NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

CORCEPT THERAPEUTICS, INC.,
Plaintiff-Appellant

v.

TEVA PHARMACEUTICALS USA, INC.,
Defendant-Appellee

2024-1346

Appeal from the United States District Court for the District of New Jersey in No. 1:18-cv-03632-RMB-LDW, Judge Renee Marie Bumb.

Decided: February 19, 2026

BRIAN C. CANNON, Quinn Emanuel Urquhart & Sullivan, LLP, Redwood Shores, CA, argued for plaintiff-appellant. Also represented by WILLIAM ADAMS, FRANCIS DOMINIC CERRITO, EVANGELINE SHIH, ERIC C. STOPS, DANIEL C. WIESNER, New York, NY.

JOHN CHRISTOPHER ROZENDAAL, Sterne Kessler Goldstein & Fox PLLC, Washington, DC, argued for defendant-appellee. Also represented by UMA EVERETT, BRADY

GLEASON, MICHAEL E. JOFFRE, WILLIAM MILLIKEN, ANNA G. PHILLIPS.

Before MOORE, *Chief Judge*, STOLL, *Circuit Judge*, and WANG, *District Judge*.[1]

PER CURIAM.

Corcept Therapeutics, Inc. (Corcept) appeals a decision from the United States District Court for the District of New Jersey finding no infringement of U.S. Patent Nos. 10,195,214 and 10,842,800. For the following reasons, we *affirm*.

BACKGROUND

Corcept owns the '214 patent and its continuation, the '800 patent, both directed to methods of coadministering mifepristone with a strong CYP3A inhibitor (e.g., ketoconazole) to treat Cushing's syndrome, a disorder that causes excessive cortisol production. Mifepristone blocks cortisol's effects on the body while CYP3A inhibitors block cortisol production. J.A. 10–11. Coadministration of mifepristone with strong CYP3A inhibitors, however, can cause adverse drug-drug interactions. J.A. 11.

In 2012, Corcept's mifepristone product, Korlym®, was approved with a product label that warned against coadministration due to safety concerns. J.A. 14. The 2012 label contained the following warnings:

> *Use of Strong CYP3A Inhibitors*: Concomitant use can increase mifepristone plasma levels

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[1] Honorable Nina Y. Wang, District Judge, United States District Court for the District of Colorado, sitting by designation.

> significantly. Use only when necessary and limit mifepristone dose to 300 mg.

J.A. 4212 (Warnings and Precautions section).

> CYP3A inhibitors: Caution should be used when Korlym is used with strong CYP3A inhibitors. Limit mifepristone dose to 300 mg per day when used with strong CYP3A inhibitors.

Id. (Drug Interactions section).

> Korlym should be used with extreme caution in patients taking ketoconazole and other strong inhibitors of CYP3A . . . as these could substantially increase the concentration of mifepristone in the blood. The benefit of concomitant use of these agents should be carefully weighed against the potential risks. Mifepristone should be used in combination with strong CYP3A inhibitors only when necessary, and in such cases the dose should be limited to 300 mg per day.

J.A. 4217 (Use of Strong CYP3A Inhibitors subsection under Warnings and Precautions section).

> Medications that inhibit CYP3A could increase plasma mifepristone concentrations and dose reduction of Korlym may be required. Ketoconazole and other strong inhibitors of CYP3A . . . may increase exposure to mifepristone significantly. The clinical impact of this interaction has not been studied. Therefore, extreme caution should be used when these drugs are prescribed in combination with Korlym. The benefit of concomitant use of these agents should be carefully weighed against the potential risks. The dose of Korlym should be limited to 300 mg and used only when necessary.

J.A. 4220–21 (CYP3A Inhibitors subsection under Drug Interactions section).

In connection with the product's approval, the FDA required Corcept to conduct drug-drug interaction studies to determine the effects of coadministration. J.A. 13–15. Corcept found a physician can safely coadminister up to 900 mg of mifepristone with a strong CYP3A inhibitor without undesirably increasing mifepristone blood levels. J.A. 15–17. The '214 and '800 patents are based on this discovery.

In 2019, Corcept revised Korlym's label accordingly. J.A. 15. The 2019 label contained the following language regarding coadministration:

> *Use of Strong CYP3A Inhibitors*: Concomitant use can increase mifepristone plasma levels. Use only when necessary and limit mifepristone dose to 900 mg.

J.A. 4235 (Warnings and Precautions section).

> CYP3A inhibitors: Caution should be used when KORLYM is used with strong CYP3A inhibitors. Limit mifepristone dose to 900 mg per day when used with strong CYP3A inhibitors.

Id. (Drug Interactions section).

