CHEMICAL & LIFE SCIENCE PATENTS

QUICK NEWS & PRACTICE TIPS

HARNESS IP

USPTO UPDATES

1 | FEWER IPR PETITIONS LIKELY TO BE GRANTED UNDER *FINTIV*

Section 314(a) provides the Patent Trial and Appeal Board ("the Board") with discretionary power to deny instituting Inter Partes Review (IPR) proceedings. In exercising that discretion, the USPTO provided the Board with updated guidance on March 24, 2025, to apply the six *Fintiv* factors. The *Fintiv* factors have been around for about five years, and they generally focus on activity at the district court level or at the International Trade Commission (ITC) to see if enough has happened there to warrant denying institution of IPR. Because proceedings at the ITC typically have a built-in schedule that outpaces IPR proceedings, the USPTO's updated guidance specifically states that "the Board is more likely to deny institution where the ITC's projected final determination date is earlier than the Board's deadline to issue a final written decision." Since February of this year, *Fintiv*-based discretionary denials have increased significantly. Following the rescission of the USPTO's prior guidance on discretionary denials, Acting USPTO Director Stewart has granted director review, and denied institution, in multiple instances, and it appears that trend will continue.

Practice Tips:

i. Pharmaceutical companies frequently face patent challenges through IPRs, especially for generic drug approvals under the Hatch-Waxman Act. The *Fintiv* guidance may lead to fewer IPRs being instituted if parallel district court litigation is progressing quickly.

ii. Complex patents in biotechnology and chemistry often involve extensive litigation. If district court proceedings are well underway, petitioners may struggle to get an IPR instituted, making early litigation strategy planning even more critical.

iii. Life science companies may benefit from using *Sotera* stipulations, agreeing not to pursue the same invalidity arguments in district court that they raise in an IPR petition. This could help avoid discretionary denials.

2 | USPTO UPDATES PATENTS DASHBOARD

The **Patents Dashboard** now provides expanded data on filings and prosecution trends. As of May 14, 2025, 814,500 applications awaited first office action, while 1,238,141 were pending at any stage. New features, including 10-year trends and fraud mitigation efforts, enhance transparency and may help applicants strategize filings.

3 | USPTO EXPEDITING PATENT ISSUANCE PROCESS

The USPTO has accelerated its patent issuance timeline, cutting the delay between Issue Notification and Issue Date from three weeks to two, effective May 13, 2025. This change enhances efficiency, allowing applicants to receive patents faster. The USPTO advises filing continuing applications before paying the Issue Fee to ensure co-pendency.

More details can be found at the USPTO's website. LEARN MORE

4 | USPTO FORMALLY TERMINATES CLIMATE CHANGE MITIGATION PILOT PROGRAM

The USPTO has terminated the Climate Change Mitigation Pilot Program, suspended since January 28, 2025. Petitions filed after 5 p.m. ET on January 28 will not be granted. Originally launched to accelerate climate-related innovations, the program was extended in 2023 but discontinued due to policy shifts.

More details are available in the Federal Register Notice. LEARN MORE

5 | USPTO DISCONTINUING ACCELERATED EXAMINATION PROGRAM FOR UTILITY APPLICATIONS

Beginning on July 10, 2025, the U.S. Patent and Trademark Office (USPTO) will no longer accept petitions under the **Accelerated Examination program** for utility patent applications. This decision does not affect Track One prioritized examination, which is an alternative to the Accelerated Examination program and will still be available after July 10, 2025. The Accelerated Examination program will remain in effect for design applications, which do not currently have an alternative expedited examination program. According to the USPTO, discontinuing Accelerated Examination for utility applications frees up examining resources to be devoted to older, unexamined utility applications, thereby supporting broader efforts to reduce pendency. In each of the fiscal years 2014 to 2024, fewer than 100 applicants have utilized Accelerated Examination, which is substantially less than the number of applications utilizing the Track One program.

Please visit the Federal Register to read the Final Rule in its entirety. LEARN MORE

US CHEMICAL AND LIFE SCIENCE CASE LAW UPDATES

1 |

On February 13, 2025, in ***US Synthetic v. ITC*, 128 F.4th 1272, 1287 (Fed. Cir. 2025)**, the court reversed the ITC and held that the asserted claims in U.S. Patent No. 10,508,502 for a polycrystalline diamond compact (PDC) were patent eligible subject matter under 35 U.S.C. § 101. The asserted claims defined the PDC based on its constituent elements and material properties (e.g., coercivity, permeability, magnetic saturation). *Id.* at 1279. The ITC acknowledged that the asserted claims were not a natural composition, but the ITC decided the asserted claims related to an abstract idea because the claims recited properties that were an unintended consequence of the manufacturing process. *Id.* at 1280. In reversing the ITC, the Federal Circuit determined that the ITC erred by relying on inapplicable cases that do not relate to a physical composition, such as cases relating to functions on a generic computer, and because the claimed properties correlate to the PDC structure. *Id.* at 1282-84. The Federal Circuit also considered how the '502 Patent describes how conventional PDCs and the claimed PDCs have differences corresponding to the claimed properties. *Id.* at 1278. As a result, the Federal Circuit determined the asserted claims were not abstract, but instead defined the PDC by its constituent elements and structurally-correlated properties to inform a skilled artisan about the claimed PDC. *Id.* at 1285.

> ***Claim Drafting Practice Tip:***
>
> i. When drafting a claim directed to a composition of matter, include constituent elements that correspond to the claimed properties, such as permeability, etc.

