OBLON

IP UPDATES

JANUARY 29, 2026

USPTO UPDATE

USPTO Launches SEP Working Group and SPARK Program to Address Standards-Related Issues

BY SAMEER GOKHALE

The USPTO has recently launched a working group and a program to address issues related to standards based technology.

On December 29th, the USPTO **announced** a Standard-Essential Patent (SEP) Working Group. The SEP Working Group seeks to ensure that all patent holders — regardless of their size or sophistication — are treated fairly and that their rights receive strong and predictable enforcement wherever standards incorporate patented technologies.

The group will be co-chaired by USPTO Deputy General Counsel for Intellectual Property Law and Solicitor Nicholas Matich, and USPTO Senior Legal Advisor Austin Mayron. In recent months, the USPTO has filed express court **statements** and tribunal **comments** related to the issue of patent enforcement. These pronouncements underscore the USPTO's commitment to advance consistent and correct application and enforcement of the intellectual property laws, including the Patent Act, to safeguard patents, fuel economic growth, and spur innovation to advance American freedoms.

Specifically, the SEP Working Group will focus on three core objectives:

1. Restoring Robust Remedies for Patent Holders – Clarifying that valid patent rights, including SEPs, deserve strong and predictable enforcement;
2. Facilitating Meaningful Participation in Standards Development – Exploring mechanisms to incentivize and enable broader participation in standard developing organizations (SDOs), particularly by small and medium-sized U.S. enterprises; and

3. Engaging Stakeholders and Promoting Transparency Across the Innovation Ecosystem – Creating channels for dialogue with patent holders, implementers, SDOs, and other stakeholders to understand the challenges they face and identify solutions, and supporting these groups by developing resources to increase predictability in SEP licensing negotiations and standards development.

On January 12th, the USPTO further **announced** the Standards Participation and Representation Kudos (SPARK) Pilot Program as the first initiative of the USPTO's SEP Working Group. The program was created to address concerns that resource constraints often prevent smaller U.S. entities from participating meaningfully in standards development organizations (SDOs). This program will offer a limited number of acceleration certificates to eligible U.S. entities that make technical contributions to or otherwise meaningfully participate in SDO activities.

John A. Squires, Director of the USPTO, stated "The SPARK program recognizes that small and medium-sized businesses, universities, and non-profits bring critical expertise and innovative thinking to standards development, but often lack the resources of larger enterprises to sustain participation. By offering meaningful incentives here at the USPTO, we're continuing to invest in broader and more robust U.S. representation in the very forums where tomorrow's technologies are taking shape today."

CAFC/SCOTUS UPDATE

Supreme Court Grants Certiorari in the "Skinny Label" Case of *Hikma v. Amarin*

BY SAMEER GOKHALE

On January 16, 2026, the Supreme Court of the United States granted certiorari in *Hikma Pharmaceuticals USA Inc. v. Amarin Pharma, Inc.* (No. 24-889) to address when induced-infringement liability can attach to a generic drug launched under a "skinny label."

As was noted in our June IP Update, Hikma was seeking Supreme Court review of the Federal Circuit's reversal of the district court's grant of a motion to dismiss Amarin's infringement claim complaint for failure to state a claim.

The drug at issue is Vascepa® which is approved for two indications: (1) treatment of severe hypertriglyceridemia (the "SH indication"); and (2) cardiovascular risk reduction (the "CV indication"). Only the CV indication is protected by patents. Hikma filed its ANDA application before CV indication was approved and its label matched the Vascepa® for the SH indication. After Vascepa® was also approved for the CV indication, Hikma submitted Section viii statements for the listed patents. Hikma did not add the CV indication to its label keeping only the SH indication.

The **Petition for Writ of Certiorari** included the following description of the questions presented.