> KORLYM should be used with caution in patients taking ketoconazole and other strong inhibitors of CYP3A . . . as these could increase the concentration of mifepristone in the blood. The benefit of concomitant use of these agents should be carefully weighed against the potential risks. KORLYM should be used in combination with strong CYP3A inhibitors only when necessary, and in such cases the dose should be limited to 900 mg per day.

J.A. 4240 (Use of Strong CYP3A Inhibitors subsection under Warnings and Precautions section).

> Medications that inhibit CYP3A could increase plasma mifepristone concentrations and dose

> reduction of KORLYM may be required. Ketoconazole and other strong inhibitors of CYP3A . . . may increase exposure to mifepristone. Caution should be used when strong CYP3A inhibitors are prescribed in combination with KORLYM. The benefit of concomitant use of these agents should be carefully weighed against the potential risks. The dose of KORLYM should be limited to 900 mg, and strong inhibitors of CYP3A should be used only when necessary.

J.A. 4245 (CYP3A Inhibitors subsection under Drug Interactions section).

The 2019 label also included a new subsection on dosage and administration of mifepristone with a strong CYP3A inhibitor.

2.5 Concomitant Administration with CYP3A Inhibitors

Ketoconazole and other strong inhibitors of CYP3A, such as itraconazole, nefazodone, ritonavir, nelfinavir, indinavir, atazanavir, amprenavir and fosamprenavir, clarithromycin, conivaptan, lopinavir/ritonavir, posaconazole, saquinavir, telithromycin, or voriconazole may increase exposure to mifepristone. KORLYM should be used in combination with strong CYP3A inhibitors only when necessary. *[See Warnings and Precautions (5.6), Drug Interactions (7.2)]*

Administration of KORLYM to patients already being treated with strong CYP3A inhibitors:

- Start at a dose of 300 mg. If clinically indicated, titrate to a maximum of 900 mg.

Administration of strong CYP3A inhibitors to patients already being treated with KORLYM:

- Adjust the dose of KORLYM according to Table 1.

Table 1. Dose adjustment of KORLYM when strong CYP3A inhibitor is added

Current dose of KORLYM	Adjustment to dose of KORLYM if adding a strong CYP3A inhibitor
300 mg	No change
600 mg	Reduce dose to 300 mg. If clinically indicated, titrate to a maximum of 600 mg
900 mg	Reduce dose to 600 mg. If clinically indicated, titrate to a maximum of 900 mg
1200 mg	Reduce dose to 900 mg

J.A. 4238 (under Dosage and Administration section). This new label expressly instructs dosing with up to 900 mg of mifepristone along with a strong CYP3A inhibitor.

Teva Pharmaceuticals USA, Inc. (Teva) filed an Abbreviated New Drug Application (ANDA) for a generic version of Korlym with a proposed product label identical

in all material respects to Korlym's revised 2019 label. J.A. 20. Corcept sued Teva for infringement of claims 10–13 of the '214 patent and claims 1, 6–7, and 9 of the '800 patent. J.A. 19–20. Claim 10 of the '214 patent and claims 1 and 6 of the '800 patent are representative:

> 10. A method of controlling hyperglycemia secondary to hypercortisolism in a patient with endogenous Cushing's syndrome who is taking an original once-daily dose of 1200 mg or 900 mg per day of mifepristone, comprising the steps of:
>
> > reducing the original once-daily dose to an adjusted once-daily dose of 600 mg mifepristone,
> >
> > administering the adjusted once-daily dose of 600 mg mifepristone and a strong CYP3A inhibitor to the patient,
> >
> > wherein said strong CYP3A inhibitor is selected from the group consisting of ketoconazole, ...
>
> 1. A method of controlling hyperglycemia secondary to hypercortisolism in a patient with endogenous Cushing's syndrome, said patient taking an original once-daily dose of 1200 mg per day of mifepristone, the method comprising the steps of:
>
> > reducing the original once-daily dose to an adjusted once-daily dose of 900 milligrams (mg) per day of mifepristone, and
> >
> > administering the adjusted once-daily dose of 900 mg per day of mifepristone and a strong CYP3A inhibitor to the patient,
> >
> > wherein said strong CYP3A inhibitor is selected from the group consisting of ketoconazole, ...
>
> 6. A method of controlling hyperglycemia secondary to hypercortisolism in a patient with endogenous Cushing's syndrome, said patient taking a strong

> CYP3A inhibitor selected from ketoconazole, . . . , the method comprising administering to the patient a once-daily dose of mifepristone of 900 milligrams (mg) per day.

