No. 23-2042

In the United States Court of Appeals for the Federal Circuit

JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA NV, AND JANSSEN RESEARCH & DEVELOPMENT, LLC,

Plaintiffs-Appellees,

v.

MYLAN LABORATORIES LTD.,

Defendant-Appellant.

Appeal from the U.S. District Court for the District of New Jersey
No. 2:20-cv-13103, Hon. Evelyn Padin

COMBINED PETITION FOR PANEL REHEARING OR REHEARING EN BANC

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May 28, 2025

CERTIFICATE OF INTEREST

Counsel for appellant Mylan Laboratories Ltd. certifies the following:

1. The full names of all entities represented by me in this case are:

Mylan Laboratories Ltd.

2. The full names of all real parties in interest (if the parties named in the caption are not the real parties in interest) are:

None.

3. The full names of all parent corporations and publicly held companies that own 10% or more of the stock of the entities represented by me are:

Mylan, Inc. and Viatris, Inc.

4. The names of all law firms, partners, and associates that (a) appeared for the entities represented by me in the originating court or agency or (b) are expected to appear in this court for the entities are:

Saiber LLC: Arnold B. Calmann, Jeffrey Soos, Katherine A. Escanlar

Katten Muchin Rosenman LLP: Joseph M. Janusz, Brian Sodikoff, Rachel Schaub

5. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

No.

6. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees):

None.

Date: May 28, 2025 /s/ Deepro R. Mukerjee

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STATEMENT OF COUNSEL CONCERNING REHEARING EN BANC

Based on my professional judgment, I believe the panel decision is contrary to the following decision of the Supreme Court of the United States and precedent of this Court:

1. *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915 (2014);

2. *HZNP Medicines LLC v. Actavis Lab'ys UT, Inc.*, 940 F.3d 680 (Fed. Cir. 2019).

Date: May 28, 2025 /s/ Deepro R. Mukerjee

OVERLOOKED OR MISAPPREHENDED POINTS OF LAW AND FACT

1. The panel affirmed the judgment of induced infringment by relying on evidence of attempted-but-failed infringment. Attempted infringment cannot suffice to prove practice of all claim elements.

2. The panel's specific intent holding failed to consider noninfringing uses or recognize the district court's erroneous analysis thereof. All of this product's indicated uses are noninfringing.

3. A patient missing a dose is a limitation of the asserted method claim. Practice of the method is conditioned on a patient interrupting their therapy. Although *HZNP* indicates conditionality defeats specific intent, the panel assessed intent in the hypothetical world where a dose has already been missed—assuming conditionality away and eliding critical label warnings against missing doses.

INTRODUCTION

Mylan seeks to market a low-cost generic version of Invega Trinza®, an unpatented therapy that uses an off-patent drug. All indicated usages of Mylan's generic product are noninfringing. But Janssen is monopolizing access to both drug and treatment with a patent directed to a fraction of patients who ignore warnings on the label, stop the indicated therapy, and, after exactly 4 to 9 months, decide to resume treatment. Then, to complete the claimed method, these nonadherent patients must comply with a two-drug, three-shot reinitiation regimen on a tightly prescribed schedule.

Performing this method with this population is virtually impossible. As Judge Dyk observed during oral argument, "this is a complex protocol with a group of patients who are, by definition, non-compliant in the first place."[1] Unsurprisingly, the infringement record showed that physicians' attempts to practice Janssen's reinitiation method consistently failed.

That should have been fatal. Direct infringement that *will* happen is a predicate for induced infringement. Based on the infringement evidence, the

[1] Oral Arg. at 16:30-40, https://oralarguments.cafc.uscourts.gov/default.aspx?fl=23-2042_02062025.mp3.

district court could only say that healthcare providers (HCPs) "would *at least* ***attempt*** the claimed reinitiation regimen." Appx00036.[2] But a method patent "is not infringed unless ***all*** the steps are ***carried out***." *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915, 921 (2014). For that finding, the district court had to rely upon witness testimony (Dr. Christian Kohler) not admitted on infringement. Appx00034-00035. Because that was an abuse of discretion, the panel appropriately did not rely on Dr. Kohler's testimony. Op.8.

But then it went astray. Without Dr. Kohler's testimony, the judgment should have been reversed or vacated. Instead, the panel affirmed the direct-infringement holding by crediting evidence that shows only attempted-but-failed infringement or had no bearing on the practice of the claimed method. Janssen made the risky decision to rely on Dr. Kohler's testimony in post-trial briefing because it knew its infringement evidence was deficient. The district court followed Janssen down this ill-conceived path. The judgment cannot be saved by the district court's "see also" and footnote references to evidence it held supported only attempted infringement. If the infringement

[2] All emphasis added.

record somehow supports a finding of completed infringement, the district court should explain how in the first instance. Or perhaps it will agree with Mylan that Janssen failed to prove its case. Either way, Mylan urges the panel to correct this oversight.

If the panel does not reconsider its decision, the *en banc* court should review this case. That's for two reasons.