> Congress passed the Hatch-Waxman Act '[t]o facilitate the approval of generic drugs as soon as patents allow.' *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012). Recognizing that many drugs are approved for both patented and unpatented uses, Congress sought to ensure 'that one patented use will not foreclose marketing a generic drug for other unpatented ones.' *Id.* at 415. The statutory mechanism is a 'skinny label': Generic drugmakers 'carve out' patented uses from their labels, leaving only instructions to use generic drugs for their unpatented uses. *See* 21 U.S.C. § 355(j)(2)(A)(viii).
>
> Congress designed this carve-out mechanism to encourage competition and to protect generic drugmakers from allegations that marketing a generic drug for an unpatented use 'actively induces infringement.' 35 U.S.C. § 271(b). After all, active inducement requires 'clear expression or other affirmative steps taken to foster infringement'—there is no 'liability when a defendant merely sells a commercial product suitable for some lawful use.' *Metro-Goldwyn-Mayer Studios Inc. v. Grokster*, Ltd., 545 U.S. 913, 936–937 & n.11 (2005).
>
> The questions presented are:
>
> 1. When a generic drug label fully carves out a patented use, are allegations that the generic drugmaker calls its product a 'generic version' and cites public information about the branded drug (e.g., sales) enough to plead induced infringement of the patented use?
>
> 2. Does a complaint state a claim for induced infringement of a patented method if it does not allege any instruction or other statement by the defendant that encourages, or even mentions, the patented use?

We will be following this case very closely and we will continue to provide updates on the proceedings.

AI UPDATE

USPTO Issues New Guidance and Updates the MPEP Following *Ex Parte Desjardins*

BY SAMEER GOKHALE

On December 5th, the USPTO issued new guidance on subject matter eligibility declarations and also updated subject matter eligibility guidance in the MPEP. Each action follows the *Ex Parte Desjardins* Appeals Review Panel decision. This decision, now designated as precedential, held that improvements to the functioning of machine learning models can constitute practical applications for determining subject matter eligibility. The decision emphasized that proper consideration should be given to technological improvements reflected in the claims and specification.

On the new guidance, the USPTO issued two new memoranda authored by USPTO Director John A. Squires. **The first memorandum**, directed to examiners, explains that Subject Matter Eligibility Declarations (SMEDs) are a voluntary option under existing Rule 132 practice. Applicants may submit a declaration to provide factual evidence relevant to the eligibility inquiry, such as evidence of technological improvement, the state of the art at the time of filing, or information demonstrating how a judicial exception is integrated into a practical application. When a SMED is properly submitted, examiners must consider it and evaluate it using the preponderance-of-the-evidence standard. The memorandum includes several examples illustrating how to consider such evidence.

The second memorandum, directed to applicants and practitioners, outlines best practices for preparing and submitting SMEDs. It explains that when testimony is being submitted, a separate declaration focused solely on subject matter eligibility should be utilized instead of combining testimony on eligibility and other statutory requirements. It further explains that SMEDs should provide objective evidence tied to the claimed invention without attempting to supplement the original disclosure.

The updated guidance in the two new memoranda is effective immediately and additional training materials will follow. Find the USPTO announcement **here**.

The USPTO further provided advanced notice of an update to the Manual of Patent Examining Procedure (MPEP) to reflect the decision in *Ex Parte Desjardins*. The advanced notice was provided in a **memorandum** authored by Charles Kim, Deputy Commissioner for Patents. The update explains how examiners should evaluate claims that recite improvements to technology, computer functionality, data structures, learning models, and other applied fields when conducting an eligibility analysis under 35 U.S.C. § 101. The updates to the MPEP reaffirm that examiners must consider the claimed invention as a whole, including any described technological advance, when determining whether the claim integrates a judicial exception into a practical application.

The MPEP revisions include the following:

- Updates to §2106 and associated sections to reflect controlling case law on technological improvements.
- A further explanation of Step 2A, Prong Two and the evaluation of asserted improvements to technology or technical fields.
- New examples based on the decision in *Ex Parte Desjardins* addressing applied technologies, computer functionality, structured data processing, and learning systems.
- A clarification on the examiner's responsibilities when assessing whether a claim improves technology, and how such improvements may satisfy the eligibility standards.

These changes to the MPEP are effective upon issuance of the advanced notice memorandum and supersede the latest publication of the MPEP. Find the USPTO announcement **here**.

