POLSINELLI

Publications

July 6, 2026 • Updates

Federal Circuit Affirms Nuedexta® Injunction but Vacates Zero-Dollar Bond

In *Otsuka America Pharmaceutical, Inc. v. Hetero Labs Ltd.*,[1] the Federal Circuit affirmed a preliminary injunction blocking Hetero's generic for Nuedexta®, upholding the construction of a dose-ratio limitation, whereby the ratio is measured by the salt forms of the drugs as administered, but vacated the district court's waiver of an injunction bond, holding that a generic barred from launching must be given security for the sales it stands to lose.

Key Takeaways

- **Dose ratio claims construed to include the salt forms administered in the formulation.** The asserted claim caps the weight-to-weight ratio of dextromethorphan to quinidine at "1:0.5 or less." Nuedexta® and the proposed generic included the same 1:0.5 ratio when measured by the salt forms administered. But, when measured by the free-base form of the active moieties, the ratio is about 1:0.56, falling outside the claim. A divided panel adopted the salt-as-administered reading and affirmed the preliminary injunction.
- **Construing a claim to cover the patentee's own product carried the day, over a pointed dissent.** The majority relied on the intrinsic record to support construing the "dextromethorphan" and "quinidine" as not limited to their free-base forms, but also as including their salt forms. The majority also found the construction confirmed by extrinsic evidence. Judge Dyk dissented.
- **A generic enjoined from launching must get a real bond.** The court unanimously vacated the district court's waiver of security under Federal Rule of Civil Procedure 65(c). Applying Third Circuit law, it noted that a bond is so rarely excused as to be "almost mandatory," and that the Third Circuit has "never excused a district court from requiring a bond where an injunction prevents commercial, money-making activities."

What Happened: The Federal Circuit Affirms the Injunction but Vacates the Bond Waiver

Nuedexta® (NDA 021879) is a fixed-dose capsule of 20 mg dextromethorphan hydrobromide and 10 mg quinidine sulfate, marketed by Otsuka and its subsidiary Avanir, which owns U.S. Patent No. 7,659,282 (the '282 patent). Claim 1 recites a method of

Related People

- Chad A. Landmon
- Mark T. Deming
- Corey M. Casey, Pharm.D.

Related Capabilities

- Hatch-Waxman & Biologics
- Life Sciences
- Intellectual Property
- Intellectual Property Litigation

administering the two drugs within specified dose ranges, “with the proviso that the weight to weight ratio of dextromethorphan to quinidine is 1:0.5 or less.” The patent expires August 13, 2026.

In August 2024, FDA approved Hetero’s abbreviated new drug application for a generic carrying the same indication and the same amount of each ingredient. After Hetero signaled that it would launch on or after July 10, 2025, Otsuka sued in the District of Delaware. The district court granted a temporary restraining order and, on July 23, 2025, a preliminary injunction, but waived the Rule 65(c) bond, reasoning that Hetero’s risk of financial harm was “speculative at best” and that a multimillion-dollar bond would have a “chilling effect on access to justice.” Hetero appealed both the injunction and the bond waiver.

The Federal Circuit affirmed the injunction and vacated the bond waiver. The panel majority — Judge Bryson, joined by Judge Stoll — resolved the claim-construction dispute in Otsuka’s favor and sustained the injunction. Judge Dyk dissented on the claim construction question but joined the court overturning the district court’s waiver of the bond requirement.

The Salt-Versus-Free-Base Question, and Why the Salt Reading Won

The likelihood of success question turned on a single point of construction: when the claim limits the weight ratio of “dextromethorphan” to “quinidine,” are those weights measured for the salt forms actually administered, or for the free-base active moieties they contain?

Nuedexta® and Hetero’s generic both deliver 20 mg of dextromethorphan hydrobromide and 10 mg of quinidine sulfate — a 1:0.5 ratio by salt weight within the limits of the claim. Converted to their free-base equivalents, however, the ratio becomes roughly 15.41 mg dextromethorphan to 8.69 mg quinidine — about 1:0.56, outside the claimed ratio.

The majority held that the terms refer to the compounds in “the form in which those compounds are administered.” It grounded that reading in the intrinsic evidence: dependent claims recite salt forms; the specification states, for all 16 embodiments, that “the quinidine includes quinidine sulfate and the dextromethorphan includes dextromethorphan hydrobromide”; the clinical studies that the patent describes report doses in salt terms; and the prosecution history treated the terms as encompassing the salts.

