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ACC SFBA LIFE SCIENCES CONFERENCE

IP Strategies for Life Sciences and Med Tech in 2026: Court Decisions and Trends to Watch and Why They Matter

MARCH 12, 2026

ACC Association of Corporate Counsel
SAN FRANCISCO BAY AREA

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Hikma Pharmaceuticals v. Amarin Pharma

104 F.4th 1370 (Fed. Cir. Feb. 20, 2024)

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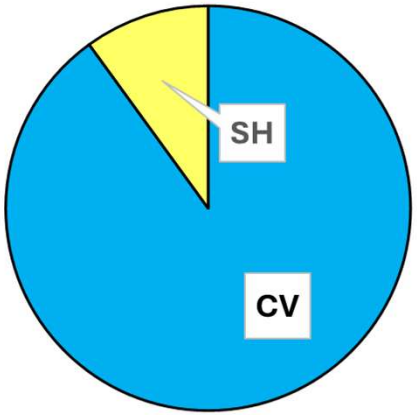
– Two FDA-approved uses for VASCEPA®

1. **Off-patent:** severe hypertriglyceridemia (SH)
2. **Patented:** reducing cardiovascular risk (CV) in patients with elevated triglyceride levels

Vascepa® (icosapent ethyl)

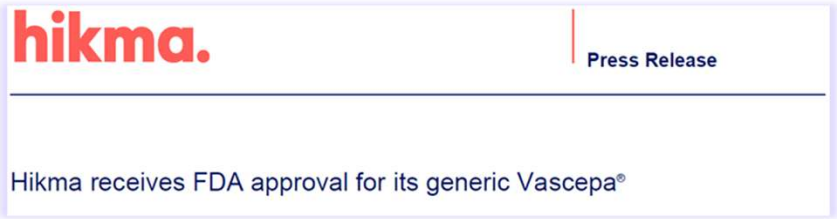


– Hikma's skinny-label generic approved only for treating SH

– Most prescriptions are for the patented CV indication

Amarin's complaint for induced infringement

– Amarin alleged that Hikma's carved-out label and marketing materials induced infringement of claims to reducing CV risk


hikma.

Press Release

Hikma receives FDA approval for its generic Vascepa®


Generic Name: Icosapent Ethyl Capsules

Therapeutic Category: Hypertriglyceridemia

Rating: AB

Storage + Safety: Store at 20° to 25°C (68° to 77°F). See USP Controlled Room Temperature.

– **District court** (Andrews, D. Del.) *dismissed*

– **Federal Circuit** (Moore, Lourie, Albright by designation) *reversed*

- No dispute over Hikma's intent or actual direct infringement by doctors
- Amarin's theory was plausible and turned on factual questions

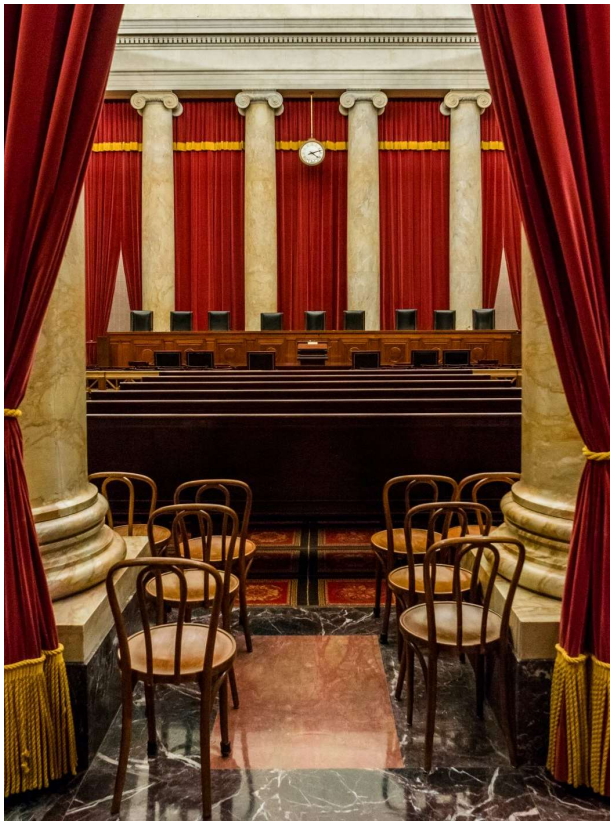
The Supreme Court granted certiorari

No. 24-889 (U.S.)

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?

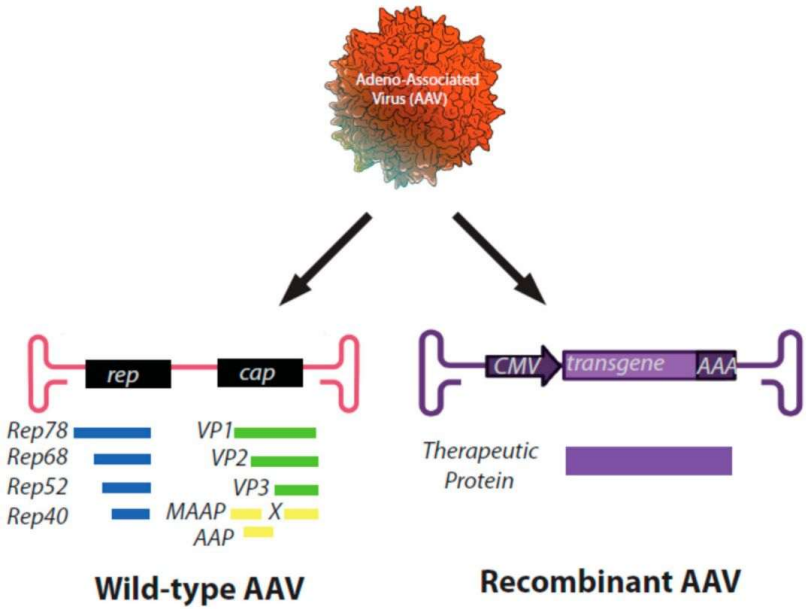
2. Does a complaint state a claim for induced infringement of a patented method if it does not allege any instruction or other statement by the defendant that encourages, or even mentions, the patented use?