LIFE SCIENCES NEWS

Written Description-Enablement and Antibody-Drug Conjugates (ADCs)

BY RICHARD KELLY

The Federal Circuit's decision in *Daiichi Sankyo Co. v. Seagen Inc.,* (Fed. Cir. Dec 02, 2025, appeal 2023-2424, represents a decisive rejection of Seagen's attempt to assert broad

antibody-drug conjugate (ADC) claims that were not adequately supported by their original 2004 patent filing. At trial, a Texas jury had sided with Seagen, finding that Daiichi's cancer drug Enhertu infringed the asserted claims of Seagen's U.S. Patent 10,808,039 ('039), and awarding more than $41 million in damages. But on appeal, the Federal Circuit concluded that the district court should have granted judgment as a matter of law because the asserted claims were invalid for lack of written description and lack of enablement.

The heart of the dispute centered on whether Seagen's 2019 patent could claim priority back to a 2004 application. The 2019 claims required a very specific type of linker peptide — a tetrapeptide composed only of glycine and phenylalanine in any of 81 possible configurations. The 2004 application, however, disclosed an enormous combinatorial universe of possible peptides: 39 amino acids, peptide lengths ranging from 2 to 12 residues, and more than 47 million possible tetrapeptides as agreed to by both Seagen's and Daiichi's experts. Crucially, none of those disclosures singled out, exemplified, or even hinted at a tetrapeptide made exclusively of glycine and phenylalanine.

The Federal Circuit emphasized that written description requires more than a broad genus that merely *encompasses* the later-claimed subgenus. The court drew heavily on the classic *In re Ruschig,* 379 F.2d 990,993,996 (CCPA 1967) "blaze marks" doctrine, explaining that a skilled artisan must be able to identify the claimed invention within the earlier disclosure without making creative leaps. Seagen's own expert conceded that one would need to make a "straightforward leap" from the disclosed GFLG tetrapeptide to an all-Gly/Phe tetrapeptide — an admission the court found fatal. If a leap is required, the disclosure is not there.

The inventors' testimony further undermined Seagen's case. Multiple named inventors admitted that they had not conceived of Gly/Phe-only tetrapeptides in 2004 and first encountered such structures only after Daiichi publicly disclosed Enhertu in 2015. The court invoked the long-standing principle that "one cannot describe what one has not conceived," citing *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993), concluding that the inventors' own statements confirmed the absence of possession at the priority date. Further, Seagen's expert testified that because the 2004 application did not support the claimed subgenus, the '039 patent could not claim the 2004 priority date. That meant Enhertu's 2015 public disclosure — found to meet every claim limitation — became prior art that anticipated the claims. The court therefore held the claims invalid on written-description grounds alone.

The panel also found the claims invalid for lack of enablement. The '039 patent purported to cover a broad range of ADCs with a functional requirement — intracellular cleavage — but offered little guidance on how to make and use the full scope of the claimed genus without undue experimentation. In the court's view, the patent left skilled artisans to engage in extensive trial-and-error across a vast landscape of possible ADC configurations, falling short of the enablement standard reaffirmed by the Supreme Court in *Amgen v. Sanofi,* 98 U.S. 594 (2023).

Because the claims were invalid, the Federal Circuit did not reach Daiichi's challenges to damages or infringement. The court also dismissed as moot Seagen's appeal from a parallel PTAB post-grant review, which had similarly found the claims unpatentable. The combined effect of these rulings leaves Seagen without enforceable rights over the Gly/Phe-only tetrapeptide linker technology and clears the way for Daiichi's Enhertu to remain on the market without risk of infringement liability.

In sum, the decision reinforces the Federal Circuit's increasingly strict approach to written description and enablement in biotechnology. Broad genus claims — especially those drafted after a competitor's successful product becomes public — must be anchored in concrete, specific disclosures in the original application. Seagen's failure to provide such support in 2004 proved fatal, and the court's opinion stands as a cautionary reminder that sweeping chemical or biological claims cannot be retrofitted onto sparse early filings.

NEWSLETTER EDITOR: **SAMEER GOKHALE**

Oblon | 1940 Duke Street | Alexandria, VA 22314 US

Unsubscribe | Update Profile | Constant Contact Data Notice

Constant Contact

Try email marketing for free today!