

CHEMICAL & LIFE SCIENCE PATENTS

QUICK NEWS & PRACTICE TIPS



USPTO UPDATES

1 | USPTO ENDS ACCELERATED EXAMINATION FOR UTILITY PATENTS

As of July 10, 2025, the USPTO stopped accepting petitions for Accelerated Examination of utility patent applications, citing low usage and a need to redirect resources toward older, unexamined cases. Track One prioritized examination will remain available for utility applications, while Accelerated Examination will continue for design applications, which have no alternative expedited option. From 2014 to 2024, fewer than 100 utility applications per year used the program compared to far greater use of Track One (nearly 1,400 requests per month in 2025).

Visit the [Federal Register](#) to access the Final Rule in its entirety.

[LEARN MORE](#)

2 | USPTO RAISES TRACK ONE ANNUAL LIMIT

The USPTO has issued a final rule to increase the annual limit for Track One prioritized examination requests from 15,000 to 20,000 starting this fiscal year. Track One enables applicants to receive a final disposition on their patent applications in about 12 months.

More information on Track One can be found [here](#).

[LEARN MORE](#)

3 | USPTO RESUMES IN PERSON PTAB HEARINGS

Beginning September 1, 2025, all Patent Trial and Appeal Board (PTAB) hearings are conducted in person at USPTO offices, with virtual participation allowed only for good cause such as financial hardship or medical emergencies. Public access to hearings will continue to be available remotely.

More information on PTAB hearings can be found [here](#).

[LEARN MORE](#)

4 | USPTO UNVEILS DESIGNVISION AI TOOL TO ENHANCE DESIGN PATENT SEARCHES

On July 17, 2025, the USPTO launched DesignVision, its first AI-based image search tool for design patent examiners. Integrated into the Patents End-to-End search suite, DesignVision can search U.S. and foreign industrial design collections using images as queries, returning results ranked by visual similarity. The tool aims to streamline and modernize examination, complementing existing search resources while helping reduce application pendency.

The Official Notice can be found on the [USPTO's patent related notices page](#).

[LEARN MORE](#)

US CHEMICAL AND LIFE SCIENCE CASE LAW UPDATES

- 1 | On May 12, 2025, in ***Regents of the University of California v. Broad Institute, Inc.*, Nos. 2022-1594, 2022-1653 (Fed. Cir. 2025)**, the Federal Circuit partially overturned a USPTO ruling that had rejected Regents' assertion of having conceived the CRISPR Cas9 system with a 'single guide' RNA before Broad. CRISPR Cas9 is a gene editing tool in which the Cas9 protein functions like molecular scissors, cutting DNA with pinpoint accuracy. In its natural bacterial form, two RNA molecules work together to guide Cas9 precisely to its target sequence. The key advance was fusing the two natural RNAs into a single guide RNA (sgRNA) to streamline the process. Regents argued that after demonstrating CRISPR Cas9 with sgRNA *in vitro*, applying it to eukaryotic cells required only routine molecular

biology techniques, while Broad countered that Regents had not conceived the eukaryotic application before Broad achieved it, citing Regents scientists' own doubts. If an inventor has fully formed the invention in their mind and only ordinary skill is needed to make it work, conception is considered complete (even without a working prototype). The Federal Circuit found the USPTO erred by focusing on Regents scientists' doubts and disregarding evidence that those skilled in the art, using standard methods and supported by early third party successes, could have readily made the leap to eukaryotic systems. Regents' claims described the function of the CRISPR-Cas9 system, not a specific experimental result. Thus, the correct legal question was whether, after the invention was described, completing it required nothing more than the application of ordinary skill to reduce it to practice. This decision makes clear that **inventor doubts do not defeat conception if a skilled artisan could, using routine techniques, reduce the invention to practice**, and that objective evidence from the broader scientific community can be critical in such disputes. The case now heads back to the PTAB, which must evaluate Regents' conception date under the Federal Circuit's clarified standard.

Conception Practice Tips:

- i. When drafting patent applications, clarify which steps (if any) rely on well-established techniques to show that only ordinary skill is needed for reduction to practice. Be careful as this could be an admission that these steps do not "add significantly more" to the claim in a subject matter ineligibility rejection, and also cannot be relied upon to support non-obviousness.
- ii. Use publications, expert declarations, and lab protocols to demonstrate that a person of ordinary skill would expect the invention to work.
- iii. Preserve and present evidence of others' experimental wins to reinforce conception and enablement arguments.

2 | On June 4, 2025, in ***Alnylam Pharms., Inc. v. Moderna, Inc.*, 138 F.4th 1326 (Fed. Cir. 2025)**, the Federal Circuit affirmed a district court's judgment that Moderna's COVID-19 vaccine did not infringe the claims for a cationic lipid in Alnylam's patents because Moderna's vaccine lacked a "branched alkyl" within the meaning of the asserted claims. The district court construed "branched alkyl" as requiring a tertiary or quaternary carbon at the alpha position because Alnylam's patents had the following definition:

Unless otherwise specified, the terms "branched alkyl", ... **refer to** an alkyl, alkenyl, or alkynyl group in which one carbon atom in the group (1) is bound to at least three other carbon atoms and (2) is not a ring atom of a cyclic group. . .