First, Janssen must be held to its burden to prove inevitable direct infringement—particularly when it is clawing unpatented drugs and therapies back from the public with a narrow method-of-treatment claim it failed to prove will be practiced. Evidence of attempted infringement falls short of demonstrating infringement of all limitations. This case is an important opportunity for the Court to make that clear.

Second, the panel's specific-intent analysis is deeply flawed. When used as directed, Mylan's product will ***never*** infringe Janssen's patent. This illustrates Mylan's lack of intent to encourage practice of the claim. *HZNP Medicines LLC v. Actavis Laboratories UT, Inc.*, 940 F.3d 680, 702 (Fed. Cir. 2019). Yet noninfringing uses are not mentioned in the panel decision, even though the district court's analysis thereof was plainly erroneous. Likewise, the panel discounted the conditional "if/then" nature of Janssen's method

and the explicit warnings in the label not to miss doses. Missing a dose is a limitation and prerequisite. Mylan's label repeatedly tells patients and HCPs not to satisfy it. The facts here echo *HZNP*'s—but the panel did not cite it, let alone distinguish it.

That this decision is unpublished does not alter the need for review. The decision blesses a new breed of "missed-dose" patents, multiplying even now,[3] that subvert Hatch-Waxman's balance between innovation and public access. A patentee cannot "bar the sale of a drug for a use covered only by patents that will have expired simply by securing a new patent for an additional, narrower use." *H. Lundbeck A/S v. Lupin Ltd.*, 87 F.4th 1361, 1370 (Fed. Cir. 2023). But that's exactly what Janssen is doing. Absent intervention, the problem can and will repeat itself.

BACKGROUND

A. Paliperidone Palmitate and the '693 Patent.

Paliperidone palmitate is used to treat patients with schizophrenia. Janssen sells an unpatented three-month long-acting injectable formulation of paliperidone palmitate ("PP3M"). Janssen nevertheless maintains a

[3] *E.g.*, U.S. Pat. Nos. 11,304,951 (Orange Book listed April 25, 2022) and 11,951,097 (listed May 2, 2024).

monopoly on PP3M and its indicated uses through U.S. Patent No. 10,143,693 (the '693 Patent).

The '693 Patent claims a "missed-dose" regimen applicable only in "exceptional" circumstances. Appx00088. The claim at issue, Claim 5, requires that a patient:

- start unpatented PP3M therapy;
- miss a dose;
- return for administration of a dose of one-month paliperidone palmitate (PP1M) between 4 and 9 months after missing the PP3M dose; and
- be successfully "reinitiated" on PP3M by showing up for two additional shots on a strict schedule—another PP1M 4 to 12 days later, and a PP3M 23 to 37 days after that.

Appx00095-00096.

Mylan's label instructs patients to "[f]ollow" the indicated treatment schedule "exactly as [their] [HCP] tells [them] to." Appx10288. But nothing in the "Indications and Uses" section is at issue in this case—that's all noninfringing. Appx10241. The first-page summary of the label states, "Missing doses of [PP3M] should be avoided. To manage missed doses on

exceptional occasions, refer to the Full Prescribing Information. (2.3)[.]" Appx10238. Section 2.3 again cautions that "[m]issing doses…should be avoided." Appx10243. But it says that if a patient last received a PP3M dose between four and nine months ago, "use the re-initiation regimen shown in Table 2." *Id.* That regimen tracks the missed-dose regimen claimed by the '693 Patent. Appx10244.

B. The District Court's Judgment.

Janssen sued Mylan, asserting Mylan's generic label would induce HCPs to infringe the '693 Patent. Mylan disputed liability, arguing Janssen failed to prove both inevitable direct infringement and specific intent to induce infringement.

On direct infringement, it was undisputed that inevitable nonadherence is not the same thing as inevitable infringement. Appx01992-1993 (130:16-131:22); Appx2213 (310:2-8). Patients must appear for treatment during all claimed windows, and they must take all the claimed shots. But a nonadherent patient may not inevitably decide to reinitiate treatment at all, much less during the specific 4-to-9-month window claimed by the '693 Patent. Nor—most importantly—does a nonadherent patient spontaneously become adherent for a strictly scheduled three-shot reinitiation regimen.

On specific intent, Mylan stressed that *all* indicated uses of its proposed generic products are noninfringing. Though the label describes the method claimed by the '693 Patent, any potential practice of that method is conditioned on a patient first missing a dose—something Mylan does *not* intend and the label repeatedly tells patients *not* to do.

The district court nevertheless ruled for Janssen.

It made two relevant holdings on direct infringement. *First*, it said Janssen proved HCPs would complete the missed-dose regimen. Appx00035. However, the district court improperly relied upon the testimony of Dr. Kohler, an expert limited by agreement of the parties to secondary considerations of obviousness. *Id.*; *see* Appx03076 (939:20-22); Appx03249 (1067:11-13).