2 On March 13, 2025, in **In *re Xencor, Inc.*, 130 F.4th 1350 (Fed. Cir. 2025)**, the Federal Circuit affirmed decisions by both the Patent Trial and Appeals Board and the Appeals Review Panel regarding the patentability of claims 8 (a Jepson claim) and 9 (a method claim) of Xencor's application directed to treating a patient with a modified anti-C5 antibody. Ultimately, both claims were found unpatentable by the Court for a lack of written description.

As to claim 8, the Court explained that the preambles of claims written in the Jepson format require written description; not just written description for the claimed improvement. This, they said, is because the claimed invention consists of not only the claimed improvement, but also includes the claimed improvement as it applies to the prior art. Therefore, the inventor must provide written description sufficient to establish that what is claimed to be well-known in the prior art is actually well-known in the prior art. The amount and content of that disclosure, the court explained, will vary depending on factors such as "the level of knowledge of the person of ordinary skill in the art, the unpredictability of the art, and the newness of the technology."

As to claim 9, the Court found that the preamble phrase "treating a patient," limited the claim, and that the claim lacked written description because the application did not define the word "treating" and did not "describe or provide any data associated with treating any patient with any disease or condition with any anti-C5 antibody, including an anti-C5 antibody with the claimed Fc modifications."

Antibody Written Description Practice Tips:

i. Describe in the specification, with particularity, as many embodiments of the antibody as reasonably possible, preferably in both functional terms and structural (at least the CDR sequences) terms;
ii. Describe experiments that set out how one skilled in the art can reliably produce antibodies that perform the intended function;
iii. Ensure description of relevant experimental data and treatment steps within the specification as it pertains to the invention;
iv. Ensure description of the prior art at large such that it is clear that the applicant understands the scope of the relevant prior art; and
v. Describe a common quality amongst all of the functional embodiments that enable a person skilled in the art to make all or most of what is claimed, rather than only the isolated antibodies.

Dive deeper into the insights with Troy Associate Caley Bennett in her blog post! **CLICK HERE**

3 On June 11, 2025, in ***Agilent Technologies, Inc. v. Synthego Corp.*, Nos. 2023-2186, 2023-2187 (Fed. Cir. June 11, 2025)** the Federal Circuit addressed whether the enablement requirement for anticipation under 35 U.S.C. § 102 (novelty) should mirror the heightened enablement standard of *Amgen Inc. v. Sanofi*, 598 U.S. 594 (2023), which requires the specification to enable the full scope of claimed embodiments to satisfy the enablement requirement under 35 U.S.C. § 112. The Federal Circuit held that a reference can anticipate even if it would not function in the real world, so long as it teaches enough for a person of ordinary skill in the art to replicate the invention without undue experimentation.

Synthego challenged the validity of Agilent's patents (relating to chemically modified gRNAs used in CRISPR gene-editing) at the Patent Trial and Appeal Board (PTAB), which invalidated all of Agilent's claims. Agilent appealed, but the Federal Circuit affirmed the PTAB's decision, and held that the cited prior art reference (a published patent application) qualified as an enabling, anticipatory reference because a reference need only enable a single embodiment of the asserted claims to satisfy the enabling disclosure under § 102. The Federal Circuit distinguished *Amgen* on two grounds. First, *Amgen* addressed enablement under § 112, not whether prior art is enabled under § 102. Second, in contrast to *Amgen*, the combination of the state of the art and the cited reference provided sufficient guidance to avoid undue experimentation. Accordingly, the heightened *Amgen* enablement standard does not apply to anticipatory references under § 102.

Enablement Practice Tips:

i. A single prophetic embodiment can be anticipatory if it enables one way of practicing the claimed invention. Because the enablement bar under § 102 is low, prophetic examples in prior art must be carefully considered when drafting claims for a new patent application.

ii. Include both working and prophetic examples in your patent application to bolster the disclosure and potentially qualify as enabled prior art against competitors' applications. Working examples and experimental data strengthen § 112 enablement by demonstrating that the invention can be practiced across its full scope.

Explore more perspectives from St. Louis Principal Kisuk Lee and Associate Jeffrey Lin in their full blog post! CLICK HERE

HOW TO MAXIMIZE PATENT TERM ADJUSTMENT (PTA):

Gain valuable insights on Patent Term Adjustment (PTA) from St. Louis Principal **Elisabeth Koral** in **this informative PowerPoint presentation**. Discover how applicants can earn, retain, or even lose PTA—plus expert tips to make the most of it!

LET'S MEET UP!

CLS group members plan to attend upcoming conferences, so reach out to coordinate a meet-up!

i. July 17-18, 2025: 50th Annual Institute of Continuing Legal Education (ICLE) Intellectual Property Law Institute, Grand Traverse Resort - **Caley Bennett**

ii. July 21-22, 2025: LCLD 2025 Fellows Regional Meeting; Chicago - **Leanne Rakers** (2025 Fellow)

iii. July 30-31, 2025: Volta Foundation's Women in Battery Conference (Stanford University) - **Jennifer Woodside Wojtala**, **Elisabeth Koral**

iv. September 7-9, 2025: Intellectual Property Owners Association (IPO) Annual Meeting; San Diego, CA – **Michael Gamble**, **Leanne Rakers**, **Colleen Shovlin**, **Chris Cauble**

CONTRIBUTORS:

Caley Bennett, Christopher Clayton, Jordyn Grawe, Elisabeth Koral, Kisuk Lee, Jeffrey Lin, Leanne Rakers, Doug Robinson, Michael Varco