CHEMICAL & LIFE SCIENCE PATENTS

QUICK NEWS & PRACTICE TIPS

US CHEMICAL AND LIFE SCIENCE CASE LAW UPDATES

1 | WEIGHTY ISSUES AROUND SKINNY LABELS

In recent years, the Federal Circuit has issued several important decisions that affect how brand and generic drug companies think about patents and drug labels. For a long time, the main question was whether a generic drug directly infringed a patent. More recently, courts have looked closely at the wording of generic drug labels, finding infringement even when companies tried to carve out patented uses with so called "skinny labels."

The first big case was *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320 (Fed. Cir. 2021), reh'g denied, cert. denied, 142 S. Ct. 1369 (2022). Teva launched a generic of the drug 'Coreg' with a label that left out the patented use for congestive heart failure. The court said Teva induced infringement because the label and marketing still led doctors to prescribe the drug for that use. The same reasoning showed up again in *H. Lundbeck A/S v. Lupin Ltd.*, 87 F.4th 1361 (Fed. Cir. 2023), where Lupin's skinny label for 'Trintellix' was also found to induce infringement. In contrast, in *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, No. 2023-1169, 2024 WL 3152087 (Fed. Cir. June 25, 2024), Hikma's generic 'Vascepa' had a very carefully written skinny label, and the court ruled there was no induced infringement. That case showed that carve outs can work, but only if they are drafted with extreme precision.

In the most recent case, *Corcept Therapeutics, Inc. v. Teva Pharms. USA, Inc.*, No. 24-1346 (Fed. Cir. Oct. 2025), the Federal Circuit ruled that Teva's generic 'Korlym' would directly infringe Corcept's patent covering mifepristone dosing with CYP3A inhibitors. Because the product itself overlapped with the patent claims, FDA approval was blocked outright. That made the induced infringement issue irrelevant for now. This is the strongest outcome for a brand company, keeping generics off the market until the patent expires or is invalidated. The decision also leaves open several possible paths forward: Teva may seek Supreme Court review, insurers are pursuing antitrust claims against Corcept, and other generics could attempt entry with different label strategies. Each of these could shift the balance, but for now, direct infringement has created a brick wall for generic 'Korlym'.

Taken together, these cases show two big risks for generics: direct infringement, which can stop approval completely, and induced infringement, which can catch even skinny labels. For brand companies, the rulings highlight the importance of strong method of use patents. For generics, they show how careful label drafting and launch planning are critical.

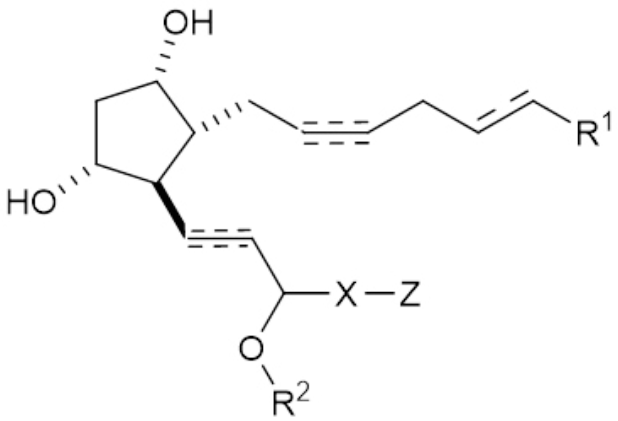
Pharmaceutical Practice Tips:

i. Write and maintain method of use patents with clear technical detail as courts are paying close attention.

ii. Be cautious with skinny labels. They may not avoid infringement if doctors still prescribe for patented uses.

2 | FEDERAL CIRCUIT REVERSES JURY VERDICT BECAUSE ASSERTED CLAIM HAD INADEQUATE WRITTEN DESCRIPTION

In *Duke University v. Sandoz, inc.,* No. 24-1078, (Fed. Cir. Nov. 18, 2025), the Federal Circuit reversed a jury verdict of patent infringement against Sandoz and held the jury should have found the asserted patent claim was invalid for inadequate written description. The asserted patent, U.S. Patent 9,579,270, related generally to treating hair loss using compositions containing prostaglandin F ("PGF") analogs, and claim 30 of the '270 patent recited a subgenus of PGF analogs having the structure below:



Sandoz stipulated that its generic drug product infringed claim 30 of the '270 Patent, but Sandoz challenged the validity of claim 30 for having inadequate written description. Sandoz argued that the specification of the '270 patent covered billions of compounds but lacked an example compound within the scope of claim 30, and also lacked a discussion of "commonalities of structure" for guiding a person of ordinary skill in the art toward the subgenus of PGF analogs (between 1,620 and 4,230 compounds) within the scope of claim 30 of the '270 patent. Allergan had rights in the '270 patent and argued that the '270 patent describes three features common to the PGF analog subgenus in claim 30: (1) the hairpin structure, (2) amides at the C1 position (i.e., R^1 in claim 30), and (3) an unsubstituted phenyl ring at the omega position (i.e., Z in claim 30).