The district court bolstered this conclusion with a "see also" citation to another piece of secondary-considerations evidence: a study demonstrating "'[t]he vast majority of patients' *were initiated* onto Trinza 'based on the prescribing guidelines.'" Appx00035 (quoting Appx12881). That "majority" *definitionally* comprised patients with a pattern of adherence, Appx12875; Appx12881, and the study said nothing about Janssen's missed-dose method. Further, in a footnote, the district court asserted that Dr. Kohler's

testimony was unnecessary because "there is other evidence in the record, including Dr. [Steven] Berger's testimony, of inevitable infringement." Appx00035 n.14. The footnote didn't explain how Dr. Berger's testimony supported this conclusion. It couldn't. As discussed below, the district court's findings and the record demonstrate that he did ***not*** say infringement was "inevitable."

Second, the district court held that attempting infringement was sufficient to establish direct infringement. Appx00036. It cited testimony from Mylan's expert, Dr. Berger, that nonadherent patients may return and choose to receive a PP1M shot 4 to 9 months after missing a dose. Appx00035. But those are just the first limitations of the claim. Dr. Berger testified that he had never successfully completed Janssen's missed-dose method himself, nor seen the method successfully completed by residents he supervised. Appx02134 (231:1-8); Appx02160-02161 (257:14-258:8). He testified that the method "calls for something that can't be done"—expecting nonadherent patients to follow a strict schedule. Appx02165 (262:13-19). And he explicitly disagreed that "it is inevitable that someone would infringe." Appx2134 (231:22-24).

For specific intent, the district court reframed the inquiry to elide the conditional, unintended prerequisite to Janssen's claimed method: a patient missing a dose. It said, "in the inevitable situation that doses are missed," the label does not "discourage or make optional the practice of the [a]sserted [c]laims (or any claimed steps)." Appx00037. In doing so, it side-stepped this Court's binding decision in *HZNP*. *Id.*

C. The Panel's Decision.

A panel of this Court affirmed in an unpublished decision. On direct infringement, the panel did not rely on Dr. Kohler—tacitly agreeing the district court shouldn't have, either. Op.7-8. Instead, the panel found no clear error in the district court's completed-infringement holding based on Dr. Berger's testimony and the PP3M initiation study. *Id.* As for specific intent, the panel accepted the district court's improper framing, without citing—let alone distinguishing—*HZNP*. Op.6-7.

ARGUMENT

I. PANEL REHEARING IS WARRANTED.

A. Evidence of Failed Attempts to Practice a Method Cannot Establish Inevitable Infringement of the Method.

Panel rehearing is warranted because the district court's flawed direct-infringement fact-finding cannot be salvaged on appeal.

Infringement must be proven, not assumed. *Genentech, Inc. v. Sandoz Inc.*, 55 F.4th 1368, 1379 (Fed. Cir. 2022). Induced infringement under Hatch-Waxman requires a plaintiff to "show[] that if the proposed ANDA product were marketed, it would infringe the [] patent." *Vanda Pharms. Inc. v. W.-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1130 (Fed. Cir. 2018). That means the patentee must prove the proposed generic would affirmatively induce practice of *all* elements of the asserted claims: "a patentee's rights extend only to the claimed combination of elements, and no further." *Akamai*, 572 U.S. at 921. In the context of a method claim, "the patent is not infringed unless *all* the steps are carried out." *Id.* Proving direct infringement is always required, irrespective of a defendant's intent. *Id.*

Janssen concedes "an attempt is not sufficient."[4] But evidence of attempt is all Janssen produced. Setting Dr. Kohler aside, *see supra* p.8, Janssen's only other evidence was cross-examination testimony from Dr. Berger. He stated that (a) some fraction of nonadherent patients would show back up for treatment within 4 to 9 months of missing a dose, but (b) neither he nor any resident under his supervision had successfully completed

[4] Oral Arg. at 18:03-04.

Janssen's missed-dose regimen. Appx02160-02161 (257:14-258:8); Appx2066 (263:22-264:2).

The most the district court could say of the infringement record is that "some percentage of PP3M patients would inevitably ***return*** between 4 to 9 months after their last missed dose," Appx00035 n.13, and that "an HCP would at least ***attempt*** the claimed reinitiation regimen." Appx00036. Without Dr. Kohler's testimony, the record offered zero support for the necessary finding that HCPs would *complete* the missed-dose method. Dr. Berger stated unequivocally that all attempts to practice Janssen's missed-dose method he'd observed "were unsuccessful." Appx2160 (257:21-25).

