CHEMICAL & LIFE SCIENCE PATENTS

QUICK NEWS & PRACTICE TIPS

HARNESS IP

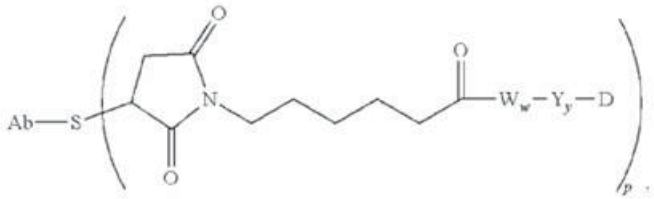
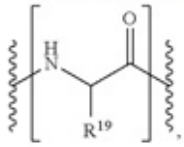
US CHEMICAL AND LIFE SCIENCE CASE LAW UPDATES

1 | U.S. SUPREME COURT TO HEAR SKINNY LABELING PATENT CASE

The U.S. Supreme Court has granted certiorari in *Hikma Pharmaceuticals USA Inc. v. Amarin Pharma, Inc.*, marking the Court's first patent case since *Amgen v. Sanofi* in 2023 and placing "skinny labeling" back in the spotlight. The case will address when a generic manufacturer may face induced-infringement liability even after carving out a patented indication from its FDA-approved label, and how marketing statements or related conduct may factor into that analysis. Oral argument is set for April 29, 2026, with a decision expected by the end of the Term in June. The Court is also weighing several additional IP-related petitions involving trademark standing and strength, as well as PTAB standards and claim construction issues, making this a notable term for IP watchers.

2 | FEDERAL CIRCUIT MAINTAINS STRICTER STANCE ON WRITTEN DESCRIPTION AND ENABLEMENT SUPPORT FOR CHEMICAL MOLECULES

In *Seagen Inc. v. Daiichi Sankyo Co., Ltd.* (Fed. Cir. 2025), the Federal Circuit reversed a judgment of willful patent infringement against Daichi Sankyo Company, Ltd and some AstraZeneca subsidiaries, holding that the asserted patent claim was invalid for lack of written description and enablement. The case related to an antibody-drug conjugate ("ADC") with 3 parts – an antibody, a cytotoxic drug, and a linker – and whether an earlier priority application provided written description and enablement support for the asserted claims. Claim 1 of the asserted patent, US 10,808,039, was directed to an ADC having the formula below.

'039 Patent – Claim 1 Formula	'039 Patent – W variables
	*each —W_w— unit is a tetrapeptide; wherein each —W— unit is independently an Amino Acid unit having the formula denoted below in the square bracket:*  *wherein R^{19} is hydrogen or benzyl,*

In claim 1 of the '039 patent, Ab is the antibody, D is the drug moiety, and the "Ww" and "Y" correspond to the tetrapeptide and spacer units of the linker protein. The court construed "W_w" as requiring a Gly/Phe-only tetrapeptide (i.e., four-amino-acid long unit), which encompassed 81 different species (i.e., 3^4) because glycine (Gly) has one spatial arrangement and phenylalanine (Phe) has two spatial arrangements.

The '039 patent claimed priority to a 2004 application describing the same general formula as claim 1 of the '039 patent, except the 2004 application disclosed a GFLG linker (i.e., leucine (Leu) in addition to Gly and Phe) and the 2004 application was limited to dolastatin/auristatin derivatives ("D/A-type drugs").

The Federal Circuit held the 2004 application did not have written description support for claim 1 of the '039 patent. The court reasoned that the 2004 application had a broad disclosure for over 47 million potential tetrapeptide combinations, including the 81 Gly/Phe-only tetrapeptide species covered by claim 1 of the '039 patent, but the 2004 application did not provide a "reasonably specific supporting disclosure" to show the inventor possessed the compound having the Gly/Phe-only tetrapeptide species. The court also determined that inventor testimony supported a finding for lack of written description support. For the enablement issue, the Federal Circuit held the 2004 application did not enable the asserted claims of the '039 patent because the claimed "drug moiety" encompassed any drug moiety with the recited cleaving function. The court reasoned that the skilled artisan would have to engage in undue experimentation because ADC science was unpredictable and the specification failed to disclose a "quality" common to the claimed "drug moiety" with the cleaving function.

Written Description and Enablement Takeaways:

i. To satisfy the written description requirement for a claimed subgenus in an application disclosing a broad genus with countless options, a patent specification must show adequate blaze marks that would lead a skilled artisan to the claimed subgenus or any species within it. Build subgenus claims and description that closely resemble the compounds of interest.

ii. To satisfy the enablement requirement for a claimed subgenus with functional characteristics in an application disclosing a broad genus for an unpredictable art, the patent specification should show a quality common to the claimed subgenus. Add biological assays showing a common quality to the preferred subgenus if possible. Be careful when claiming purely functionally. Be prepared to add structure that has the common function.