The court, in deciding claim 30 of the '270 patent had inadequate written description, explained that written description for a claimed genus of chemical compounds requires the description in the patent of (1) outer limits of the genus and (2) a representative number of species in the genus or structural features common to the genus with enough precision for a relevant artisan to recognize the members of the genus. Because the '270 patent did not describe an example chemical compound covered by claim 30, the court explained the '270 patent needed to satisfy the "common structural features test." In the court's analysis, the '270 patent did not satisfy the "common structural features test" for written description because the "hairpin structure" was generic for all PGF compounds, not just the subgenus in claim 30, because the '270 patent did not provide enough guidance for choosing R^1 and Z in claim 30 among the different categories and subcategories for R^1 and Z in the '270 patent specification, and because preferred embodiments in the '270 patent did not have the same R^1 group required in claim 30 of the '270 patent.

Written Description Practice Tips:

i. To satisfy the written description requirement for a claimed genus of chemical compounds, a patent must describe the outer limits of the claimed genus and describe (1) a representative number of example compounds (i.e., species) in the genus and/or (2) describe common structural features that would lead a person of ordinary skill in the art to the claimed genus from the disclosure in the patent.

ii. Describing preferred embodiments in the specification may weaken the written description support for a claimed compound (or a claimed genus of compounds) if the claim lacks features in the preferred embodiment.

USPTO UPDATES

1 | NEW USPTO DIRECTOR

John Squires was sworn in as the new Director at the USPTO. The USPTO under Director John Squires is signaling a shift toward a more flexible approach to subject-matter eligibility, including **new guidance** that encourages applicants to use Subject Matter Eligibility Declarations to help address §101 rejections. This could be especially helpful for chemical and life science innovations, where diagnostics, natural products, and other biologically-based technologies have faced extra uncertainty in recent years.

2 | USPTO ANNOUNCES LAUNCH OF AUTOMATED SEARCH PILOT PROGRAM – PETITION FOR AUTOMATED SEARCH RESULTS NOTICE (ASRN) BEFORE HUMAN EXAMINER INTERVIEW

On October 20, 2025, the USPTO began accepting petitions to participate in a new **Automated Search Pilot Program** aimed at assessing the impacts of pre-examination search reports on application prosecution, evaluating the scalability of generating search reports, and collecting data to inform the USPTO on next steps once the program is concluded. This program provides applicants filing original, noncontinuing, nonprovisional utility applications with the opportunity to receive an automatic prior art search prior to examination. Searches within the program are conducted using an internal AI tool configured to utilize the application's Cooperative Patent Classification (CPC) codes, specification, claims, and abstract to procure relevant prior art. Once an automated search is completed for a given application, the applicant will be provided an Automated Search Results Notice (ASRN), which will list up to ten documents returned by the AI tool listed in descending order of relevance. The ASRN will additionally include a search string which may be entered into the Patent Public Search tool to easily retrieve copies of the provided art. This pilot program will continue until April 20, 2026, or until each Technology Center has docketed at least 200 applications, with an Office goal of accepting 1,600 applications. Applicants who are interested in applying for this program must file a petition under 37 CFR 1.182, and pay the accompanying fee of $450 ($180 for small entity).

3 | USPTO PROPOSES LIMITS ON REPEAT IPR CHALLENGES

Recently, the USPTO **proposed new PTAB rules** aimed at limiting IPR proceedings to "patent claims that have not previously been challenged in litigation or where prior litigation was resolved at an early stage." The proposal would amend 37 CFR § 42.108 and directly affect whether an IPR can be instituted. Here is a high-level summary of the proposed rule changes. First, an IPR could not be instituted unless the petitioner stipulates that it will not challenge the patent under 35 U.S.C. §§ 102 or 103 in any other proceeding. Second, an IPR could not be instituted if the challenged claims had already been upheld in a prior challenge before a district court, the ITC, the USPTO (including prior IPR, PGR, or non-patent-owner Ex Parte Reexamination), or on appeal to the Federal Circuit. Third, an IPR could not be instituted if it is more likely than not that the challenged claims will go to trial in district court, receive an initial determination at the ITC, or be decided by the PTAB before the petition's final written decision is due. Finally, the proposal includes an "extraordinary circumstances" provision allowing the Director to institute an IPR even when prior unsuccessful challenges would otherwise bar it.