All Janssen could show in its infringement case was failed attempts. That's legally not enough. Janssen knew as much, and that's why it turned to Dr. Kohler in its post-trial briefing. The district court erred in considering Dr. Kohler's testimony: agreeing with the parties, it had limited that testimony to secondary considerations. Appx03046 (909:22-25); Appx03064-3067 (927:18-20, 928:18-21, 929:11-18, 930:21-23); Appx03076 (939:20-22); Appx03249 (1067:11-13). Without Dr. Kohler, Janssen couldn't meet its burden. Proof that an HCP attempted—but failed to complete—the missed-dose regimen does not establish that "all the steps are carried out," so "the

patent is not infringed." *Akamai*, 572 U.S. at 921. Holding otherwise would expand the scope of Janssen's monopoly. *Id.*

B. The District Court's Direct-Infringement Holding Is Unsupportable Without Dr. Kohler's Testimony.

The panel correctly refused to rely on Dr. Kohler. But it nevertheless concluded that "patients returning between 4 and 9 months after a missed dose are inevitable, *meaning that* infringement of the claimed reinitiation regimen would be inevitable." Op.7 (quoting Appx00034). The latter, however, does not follow from the former. The panel pointed to the district court's footnote reference that "Dr. Berger's testimony" supported "inevitable infringement." Op.8 (citing Appx00035 n.14). And it further cited a "see also" reference to a PP3M initiation study. Op.7 (citing Appx000035). Neither piece of evidence, however, says a word about *completing* the method.

Dr. Berger's Testimony: The panel cites Dr. Berger's testimony that some missed-dose patients "return[] for an appointment 16 or more weeks (about 4 months) after the missed dose" and the district court's finding that "at least some percentage of PP3M patients would inevitably return between 4 to 9 months after their last missed dose." Op.7 (quoting Appx00035 n.13).

As the district court recognized, this testimony could, at best, establish the first steps of the method. "Dr. Berger," it held, "concedes that…upon a patient's inevitable return between 4 and 9 months after a missed dose, it is inevitable that an HCP would *at least attempt* the claimed reinitiation regimen." Appx00036.

The district court gave this "concession" dispositive weight. But Dr. Berger "conceded" only failed attempts. Only by applying the wrong test—attempts equal infringement—could the district court hold that "evidence in the record, including Dr. Berger's testimony, of inevitable infringement" sufficed as proof. Appx00035 n.14.

The PP3M Initiation Study: The panel also cited a PP3M initiation study to support inevitable infringement because that study observed the "vast majority of patients [prescribed Invega Trinza] transitioned from PP1M to PP3M based on the prescribing guidelines." Op.7 (quoting Appx12881). But that study concerned the indicated use of PP3M, which is not patented and therefore noninfringing. Appx12881-12882. It does not even mention the claimed "missed-dose" method. It involved transitioning patients from PP1M to PP3M in the first instance. *Id.* The "vast majority" of patients identified in the study were, by definition, patients who had "no

gap of > 45 days in PP1M coverage 4 months prior to PP3M," Appx12875; Appx12881—patients, in other words, who had already proven adherent. So the discussion of PP3M initiation is not plausibly probative of whether the narrow claimed method would inevitably succeed with a subpopulation of patients who have already demonstrated an inability or unwillingness to comply with treatment. "This is a complex protocol with a group of patients who are, by definition, non-compliant in the first place."[5]

C. The Panel Should Have Reversed or Vacated.

To be sure, the district court made passing reference to both pieces of evidence to support its direct-infringement holding, whose foundation was Dr. Kohler's improperly considered testimony. Appx00035 & n.14. But nowhere did it explain how this evidence independently supports the conclusion. On the face of the record, there's no reasonable way to conclude that either Dr. Berger's testimony or the PP3M initiation study suffice to prove that "*all* the steps" of Janssen's missed-dose method *would be* "carried out." *Akamai*, 572 U.S. at 921.

[5] Oral Arg. at 16:30-40.

The district court offered no reasoned explanation for how its direct-infringement holding survives without Dr. Kohler's testimony. "See also" cites and passing reference to testimony the district court itself says support something *less* than its conclusion shouldn't pass muster. In upholding the direct-infringement ruling based on these slender reeds, the panel effectively engaged in first-instance fact-finding. But appellate courts are "court[s] of review, not first view." *Cutter v. Wilkinson*, 544 U.S. 709, 718 n. 7 (2005). If the panel (rightly) believes the district court erred by considering Dr. Kohler on infringement issues, there are only two appropriate outcomes: reversal or vacatur.

II. REHEARING *EN BANC* IS WARRANTED.

A. The Panel's Direct-Infringement Analysis Is Deeply Flawed and Must Be Corrected.

If the panel does not grant rehearing on the direct-infringement issue, the *en banc* court should step in. The panel decision allows to stand a pernicious view of what induced infringement requires. It allows evidence solely pertaining to first steps and failed attempts to establish that "all the steps are carried out." *Akamai*, 572 U.S. at 921. Plaintiffs seeking to block generic alternatives from the market must prove infringement, not attempts.

Holding otherwise dilutes Janssen's burden and expands its monopoly beyond the claims.

Correction of this error is particularly important given the circumstances of this case. Janssen is monopolizing an unpatented drug and therapies that it does not own based upon a conditional missed-dose method directed to patients who misuse the drug. It has accomplished what this Court has otherwise forbidden: barring all unpatented uses by patenting a new one. *H. Lundbeck*, 87 F.4th at 1370. The Court should at a minimum insist that a patentee in Janssen's position prove that HCPs would actually practice the method successfully. Janssen did not.