- Cert. granted on January 16
- Briefing in process
- Argument scheduled for April 29



REGENXBIO v. Sarepta Therapeutics

--- F.4th --- (Fed. Cir. Feb. 20, 2026)

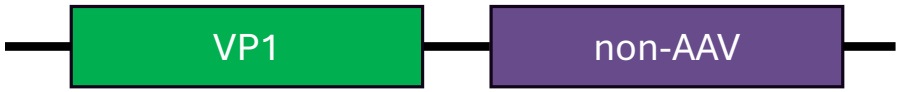


U.S. Patent No. 10,526,617

1. A **cultured host cell** containing a **recombinant** nucleic acid molecule

encoding an AAV vp1 capsid protein …

wherein the recombinant nucleic acid molecule **further comprises a heterologous non-AAV sequence.**



REGENXBIO v. Sarepta Therapeutics

--- F.4th --- (Fed. Cir. Feb. 20, 2026)

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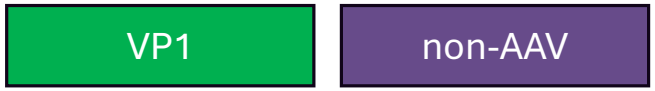
D. Del. held the claims invalid under § 101

Analysis

– Claims recite natural products/sequences:



– Neither was changed (unlike *Myriad*)

– "Mixing them together" in a cell mirrored *Funk Bros.*

REGENXBIO v. Sarepta Therapeutics

--- F.4th --- (Fed. Cir. Feb. 20, 2026)

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The Federal Circuit (Stoll, Dyk, Hughes) *reversed*

– "Markedly different" characteristics

  - Recombinant DNA did not simply mix existing natural products
  - "Nonnaturally occurring manufacture or composition"

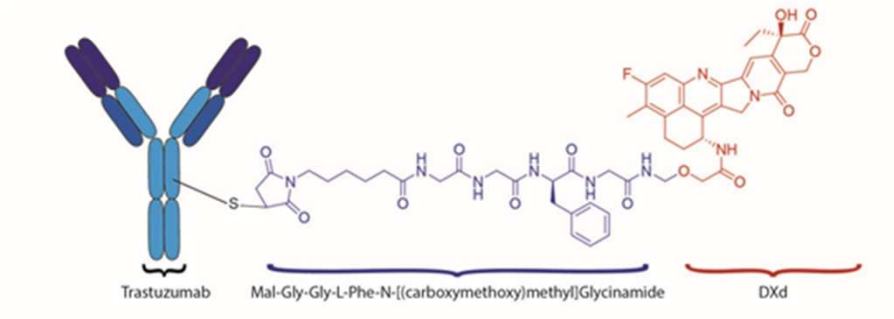
– District court took "too narrow a view" by focusing on individual limitations rather than considering the composition as a whole

Close scrutiny under Section 112 continues

Seagen v. Daiichi Sankyo

160 F.4th 1322 (Fed. Cir. 2025)

ENHERTU®
trastuzumab deruxtecan

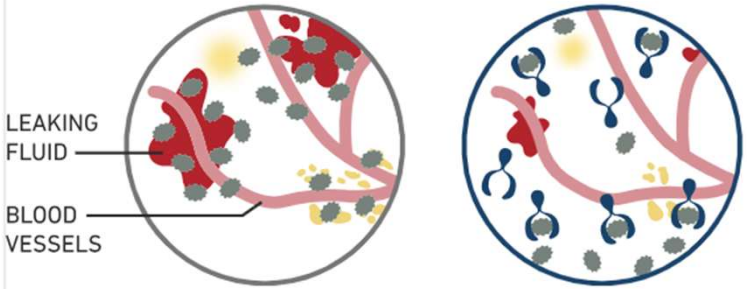


- Tetrapeptide linker, 47M possibilities
- Subgenus of 81 members claimed
- $41M+ verdict ***reversed*** (W.D. & enablement)

Regeneron v. Mylan

127 F.4th 896 (Fed. Cir. 2025)

EYLEA®
(aflibercept) Injection 2 mg



- Preliminary injunction challenged on appeal
- Disclosure of glycosylation, stability limits?
- Injunction ***affirmed***; no substantial question of invalidity for lack of W.D.

Recentive Analytics, Inc. v. Fox Corporation (Fed. Cir. 2025)

AI/ML Claims Found Patent Ineligible Under 35 U.S.C. § 101

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Alice Step One: "[T]he step-one inquiry determines whether the claims focus on the specific asserted improvement in computer capabilities . . . or, instead, on a process that qualifies as an abstract idea for which computers are invoked merely as a tool."

- No technical improvement:
  - Use of generic ML technology
  - No delineation of steps through which the ML achieves an improvement
- No specificity of implementation:
  - ML is simply "used in a new environment"

Alice Step Two: Nothing more in the claims other than the abstract idea of generating event schedules and network maps using ML

What the USPTO Requires for AI/ML Eligibility Today

Director Squires' Permissive AI Patent Eligibility Standard

- Rejects overbroad "abstract idea" characterizations
- AI/ML claims are less likely to be treated as "mental processes"
- Examiners must give meaningful weight to technical improvements and treat "practical applications" as sufficient
- Requires distinction between claims that recite a judicial exception versus those that merely involve one


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