3 | FEDERAL CIRCUIT FINDS DISTRICT COURT APPLIED OVERLY NARROW §101 ANALYSIS TO RECOMBINANT COMPOSITION

In *REGENXBIO Inc. v. Sarepta Therapeutics, Inc.,* (Fed. Cir. 2026), the Federal Circuity provides a useful reminder for practitioners drafting and defending biotechnology composition claims. The panel reversed the District Court's §101 summary-judgment ruling after concluding that the lower court improperly dissected the claim into its naturally occurring adeno-associated virus (AAV) components rather than evaluating the recombinant host cell and nucleic acid construct as an integrated, human-engineered composition. The record showed that the claimed molecule required splicing sequences from at least two different species (an arrangement that "does not and cannot exist in nature") and that this chimeric construct enabled meaningful therapeutic utility in gene-therapy applications. By focusing only on whether each individual component was "markedly different" from its natural counterpart, the District Court overlooked the structural and functional differences introduced by human intervention, which the Federal Circuit emphasized must anchor the eligibility analysis.

Patent Eligible Subject Matter Tips:

i. Highlight non-natural structural features and the specific human-directed steps required to generate the recombinant construct.

ii. Emphasize functional consequences and therapeutic utility that arise only from the engineered composition.

iii. Draft claims to capture the integrated recombinant entity, avoiding language that could be read as a mere collection of natural parts.

USPTO UPDATES

1 | USPTO IS AMENDING THE PATENT RULES TO REQUIRE FOREIGN PATENT APPLICANTS TO BE REPRESENTED BY USPTO-REGISTERED PRACTITIONERS

On March 20, 2026, the USPTO published a Final Rule that will amend the Rules of Practice in patent cases to require foreign patent applicants (i.e., patent applicants and patent owners whose domicile is not located within the US) to be represented by a USPTO-registered patent agent or attorney. This rule will become effective July 18, 2026, to permit foreign-domiciled applicants to obtain representation.

For the full text of the notice CLICK HERE

2 | USPTO EXTENDS PATENT PROSECUTION HIGHWAY PILOT PROGRAM

The USPTO has extended its IP5 Patent Prosecution Highway (PPH) pilot program through **January 5, 2029**, allowing applicants to continue leveraging positive claim rulings from partner offices to request accelerated examination in the United States. This extension maintains alignment with the other IP5 offices (the EPO, JPO, KIPO, and CNIPA).Additional details are available on the USPTO's PPH webpage.

For the notice on the USPTO's website CLICK HERE

3 | USPTO HAS MOVED THE AUTOMATED INTERVIEW REQUEST (AIR) TOOL TO PATENT CENTER

The USPTO has moved the online tool for requesting examiner interviews from the open web to the USPTO's Patent Center. After this change, it now is necessary to log in to the USPTO's Patent Center to request an examiner interview.

For more information on the USPTO announcement CLICK HERE

4 | USPTO NOW REQUIRES PATENT APPLICANTS TO OPT-IN TO RECEIVE COURTESY CEREMONIAL COPY OF PATENT EGRANTS

The USPTO will no longer send a complimentary ceremonial copy unless the ceremonial copy box on the PTOL-85 Part B is checked at the time of paying the issue fee. If an applicant desires the ceremonial copy, then the PTOL-85 Part B box must be checked at the time of paying the issue fee. Until June 9, 2026, an applicant may email eGrants@uspto.gov to request a copy if the PTOL-85 Part B box was not checked when the issue fee was paid.

For more information on the USPTO announcement CLICK HERE

HARNESS IP UPDATES

1 | A PRACTICAL GUIDE TO PATENT PROSECUTION

Harness IP is excited to announce a one-week patent prosecution training program, *A Practical Guide to Patent Prosecution*, taking place June 1–5, 2026, at our Washington, DC Metro office. The program will be led by Harness IP's Special Counsel, John White, and is designed for in-house counsel, technical specialists and patent engineers, IP coordinators, and patent attorneys/agents who practice outside the U.S. who would like to learn more about U.S. practice. The cost for attending the course is $1500 USD, but a discounted rate of $1200 USD is available for those who register by May 1, 2026.

For more details about the course and a registration link **CLICK HERE**

2 | GREEN PATENT PROGRAMS BLOG SERIES

Harness IP's Environmental Team has started a blog series on "Green Patent Programs Worldwide" and the first two articles in that series may be accessed through the following links:

a. **"Green Patent Programs Worldwide – Prologue"** by Michael Gamble
b. **"Green Patent Programs Worldwide – Expedited Examination Options in China"** by Michael Gamble

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