B. The Panel's Specific-Intent Analysis Ignores Binding Precedent.

Separately, the panel's specific-intent analysis warrants *en banc* review because it ignores binding precedent. Induced infringement requires "evidence [of] intent to encourage infringement." *Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015) (cleaned up). Intent is a statutory requirement. *Glob.-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 760 (2011). Section 271(b) requires a plaintiff to prove a defendant "***actively*** induces infringement," meaning "the inducement must involve

the taking of affirmative steps to bring about the desired result." *Id.* This imposes an "intent standard…akin to the one for willfulness, as both rest on the subjective intent of the accused infringer." *Roche Diagnostics Corp. v. Meso Scale Diagnostics, LLC*, 30 F.4th 1109, 1119 (Fed. Cir. 2022). In a Hatch-Waxman case, intent is gleaned from the proposed label as a whole. *Takeda*, 785 F.3d at 630-31.

Jansen's suit suffers from two incurable problems. First, Mylan's products have substantial—in fact, total—non-infringing uses when used as indicated. Second, Mylan's label explicitly discourages missing doses. It provides guidance on what to do *if* a patient disregards these instructions, making the method necessarily conditional. As *HZNP* explains, both circumstances are legally inconsistent with a finding of specific intent. 940 F.3d at 680.

The district court dealt with neither of these issues and the panel echoed its mistakes. The panel decision endorses an erroneously narrow analysis that imputes intent to a generic manufacturer whenever the branded label mentions a claimed method—no matter how many noninfringing uses there are, what else the label says, or whether anyone will use the method in practice.

First, the district court clearly erred in assessing noninfringing uses, and the panel decision ignores them. While a party "may still be held liable for induced infringement" "even if the proposed *ANDA product* has 'substantial noninfringing uses,'" *Vanda*, 887 F.3d at 1133, the number and extent of noninfringing uses *for the product* is highly probative of intent. They certainly cannot be dismissed based on legal error. But the district court nonsensically assessed "non-infringing uses of the 4-to-9-month clinical presentation," not the product as a whole. Appx00039. Such an error cannot slide.

HZNP illustrates why. That case also involved a product with "substantial noninfringing uses"—uses made particularly salient because the label did not require anyone to satisfy the claimed method's condition precedent. 940 F.3d at 702. The label implied a condition precedent—a "desire[] to have anything come into contact with the knee after application of the medication," *id.*—but did not mandate anyone have that desire. It was indifferent. Guidance was provided *in the event* that condition came about. So too here. Mylan's label does not require or encourage patients to miss doses. In fact, it tells them *not* to. The guidance only becomes relevant if a patient who has been on unpatented PP3M therapy *mis*uses Mylan's

products by disregarding the directive to "[f]ollow" the indicated treatment schedule "exactly as [the] healthcare provider tells [them] to." Appx10288. As in *HZNP*, the noninfringing uses of Mylan's PP3M products were highly relevant, and it was error not to consider them.

This dovetails with the second error. "[A] plaintiff must present evidence of active steps taken to *encourage direct infringement*; mere knowledge…that [a drug] may be put to infringing uses is not enough." *HZNP*, 940 F.3d at 701. "The focus is not on whether the instructions describe the mode of infringement, but rather on whether the 'instructions teach an infringing use…such that [this Court is] willing to infer from those instructions an affirmative intent to infringe the patent.'" *Id.* (quoting *Takeda*, 785 F.3d at 630-31).

In *HZNP*, the Court was rightly unwilling to draw that inference. The label's directive "operate[d] in an 'if/then' manner: if the user wants to cover the treated area with clothing or apply another substance over it, then the patient should wait until the area is dry." *Id.* at 702. While the label expressly called for the practice of the claimed method *if* the condition precedent was satisfied, it nonetheless "d[id] not encourage infringement." *Id.*

The panel decision does not cite *HZNP*. Like the district court, it reasoned that because the instructions are mandatory in the unintended, uninstructed event of a missed dose, the label suffices to establish specific intent. But the instruction was mandatory in *HZNP*, too. And that label was merely *indifferent* to the triggering event. *HZNP*'s reasoning must apply *a fortiori* when the label says not to bring the event about at all.

Infringement requires that an "allegedly infringing device or method…embod[y] every limitation of the claim[]." *IMS Tech., Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1429 (Fed. Cir. 2000). It was undisputed that a patient missing a dose 4 to 9 months ago is a *limitation* of the claim. Mylan's label says this threshold limitation *should not* be satisfied. So it cannot be encouraging meeting "every limitation of the claim[]," *id.* at 1429, and the label does not "contain[] information encouraging each claimed step *and the preamble*," *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1330 (Fed. Cir. 2021).

