

Publications

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Delaware Court Extends Hikma to Labels Without Carve-Outs

Key Takeaways

- In one of the first life sciences cases to address induced infringement after *Hikma v. Amarin*, the District of Delaware held that its affirmative-conduct standard applies even when a generic uses the full reference label, rejecting Vanda's argument that Hikma is limited to skinny-label carve-outs.
- The court also found that a warning is not an instruction. The asserted claims require discontinuing a beta blocker before giving tasimelteon. The label says only that "nighttime administration of [beta blockers] may reduce the efficacy of tasimelteon." Judge Hall held that no reasonable juror could find that sentence "encourage[s], recommend[s], or promote[s]" the claimed method.
- Vanda's contributory infringement theory fared no better, as "ample evidence" in the record that some patients continue to take beta blockers in the morning established a substantial non-infringing use for the generic products.

Why It Matters

- For later-issued method patents built around clinical-pharmacology language, *Vanda* sharpens the distinction between label language that describes a risk and language that actually directs the claimed conduct.

Next Steps

- Innovators and follow-on manufacturers should compare the claimed method against the label's actual instructions and assess whether real-world prescribing supports a substantial non-infringing use.

In one of the first cases to decide an induced infringement issue in a life sciences case after the Supreme Court's June decision in *Hikma v. Amarin*, the District of Delaware in *Vanda Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.* granted Teva and Apotex summary judgment that their generic tasimelteon products do not infringe Vanda's patents for stopping beta blockers before starting HETLIOZ®. The court held that the drug-interaction statement in the generic labels, which by law copied the reference label, is not an "affirmative step" toward infringement under the Supreme Court's June decision in

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Hikma v. Amarin and rejected Vanda's argument that *Hikma* applies only to labels that have section viii carve-outs.

What Happened: The Court Saw *Hikma* Coming

HETLIOZ (tasimelteon) 20 mg capsules were approved in 2014 for Non-24-Hour Sleep-Wake Disorder. Teva and Apotex filed their ANDAs in 2018, and in a first round of litigation successfully demonstrated that four asserted method claims were invalid as obvious.¹

FDA approved both ANDAs in December 2022. On Dec. 27, 2022, Vanda filed suit based on U.S. Patent No. 11,285,129, which had issued during the first trial. Teva launched two days later, and Apotex followed in January 2024. Vanda later added U.S. Patent No. 11,918,556, which issued on March 5, 2024. Both patents are listed in the Orange Book for HETLIOZ, expire in 2033, and carry use codes for "avoiding the administration of tasimelteon with beta-adrenergic receptor antagonists."

The claims of the '129 and '556 patents require discontinuing a beta blocker before administering prior to a "target bedtime." Section 7.3 of the labels — both the HETLIOZ label and the generics labels — states only:

Beta-adrenergic receptor antagonists have been shown to reduce the production of melatonin via specific inhibition of beta-1 adrenergic receptors. Nighttime administration of beta-adrenergic receptor antagonists may reduce the efficacy of tasimelteon.

Judge Hall noted that the neighboring sections, 7.1 and 7.2, expressly tell prescribers to "avoid use of tasimelteon in combination with" certain CYP1A2 inhibitors and CYP3A4 inducers. Section 7.3 has no such instruction, and the labels mention beta blockers nowhere else.

Teva and Apotex moved for summary judgment in March 2026. At an April 14 hearing, Judge Hall said she was concerned that the pending *Hikma* decision might affect the inducement arguments and ordered letter briefs within a week of the ruling. The Supreme Court decided *Hikma* on June 4. Judge Hall told the parties she was inclined to grant summary judgment and invited supplemental briefing.

Why It Matters: Drug-Interaction and Label-Management Patents After *Hikma*

When the Supreme Court decided *Hikma*, the immediate question was how far its affirmative-conduct standard would reach beyond skinny labels. *Vanda* offers an early answer from the busiest Hatch-Waxman court, extending the standard to full labels that lack any carve out.

That matters most for later-issued method patents, which are often built around the label's own clinical-pharmacology content. Examples include drug-interaction management, food effects, dose timing, dose adjustment for renal or hepatic impairment, and monitoring steps. These patents often issue years after approval and are listed with use codes that closely track a sentence in the label.

To evaluate the strength of exclusivity provided by such patents, innovators and follow-ons should ask:

- **Does the label direct the claimed step, or just describe a risk?** "May reduce the efficacy" describes a risk. "Avoid use," "discontinue," or "reduce the dose to" sound more like direction.

- **Does the claim require more than the label says?** The claims here required a specific sequence of determining, instructing, and then administering. The label warned of reduced efficacy but stopped short of directing a course of action. When a claim is narrower than the label language, inducement may be harder to prove.
- **Does contributory infringement square with real-world prescribing?** Vanda struggled to reconcile its contributory infringement position with record evidence that showed patients take both drugs. Telling a coherent story from the outset is critical to success.

What To Watch: Trial, Judgment and the Next Tasimelteon Filer

The court's summary judgment decision did not resolve pending invalidity, inequitable conduct and antitrust counterclaims, which are currently set for trial in late October. Upcoming status hearings may modify those expectations. Additionally, the non-infringement ruling is not yet a final judgment. Absent a Rule 54(b) certification, Vanda's appeal will likely wait for the remaining claims to be resolved.

The dispute also continues on another front: in May 2026, before Hikma was decided, Vanda sued Aurobindo over ANDA No. 221356 for infringement of several patents, including the '129 and '556 patents. Beyond the tasimelteon litigation, watch for other defendants in life sciences cases to cite *Hikma* and *Vanda* in dispositive motions on interaction, timing, and monitoring claims where the label describes a risk but does not direct a course of action. And, it looks like *Hikma* can be impactful beyond the traditional skinny label case.

For more information on the application of Hikma to generic drug labeling and related patent litigation, contact Chad Landmon, Mark Deming or your preferred Polsinelli attorney.

[1] See *Vanda Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 23-1247, 2023 WL 3335538 (Fed. Cir. 2023).