After a bench trial, the district court found Corcept had not met its burden to prove either direct infringement or specific intent to induce infringement. J.A. 3–46. Corcept appeals. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

On appeal from a bench trial, we review a district court's conclusions of law de novo and its fact findings for clear error. *Vanda Pharms. Inc. v. W.-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1123 (Fed. Cir. 2018). Infringement, including induced infringement, is a question of fact. *Id.* To establish induced infringement, a plaintiff must prove, by a preponderance of the evidence, (1) direct infringement and (2) specific intent to encourage another's infringement. *Genentech, Inc. v. Sandoz Inc.*, 55 F.4th 1368, 1376 (Fed. Cir. 2022) (citing *Vanda*, 887 F.3d at 1129–30). The district court's determination that Corcept failed to prove either element is a finding of fact that we review for clear error. *See id.* at 1375–76.

In finding that Corcept failed to prove direct infringement, the district court relied on outside-the-label evidence in a manner that is expressly authorized by this Court's precedents. *See* J.A. 24–38. For past infringement, the court found a lack of record evidence showing any physicians had ever practiced the claimed methods. J.A. 25–30. For future infringement, the court found it was highly unlikely physicians will practice the claimed methods because (1) physicians avoid coadministration due to dosing challenges and safety concerns; (2) the recently approved osilodrostat drug that blocks cortisol production is a safer and more effective non-infringing alternative; and (3) a physician can follow Teva's proposed label and not infringe the

claims. J.A. 30–38. Because we discern no clear error in that approach, we affirm the district court's decision on this basis.

In *Genentech*, this Court affirmed a district court's ruling that a proposed ANDA label that "encourages, recommends, or promotes an infringing use without any additional evidence showing such an infringing use will in fact occur, is insufficient for a finding of direct infringement." 55 F.4th at 1375. Although the label in *Genentech* contained instructions recommending an infringing use, *id.* at 1378–79, this Court affirmed the district court's finding of no direct infringement based on outside-the-label evidence of physician practice, *id.* at 1379–81. That evidence included physicians' testimony that they had never practiced the claimed methods in the past, and that if they encountered a future situation where the claimed methods might be clinically indicated, "they would choose a noninfringing response . . . instead." *Id.* at 1380. This Court concluded that the district court "did not clearly err by considering physician evidence, weighing it against the language in Sandoz's proposed label, and finding that Genentech failed to prove direct infringement." *Id.*

The district court in this case followed the approach set out in *Genentech*. First, the district court found that Corcept had provided no evidence that any physician had ever practiced the claimed methods. J.A. 28–30. The district court emphasized that evidence of prior practice is not required but may serve as a useful "starting point" to the analysis. J.A. 28. Next, the district court found that future direct infringement was "highly unlikely" based on evidence that (1) physicians avoid the claimed methods due to the safety concerns and dosing problems associated with coadministration; (2) a noninfringing alternative, osilodrostat, is available and preferred as a treatment for hypercortisolism; and (3) a physician could follow the proposed label and not infringe the claims. J.A. 31–36. Based on this evidence, the district court "reject[ed] Corcept's

conclusion that infringement will occur," and found that Corcept failed to prove direct infringement. J.A. 38.

Although the direct infringement inquiry in an ANDA case is hypothetical, a patent owner still must prove that "if a particular drug *were* put on the market, it *would* infringe the relevant patent." *Vanda*, 887 F.3d at 1129–30 (quotation omitted); *see also Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915, 921–22 (2014) (holding that direct infringement is required in an induced infringement case, because a method patent "is not infringed unless all the steps are carried out"). This panel is bound by *Genentech*, which permits district courts to consider outside-the-label evidence to determine whether direct infringement will actually occur, even where the proposed label recommends an infringing use. *See* 55 F.4th at 1379–81.

As in *Genentech*, the district court looked to evidence of how physicians weigh the potential risks of the patented method in practice. For instance, the district court specifically credited physician testimony that "the benefits of coadministering mifepristone and ketoconazole *never* outweigh the risks, especially since the introduction of osilodrostat." J.A. 34 (emphasis added). The district court also found that Corcept had "no real response" to evidence that the leading authorities on Cushing's syndrome do not recommend coadministration of mifepristone with other drugs. J.A. 32–33. We perceive no clear error in the district court's finding—based on "all the relevant evidence"—that Corcept failed to prove that if Teva's proposed product were marketed, direct infringement would result. *Vanda*, 887 F.3d at 1129–30 (quotation omitted).

Because we see no clear error in the district court's fact findings regarding direct infringement, we need not and do not reach the additional finding of specific intent to induce infringement. We do note that this suit could have been avoided had Teva filed a "section viii carveout" under

21 U.S.C § 355(j)(2)(A)(viii). *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1327 (Fed. Cir. 2021); 21 C.F.R. § 314.94(a)(8)(iv).

CONCLUSION

For the foregoing reasons, we *affirm*.

AFFIRMED

COSTS

No costs.