With this legally anomalous result, Janssen is now free to use its missed-dose methods to shield an off-patent drug with wholly unpatented uses from generic competition until 2036, reaping the windfall. *Cf. H. Lundbeck*, 87 F.4th at 1370. Patients and the public pay the price. And this is

just the beginning. Janssen has already patented additional "missed-dose" methods. *See supra* note 3. The panel's decision throws open the doors to countless more from Janssen and others. Review is warranted.

CONCLUSION

The petition should be granted.

Date: May 28, 2025

Respectfully submitted,

/s/ Deepro R. Mukerjee

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ADDENDUM

NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA NV, JANSSEN RESEARCH AND DEVELOPMENT LLC,
Plaintiffs-Appellees

v.

MYLAN LABORATORIES LTD.,
Defendant-Appellant

2023-2042

Appeal from the United States District Court for the District of New Jersey in No. 2:20-cv-13103-EP-LDW, Judge Evelyn Padin.

Decided: March 28, 2025

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Before DYK and PROST, *Circuit Judges*, and GOLDBERG, *Chief District Judge*. [1]

PROST, *Circuit Judge*.

Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica NV, and Janssen Research & Development, LLC (collectively, "Janssen") sued Mylan Laboratories Ltd. ("Mylan") for patent infringement in the United States District Court for the District of New Jersey. After a bench trial and post-trial briefing, the district court found that Janssen has demonstrated by a preponderance of the evidence that Mylan will induce health care providers ("HCPs") to infringe the asserted claims of U.S. Patent No. 10,143,693 ("the '693 patent"), and Mylan has not demonstrated by clear and convincing evidence that the '693 patent is invalid. *Janssen Pharms., Inc. v. Mylan Labs. Ltd.*, No. 20-13103, 2023 WL 3605733 (D.N.J. May 23, 2023) ("*Opinion*"). Mylan appeals, and we affirm.

BACKGROUND

The technology here concerns paliperidone palmitate ("PP"), an antipsychotic used to treat schizophrenia. PP comes in at least two long-acting injectable forms—one that lasts for one month ("PP1M") and another that lasts for three months ("PP3M"). Janssen manufactures Invega Trinza® ("Invega Trinza"), which is a United States Food &

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[1] Honorable Mitchell S. Goldberg, Chief Judge, United States District Court for the Eastern District of Pennsylvania, sitting by designation.

Drug Administration ("FDA")-approved PP3M for treating schizophrenia.

The '693 patent covers the use of Janssen's Invega Trinza and "relates to a method for treating patients who have missed a treatment of 3-month paliperidone palmitate extended-release injectable suspension formulation" or "PP3M." '693 patent col. 1 ll. 15–18. Janssen's asserted claims include independent claim 5 and dependent claims 6–7 and 9–14 of the '693 patent. All dependent claims depend directly or indirectly from claim 5. Claim 5 recites:

> A dosing regimen for administering an injectable paliperidone palmitate depot to a patient in need of treatment for psychosis, schizophrenia or bipolar disorder that has been treated with PP3M, wherein said patient had been last administered a PP3M injection 4 to 9 months ago and the next scheduled maintenance dose of PP3M should be administered to said patient, comprising:
>
> > (1) administering intramuscularly in the deltoid muscle of said patient a first reinitiation loading dose of PP1M;
> >
> > (2) administering intramuscularly in the deltoid muscle of said patient a second reinitiation loading dose of PP1M on about the 4th day to about the 12th day after administering of said first reinitiation loading dose; and
> >
> > (3) administering intramuscularly in the deltoid or gluteal muscle of said patient a reinitiation dose of PP3M on about the 23rd day to about the 37th day after administering the second reinitiation loading dose of PP1M wherein said first and second reinitiation loading doses and the reinitiation

> PP3M dose are selected from the table below based on the amount of the missed dose

Missed Dose of PP3M	Reinitiation Doses of PP1M	Reinitiation Doses of PP3M
175 mg eq.	50 mg eq.	175 mg eq.
263 mg eq.	75 mg eq.	263 mg eq.
350 mg eq.	100 mg eq.	350 mg eq.
525 mg eq.	100 mg eq.	525 mg eq.

Id. at claim 5.

The Invega Trinza dosing instructions on the label track the asserted claims of the '693 patent. Specifically, the label instructs HCPs that if a patient had his or her last dose between four and nine months ago, "do NOT administer the next dose . . . [i]nstead, use the re-initiation regimen shown in Table 2." J.A. 10037.

Mylan filed three Abbreviated New Drug Applications ("ANDA") seeking approval from the FDA to market a generic version of Janssen's Invega Trinza product before expiration of the '693 patent. Mylan's proposed ANDA labels are substantially identical to the Invega Trinza label.

Janssen initiated this lawsuit, asserting that Mylan's proposed ANDA labels will induce HCPs to infringe the asserted claims of the '693 patent. Mylan responded that the '693 patent is invalid. After an eight-day bench trial and considering the parties' post-trial briefing, the district court held that: "(1) Janssen has demonstrated by a preponderance of the evidence that Mylan will inevitably induce HCPs to infringe the [asserted claims of the '693 patent]; and (2) Mylan has not demonstrated by clear and convincing evidence that the ']693 [p]atent is obvious or otherwise invalid." *Opinion*, 2023 WL 3605733, at *2.