In support of its contrary reading, Hetero pointed to the specification’s own conversions between the compounds and their salts as indicative that the claim speaks to the active compounds. It argued that, absent the words "or a salt thereof," the terms name the compounds themselves, and pointed to the prosecution history of an original, later-amended dependent claim that measured the ratio based on the free base. It also argued that Otsuka's construction would render the claim indefinite, submitted expert opinion that a skilled artisan would read the ratio as the weights of the "active drug compounds,” and cited the European Nuedexta® label, which lists the salts' free-base equivalents.

The majority was unpersuaded, distinguishing the intrinsic record arguments, and finding the expert testimony and extrinsic evidence at odds with the patent’s text. The court also observed that it is “highly improbable that Avanir would have drafted or amended the ’282 patent claims in a manner that would exclude the very product that the patent was intended to protect.”

Judge Dyk dissented. Measuring salt weights, he wrote, “distorts the relative measurement” the invention was about — dextromethorphan provides the therapeutic

effect, while quinidine inhibits metabolism of dextromethorphan. Judge Dyk leaned heavily into that pharmacologic purpose, emphasizing that the invention was about reducing quinidine exposure while preserving dextromethorphan blood levels. “Dextromethorphan” and “quinidine” are, in his view, unambiguous names for “very specific compound[s]” with a “discernible chemical structure,” and if the patentee wanted the ratio computed on salt weights it “had the ability to draft the claim that way but it did not.” He also declined to credit the relevance of preferred embodiments in the specification or the commercial product in view of the ’282 patent’s prosecution history that originally sought much broader claim scope, but which narrowed the claims to focus on the claimed ratio to overcome an obviousness rejection.

The Injunction Bond, and Why the Waiver Did Not Stand

The court was unanimous that the district court erred in failing to require an injunction bond. Rule 65(c) provides that a preliminary injunction may issue “only if the movant gives security” in an amount the court considers proper. Here, the district court had dispensed with security altogether. Because the propriety of a bond is governed by regional-circuit law, the Federal Circuit applied Third Circuit precedent, under which the requirement is so rarely excused as to be “almost mandatory,” subject to narrow exceptions for injunctions that pose no risk of monetary loss to the enjoined party or that enforce public-welfare statutes.

Neither exception applied here. “Hetero’s attempt to enter the market with its generic pharmaceutical product,” the court held, “is clearly a commercial, money-making activity,” and the Third Circuit has “never excused a district court from requiring a bond where an injunction prevents commercial, money-making activities.” The district court’s rationales — that Hetero’s harm was speculative and that a large bond would chill access to justice — did not overcome that rule. The court vacated the waiver and remanded, directing the district court to set an appropriate amount “in light of the limited time remaining before the ’282 patent expires.”

Why It Matters: Dose-Ratio Drafting and the Price of an Injunction

For brands and generics alike, the construction holding is a reminder that how a dose or ratio limitation is expressed can be outcome-determinative.

The majority let claim silence work in the patentee’s favor here, but Judge Dyk’s dissent provides a roadmap for holding a patentee to the words it chose. A generic or biosimilar challenger evaluating a paragraph IV certification should test numeric limitations measured by both the salt as administered and the active moiety.

The bond holding is instructive to anyone involved in an at-risk-launch fight. A brand that wins a preliminary injunction blocking a generic’s commercial launch should expect to post real security rather than a waived or nominal bond. A generic enjoined on the eve of launch, in turn, has firm footing to demand a bond sized to its lost sales.

What To Watch: The Remand Bond and the Next Dose-Ratio Fight

- **The ’282 patent expiration on August 13.** Once it expires, the injunction dissolves and generic entry opens; the litigation’s remaining stakes narrow to damages and the bond.
- **The remand bond.** How the district court sizes the bond considering the length of the injunction to date and the limited remaining life of the patent.
- **Rehearing.** Watch whether Hetero seeks panel rehearing or rehearing en banc on the construction; the 2–1 split and Judge Dyk’s drafting-precision rationale make the claim construction the natural target.

- **Dose-ratio drafting going forward.** Expect both the majority's "form as administered" holding and Judge Dyk's dissent to be cited whenever a weight, ratio, or concentration limitation must be measured by salt or by free base, a recurring question for fixed-dose combinations and reformulation patents.

[1] No. 25-2016 (Fed. Cir. July 1, 2026)