO withdrew the terminal disclaimer (TD) rule proposed in May 2024, the USPTO is likely to continue utilising ODP rejections in various forms.

  ODP rejections are increasing, irrespective of the filing and expiration dates of the reference patent in relation to the application under rejection. For instance, the USPTO is issuing ODP rejections in cases where an earlier-filed patent application, which expires sooner ('earlier application') is rejected over a later-filed reference patent that expires later ('later patent').

  In such scenarios, a TD may not be available, for example for the solely-owned earlier application against a commonly-owned later patent. A joint research agreement, under the CREATE Act, is typically not helpful in this context, as such agreements are unlikely to be signed before the filing of the earlier application. This form of ODP rejection can, unintentionally, discourage collaboration between companies, directly conflicting with the intent of the CREATE Act.

  Additionally, it discourages the filing of serial applications as child applications of earlier applications are more likely to face such ODP rejections against later patents. This ODP trend interestingly aligns with the USPTO's new filing fee that effectively discourages filing child applications having a priority claim of more than six years earlier.

  Moreover, while *Allergan v MSN* clarified ODP rejections within a family of patents, ODP rejections between different patent families can still lead to a TD or an unresolvable ODP rejection. In addition, *Gilead v Natco* remains the law and can have serious consequences on a patent's term.
- **Obviousness:** The USPTO's updated guidance on obviousness, effective February 27, 2024, introduces increased flexibility for examiners. While this flexibility is intended to streamline the examination process, it has effectively raised the obviousness standard. If such rejections continue during the examination process, those cases may be subject to future review by the Patent Trial and Appeal Board (PTAB) or a court. Particularly in light of the US Supreme Court's recent overturning of the Chevron doctrine, some of the USPTO's liberal interpretations of statute may come under scrutiny.
- **Artificial intelligence:** AI will remain a prominent topic in patent law in both USPTO and private industry. As applicants seek to protect AI-assisted inventions, patent offices and practitioners will increasingly explore AI-based drafting and search tools to address rejections, for example, stemming from AI-generated prior art.

A key challenge will be properly capturing the AI-assisted inventions and inventorship in patent applications, while also addressing concerns related to protecting these inventions —sometimes as trade secrets—as well as developing effective AI-based tools, and ensuring confidentiality to prevent inadvertent public disclosure when using these tools.

Post-grant proceedings and the PREVAIL Act

The PREVAIL Act is expected to be enacted under the new Trump administration. The bill proposes several changes that will significantly impact post-grant proceedings, mostly in favour of patent owners. For example, introducing a standing requirement for petitioners will limit the number of potential petitioners, giving patent owners more comfort in their patent rights.

Similarly, increasing the petitioner's burden to require a showing of invalidity by "clear and convincing" evidence—the same standard as in US district court and higher than the current preponderance of evidence standard—further supports patent owners. Substitute claims, however, would remain subject to the lower preponderance of evidence standard.

Further patent-friendly provisions aim to reduce both parallel and serial petitions by requiring the USPTO to "reject any petition that presents prior art or an argument that is the same or substantially the same as prior art or an argument that previously was presented to the office", and by expanding the scope of estoppel to apply at the time the petition is filed as opposed to after a Final Written Decision.

The proposal to change the panel of judges assigned to a proceeding following the institution decision arguably means that the panel that oversees the full proceeding is not already "tainted" negatively toward the patent by the decision to institute. Conversely, the panel is equally not tainted by any scepticism about the strength of a ground or challenge to a claim expressed in the institution decision.

In summary

We can expect changes to the US patent system and landscape in 2025 and beyond given the change in administration, including a likely swing toward a more patent-friendly environment. Those changes, coupled with the USPTO's upcoming fee increases, continued challenges with ODP rejections, and evolving guidance on obviousness—combined with the growing impact of AI on patent law—underscore the need for careful navigation of IP strategy in the coming years.

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