Mylan appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

"On appeal from a bench trial, this court reviews the district court's conclusions of law de novo and findings of fact for clear error." *MeadWestVaco Corp. v. Rexam Beauty & Closures, Inc.*, 731 F.3d 1258, 1266 (Fed. Cir. 2013). "[I]nfringement is a question of fact that we review for clear error." *Vanda Pharms. Inc. v. W.-Ward Pharms.*, 887 F.3d 1117, 1125 (Fed. Cir. 2018). "Obviousness is a question of law, which we review *de novo*, with underlying factual questions, which we review for clear error following a bench trial." *Honeywell Int'l, Inc. v. United States*, 609 F.3d 1292, 1297 (Fed. Cir. 2010) (emphasis in original).

Mylan raises two main issues on appeal: that the district court incorrectly found that (1) Mylan will induce infringement of the asserted claims and (2) the asserted claims are not invalid for obviousness. We address each issue in turn.

I

We begin with Mylan's challenge to the district court's finding that Mylan's proposed ANDA labels will induce infringement of the asserted claims. Mylan offers three main noninfringement arguments: (1) Mylan cannot induce infringement because its proposed ANDA labels specifically discourage patients from missing doses in the first place; (2) Janssen failed to carry its burden of proof to show that infringement would "inevitably" result because Janssen did not prove that patients who missed a dose would return and follow through with the claimed reinitiation regimen; and (3) because the asserted claims involve two actors—a doctor and a patient—this gives rise to a divided-infringement problem, thus defeating Janssen's showing of direct infringement. None of these arguments are persuasive.

A

With respect to the first argument, Mylan argues that, by discouraging patients from missing doses in the first place, it has demonstrated a lack of specific intent to encourage prescribing the missed-dosage regimen in the event doses are missed. We disagree and conclude that the district court did not clearly err in finding that Mylan's proposed ANDA labels would induce infringement.

To prevail on a theory of induced infringement, Janssen must prove (1) direct infringement and (2) that the ANDA applicant has the specific intent to induce infringement. *Vanda*, 887 F.3d at 1129. "Where 'the proposed label instructs users to perform the patented method . . . the proposed label may provide evidence of [the ANDA applicant's] affirmative intent to induce infringement.'" *Id.* (quoting *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010) (alteration in original)). Induced infringement requires showing that the proposed ANDA labels "encourage, recommend, or promote infringement." *Id.*

At issue in this appeal is the second requirement of induced infringement—whether Janssen failed to prove specific intent to induce infringement of the asserted claims of the '693 patent. Mylan's proposed ANDA labels state: "To manage missed doses on exceptional occasions, refer to the Full Prescribing Information. (2.3)." *See, e.g.*, J.A. 10238. Under the subsection "Missed Dose 4 Months to 9 Months Since Last Injection," Mylan's proposed ANDA labels instruct HCPs that, if the patient received a PP3M dose four to nine months ago, "do NOT administer the next dose of [PP3M]." J.A. 10243. The labels go on to state: "Instead, use the re-initiation regimen shown in Table 2," J.A. 10243, which directs HCPs to perform the same administrating steps as the claimed reinitiation regimen. Mylan's argument that its proposed ANDA labels discourage missing doses in the first place is unpersuasive. As the district

court correctly found, the fact that Mylan's proposed ANDA labels "discourage missed doses" does not mean that the labels "discourage or make optional the practice of the [a]sserted [c]laims (or any claimed steps) in the inevitable situation that doses are missed." *Opinion*, 2023 WL 3605733, at *17. Thus, because Mylan's proposed ANDA labels explicitly instruct HCPs to reinitiate patients onto PP3M using the asserted claims' methodology, the explicit instructions in Mylan's proposed ANDA labels establish specific intent for the purposes of induced infringement.

B

As to the second argument, Mylan argues that Janssen failed to carry its burden to show that the necessary direct infringement would occur. We disagree.

The district court found that "missed doses and patients returning between 4 and 9 months after a missed dose are inevitable, meaning that infringement of the claimed reinitiation regimen would be inevitable." *Id.* at *15. The court cited Mylan's expert's—Dr. Steven Berger—testimony admitting that "'more than 50 percent' of [Invega] Trinza patients have missed a dose, including '20 to 30 percent' returning for an appointment 16 or more weeks (about 4 months) after the missed dose." *Id.* (quoting Dr. Berger's testimony). The court found that "based on Berger's testimony and other credible testimony, . . . at least some percentage of PP3M patients would inevitably return between 4 to 9 months after their last missed dose." *Id.* at *15 n.13. The district court also cited to a study that stated that the "vast majority of patients [prescribed Invega Trinza] transitioned from PP1M to PP3M based on the prescribing guidelines" to support its finding. J.A. 12881; *see also Opinion*, 2023 WL 3605733, at *16 (citing PTX-220).