Alnylam argued that "branched alkyl" should be construed to include a secondary carbon at the alpha position because the "Unless otherwise specified" phrase in the definition allowed for broader scope and because the district court's claim construction excluded some embodiments. The Federal Circuit rejected Alnylam's arguments because Alnylam met the standard for an express definition of "branched alkyl" when Alnylam placed its definition under a "Definitions" heading, used quotation marks for "branched alkyl," and used "refer to" language in the definition instead of the non-limiting language used elsewhere. Alnylam could not persuade the court that portions of the asserted patents had a "clear and unmistakable" departure from the definition for "branched alkyl" in Alnylam's patents.

Patent Drafting Tips regarding definitions:

- i. First, consider whether or not you need to include an express definition in the first place, and be careful if you do!
- ii. When drafting the specification, ask:
 - Do I want to define this term or rely on the common meaning in the art?
 - Do the express definitions limit the desired claim scope in any way?
 - Is use of the claim term in the specification consistent with the definition?

3 | On June 30, 2025, in *Eye Therapies, LLC v. Slayback Pharma, LLC*, 141 F.4th 1264 (Fed. Cir. 2025), the Federal Circuit reversed the decision of the PTAB which found all claims of U.S. Patent No. 8,293,742 unpatentable as obvious. The relevant claims of the '742 patent recite compositions "consisting essentially of" the drug 'brimonidine' and methods for reducing eye redness "consisting essentially of" administering brimonidine. In the underlying *inter partes* review, the Board held that the phrase "consisting essentially of" did "not preclude the use of additional active agents...along with low-dose brimonidine." *Id.* at 1268. Therefore, they concluded, the claims at issue were obvious because the prior art taught or suggested a combination of brimonidine and other active agents.

The Federal Circuit disagreed, finding that although the phrase "consisting essentially of" has "long been understood to permit inclusion of components not listed in the claim, provided that they do not materially affect the basic and novel properties of the invention," the prosecution history of the '742 patent supported an atypical meaning of the phrase because Eye Therapeutics had amended the claims from the broader "comprising" to "consisting essentially of" during prosecution, and explicitly argued that their claimed methods did not require the use of any other active ingredients. *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1239 (Fed. Cir. 2003). A patentee may alter the typical meaning of the phrase "consisting essentially of," the court explained, by making the intended meaning clear in the specification or disclaiming an alternative meaning in the prosecution history. *Eye Therapies* at 1269 (quoting *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335 (Fed. Cir. 2009)). Ultimately, the Federal Circuit remanded the matter for further consideration using the correct claim construction.

Transitional Phrase Practice Tips:

- i. Be deliberate in choosing transitional phrases, being mindful of the possibility of narrowing the phrase at a later time.
- ii. Maintain a careful record of prosecution history and clearly articulate the purpose of a narrowing amendment, especially when narrowing a transitional phrase.

IPO OPPOSES "SKINNY LABELS, BIG SAVINGS ACT"

The Intellectual Property Owners Association (IPO) Board has adopted a resolution opposing **S. 43, the Skinny Labels, Big Savings Act**. S. 43 would amend the Patent Act to let generic drug makers market "skinny label" versions of branded drugs that omit patented uses while still promoting them as generics or therapeutic equivalents. The IPO opposes the bill, warning it would create an overly broad infringement safe harbor for skinny-label products and is unnecessary given existing statutory and case law protections that already balance generic access with innovators' rights. If passed, S. 43 could substantially narrow infringement liability for certain generics, impacting pharmaceutical patent enforcement strategies. Patent counsel should track the bill's progress and evaluate potential impacts on both litigation and regulatory planning.



NAVIGATING PATENT TERM ADJUSTMENT AND PATENT TERM EXTENSION: RECENT COURT RULINGS AND THEIR IMPACT ON OBVIOUSNESS-TYPE DOUBLE PATENTING

The National Law Review published an article written by St. Louis Patent Agent [Jordyn Grawe](#) and Principal [Leanne Rakers](#) that discusses updates patent holders should know for Obviousness-Type Double Patenting applications, specifically those extended through Patent Term Adjustment or Patent Term Extension. The article includes tips to better protect patent term.

To access the full article

[CLICK HERE](#)

LET'S MEET UP! CLS PRACTICE GROUP UPCOMING CONFERENCES:

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

- i. Nov 4-6, 2025: Leadership Council on Legal Diversity (LCLD) Fall Meeting, Chicago, IL – [Leanne Rakers](#) (2025 Fellow)
- ii. Nov 6-8, 2025: National Asian Pacific American Bar Association (NAPABA) Convention, Denver, CO – [Alex Chang](#), [Jeffrey Lin](#)
- iii. Oct 6-9, 2025: The Battery Show and Electric & Hybrid Vehicle Technology Expo, Detroit, MI – [Jewell Briggs](#)

CONTRIBUTORS:

[Caley Bennett](#), [Jordyn Grawe](#), [Leanne Rakers](#), [Michael Varco](#)

harnessip.com

Dallas 469.777.5400

Detroit 248.641.1600

St. Louis 314.726.7500

Washington, D.C. 703.668.8000