IPR Practice Tips:

i. IPRs in pharma should be treated as a one-shot opportunity, so companies need to invest early in thorough prior art searches, including scientific literature, regulatory filings, and clinical trial disclosures.

ii. Because IPRs can be blocked if district court or ITC cases are likely to finish first, it's important to align IPR filings with Hatch-Waxman or BPCIA litigation timelines to ensure the PTAB can hear the case.

4 | USPTO LAUNCHES STREAMLINED CLAIM SET PILOT PROGRAM

The USPTO announced the **Streamlined Claim Set Pilot Program**, which is a one-year initiative running from October 27, 2025 to October 27, 2026, or until each Technology Center has accepted 200 applications. The program aims to expedite examination of eligible utility applications, with particular relevance for chemical and life science inventions where early clarity on patentability can be critical for research, regulatory approval, or commercialization. Eligible applications must be original, noncontinuing filings under 35 U.S.C. 111(a) submitted before October 27, 2025, and include no more than one independent claim, ten total claims, and no multiple dependent claims. Applicants must file Form PTO/SB/472 electronically with the required fee of $150 ($60 for a small entity), and the specification, claims, and abstract must be filed in DOCX format. Inventors are limited to three applications under the program. Accepted applications receive special status until the first Office action, and any amendments that fail to meet the claim requirements will be refused.

5 | USPTO CLARIFIES INTERVIEW POLICY

On December 3, 2025, the USPTO held a webinar to clarify recent changes to examiner interview procedures. Examiners now automatically receive non-production credit only for the first interview per new application or RCE; additional credit requires supervisor approval. Importantly, applicants remain entitled to interviews for each office action if they "move prosecution forward," and second interviews should still be granted when they help clarify or resolve issues. If an examiner denies a legitimate request, applicants are encouraged to escalate to the supervisor or ombuds office.

For more information on USPTO Interview Practice **CLICK HERE**

Interview Practice Tips:

i. Use the USPTO's Automated Interview Request form (AIR) to request interviews with a brief agenda.

ii. Focus on 1-2 key issues to maximize examiner preparation.

iii. Consider TEAMS for video interviews, which can foster more collaborative discussions.

PERA 2025: REDEFINING PATENT ELIGIBILITY IN LIFE SCIENCE

The Patent Eligibility Restoration Act (PERA) has returned in 2025 as a major development for innovators in the chemical and life science sectors. In **our earlier article on PERA 2023**, we explained how diagnostic method claims might once again be protectable; PERA 2025 now builds on that framework with clearer exclusions and a more defined impact on diagnostics.

Diagnostic method claims have faced steep hurdles after Supreme Court decisions (*e.g., Mayo Collaborative Services v. Prometheus Laboratories, Inc., Ass'n for Molecular Pathology v. Myriad Genetics, Inc., Alice Corp. Pty. Ltd. v. CLS Bank Intern*) narrowed patent eligibility by excluding claims tied to natural laws and phenomena. Many diagnostic inventions were deemed ineligible, and practitioners responded by drafting method-of-treatment claims, as seen in *Vanda* (2018), to preserve protection.

PERA 2025, introduced in both the Senate and House, keeps the foundation of PERA 2023 but refines the exclusion language. It clarifies that diagnostic methods involving human intervention (e.g., sample collection, measurement, and analysis) are not excluded, even if they rely on natural correlations. This broader scope means pure diagnostic claims, without treatment steps, can be patent eligible so long as they require human activity. For chemical and life science companies, this strengthens protection for advanced diagnostics, including sequencing technologies, biomarker quantification, and AI-driven analysis, while reducing reliance on workaround formats and providing greater certainty in prosecution and enforcement.

The bill also addresses gene and natural material claims. PERA 2025 still excludes unmodified human genes as they exist in the body, but clarifies that a gene is not "unmodified" if it is purified, enriched, or otherwise altered by human activity, or employed in a useful invention. While isolation of human genes alone does not appear sufficient, PERA 2025 specifically considers isolation of a "natural material" to be enough to confer eligibility. This distinction could have significant implications for chemical compositions, biologics, and other life science products derived from natural sources.

Beyond diagnostics and biotech, PERA 2025 would eliminate all judicially created exceptions to patent eligibility. While this sweeping effect will resonate across all sectors, PERA 2025 would revive diagnostic eligibility and drive new growth in life science.

Claim Drafting Practice Tips:

i. Include clear human activity in diagnostic claims, such as sample collection or analysis, to strengthen eligibility.

ii. When working with natural products, describe how they are isolated, purified, enriched, or otherwise altered by human activity to ensure they qualify as modified and patentable.

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