NOTE: This disposition is nonprecedential.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

ARON RUSSELL FISCHER, Patterson Belknap Webb & Tyler LLP, New York, NY, argued for plaintiffs-appellees. Also represented by LACHLAN S. CAMPBELL-VERDUYN, J. JAY CHO, ANDREW D. COHEN, COLLIN HONG, BARBARA MULLIN, JOYCE NADIPURAM.

ERIC THOMAS WERLINGER, Katten Muchin Rosenman LLP, Washington, DC, argued for defendant-appellant.

Also represented by TIMOTHY H. GRAY; JITENDRA MALIK, Charlotte, NC; DEEPRO MUKERJEE, LANCE SODERSTROM, New York, NY; JILLIAN SCHURR, Dallas, TX.

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