Mylan argues that the district court erred by relying upon Dr. Christian Kohler's testimony for infringement, because he was admitted to testify *only* regarding secondary considerations and was explicitly not admitted to

testify about infringement. The district court rejected this argument: "[T]he [c]ourt notes that its direct infringement findings do not hinge solely on Kohler's testimony—there is other evidence in the record, including Dr. Berger's testimony, of inevitable infringement." *Opinion*, 2023 WL 3605733, at *16 n.14. On this record, we conclude that there is no clear error in the district court's finding that Janssen carried its burden of proof to show infringement.

C

As to the third argument, Mylan argues that under a divided-infringement theory, Mylan cannot induce infringement because the claimed dosing regimen will be carried out by two actors—the patient and that patient's HCPs—such that there will be no direct infringement, and thus no inducement. We also do not find this argument persuasive.

The district court rejected Mylan's divided-infringement argument on two grounds. First, the district court concluded that Mylan's divided-infringement defense was untimely under the governing local rules. *See id.* at *11–12. Second, the district court rejected the divided-infringement argument on the merits, concluding that a single entity (an HCP) performs the claimed reinitiation dosing regimen. *Id.* at *12–15. Mylan challenges both grounds on appeal.

As to the first ground, we review "a district court's application of its local rules for abuse of discretion." *Howmedica Osteonics Corp. v. Zimmer, Inc.*, 822 F.3d 1312, 1320 (Fed. Cir. 2016). "[T]his court gives broad deference to the trial court's application of local procedural rules." *SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1292 (Fed. Cir. 2005). On this record, we conclude that the district court did not abuse its discretion in rejecting Mylan's divided-infringement defense because it was untimely. The district court found that "Mylan's divided infringement theory was not disclosed in its contentions, and

appeared improperly for the first time in Mylan's rebuttal expert report." *Opinion*, 2023 WL 3605733, at *12. Mylan also did not seek to amend its contentions to add the divided-infringement defense. Thus, in view of this record and our deferential review standard, we are not able to conclude that the district court abused its discretion. Because we affirm the district court's untimeliness ruling, we need not and do not address the merits of Mylan's divided-infringement argument.

II

We next address Mylan's challenge to the district court's determination of nonobviousness. Mylan challenges the district court's findings for two main reasons: (1) the claimed PP3M reinitiation regimen is obvious in view of the prior-art PP1M regimen; and (2) the prior art taught the specific four-to-nine-month reinitiation window claimed in the asserted claims. As discussed below, because we reject Mylan's first argument, we need not and do not address Mylan's second argument.

As to Mylan's first argument, the district court found that nothing in the prior art motivated a skilled artisan to use PP1M after a patient has been advanced to PP3M. *See, e.g.*, *id.* at *27 ("There was nothing obvious, in other words, about using a non-PP3M formulation to reinitiate a patient that had been advanced to PP3M."); *id.* at *28 (similar); *id.* at *27 (observing that the '693 patent "was the first [long-acting injectable antipsychotic] that recommended using two *different* long-acting injectable formulations to manage a missed dose" (emphasis added)). Mylan argues that a skilled artisan would have been motivated to ramp back up to PP3M with PP1M because a skilled artisan would have known that PP1M was "faster acting." Yet, the district court found that there was not "any credible evidence that taught that PP1M reaches therapeutic levels any faster than PP3M," and provided several reasons why Mylan's argument was not persuasive. *Id.* at *28. One of those

reasons was that Mylan's own expert's "flawed modeling suggests identical PP1M and PP3M absorption," "even though his comparison was skewed to favor faster absorption of PP1M." *Id.*

The district court also found that although the prior art showed starting a patient on PP1M to get them up to PP3M in the first place (i.e., not for reinitiation to PP3M), that prior art taught stabilizing on PP1M for at least four months before advancing to PP3M—as opposed to the asserted claim's "reinitiation dose of PP3M on about the 23rd day to about the 37th day after administering the second reinitiation loading dose of PP1M," '693 patent claim 5. The court found "[t]hus, if a patient who missed a dose of PP3M were given PP1M, there would have been no reason or motivation to advance them to PP3M without first stabilizing them on PP1M for at least 17 weeks, since that was the only way PP3M was reportedly used in the prior art." *Opinion*, 2023 WL 3605733, at *29.

On this record, we see no clear error in the district court's findings supporting its conclusion that Mylan failed to prove that the '693 patent is invalid for obviousness.

CONCLUSION

We have considered Mylan's remaining arguments and find them unpersuasive. For the foregoing reasons, we affirm the district court's determination on induced infringement and nonobviousness.

AFFIRMED

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing complies with the word limitation of Fed. R. App. P. 40 (b) because it contains 3,895 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and Fed. Cir. R. 32(b)(2). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it was prepared in Microsoft Word 2016 using a proportionally spaced typeface (Book Antiqua) in 14-point font.

Date: May 28, 2025 /s/ Deepro R. Mukerjee