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U.S. Supreme Court Weighs Inducement Liability Beyond FDA Carve-Out Labels

The U.S. Supreme Court's April 29 argument in *Hikma Pharmaceuticals USA Inc. v. Amarin Pharma, Inc.*, the skinny-label inducement case now at the center of Hatch-Waxman strategy, could redefine the legal boundary between protecting pharmaceutical patents and allowing lower-cost generic drugs onto the market.

The issue is not whether a generic may use a section viii carve-out. It may. The harder question is whether FDA-compliant carve-out labeling can still support inducement when paired with public statements, sales materials, website language, or investor communications that allegedly steer physicians back to the patented use.w

The argument appeared to test two paths: a narrow pleading decision under *Twombly* and *Iqbal*, or a broader rule that would give generic companies more protection when they follow FDA's carve-out process. Either way, the practical lesson is immediate. A skinny label is not a complete risk-control strategy. Generics should assume that launch communications, formulary materials, sales references, product descriptions, and therapeutic-category statements may be read together. Brands, meanwhile, should focus complaints on specific statements, specific audiences, and a plausible link to the patented method – not merely market substitution.

In the District of New Jersey, *Rayner Surgical Inc. v. Somerset Therapeutics, LLC* reinforced another familiar Hatch-Waxman point: early dispositive motions remain difficult in formulation-heavy ANDA cases. The court denied a Rule 12(c) motion involving generic OMIDRIA infringement allegations, signaling that where formulation details, claim construction, or doctrine-of-equivalents theories remain disputed, courts are unlikely to resolve infringement on the pleadings.

On the regulatory side, FDA's FY2027 legislative proposals remain important for both Hatch-Waxman and BPCIA clients. The proposals include domestic generic manufacturing incentives, earlier Paragraph IV incentives, biosimilar interchangeability reform, abbreviated pathways for certain biologics, drug-device combination product issues, and refinements to procedures affecting 30-month stays and complete response letters. These proposals are not law, but they show where FDA wants the conversation to move.

The Biologics Price Competition and Innovation Act (BPCIA) market also continued to sharpen around denosumab biosimilars, where settlements and launches show how quickly biologics disputes can move from patent dance to negotiated entry to commercial competition.

Why It Matters

For brands, these decisions underscore the continuing value of method-of-use patents – but also the need for disciplined pleadings and evidence. For generics and biosimilar applicants, FDA approval is not the end of legal risk. Public-facing statements, payer materials, investor messaging, and field training should be reviewed before launch.

The larger trend is convergence. Patent litigation, FDA strategy, PTAB practice, commercial messaging, and market access are no longer separate workstreams.

In the near future, expect continued analysis of *Hikma v. Amarin* and renewed attention to launch communications. A U.S. Supreme Court decision is expected before the end of the Term, and companies should not wait to audit their materials.

The Federal Circuit also has life-sciences arguments ahead, including *Wyeth v. AstraZeneca* and *Biofer v. Vifor*, with issues involving enablement, written description, claim construction, damages, and process patents.

Litigation Takeaway

The through-line is precision. In skinny-label cases, say only what the carve-out permits. In Abbreviated New Drug Application (ANDA) cases, plead and prove infringement at the right level of detail. In BPCIA matters, align patent dance strategy,

launch timing, interchangeability, and market access from the start.

This blog was drafted by Jeremy Lowe, an attorney and leader of the Spencer Fane Hatch-Waxman and Biologics Litigation group. For more information, visit www.spencerfane.com.

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