24-1346

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CORCEPT THERAPEUTICS, INC.,

Plaintiff-Appellant,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Appellee.

On Appeal from the United States District Court for the District of New Jersey,
Case No. 1:18-cv-3632

APPELLANT'S COMBINED PETITION FOR PANEL REHEARING OR REHEARING EN BANC

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 24-1346

Short Case Caption Corcept Therapeutics, Inc. v. Teva Pharmaceuticals USA, Inc.

Filing Party/Entity Corcept Therapeutics, Inc.

Instructions:

1. Complete each section of the form and select none or N/A if appropriate.
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Date: 04/22/2026 Signature: /s/ John F. Bash

Name: John F. Bash

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☐ None/Not Applicable
Corcept Therapeutics, Inc.		BlackRock, Inc. (10% or more stock owner)

☐ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

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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. *Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271 (Fed. Cir. 2013);
2. *Par Pharm., Inc. v. Eagle Pharms., Inc.*, 44 F.4th 1379 (Fed. Cir. 2022); and
3. *Vanda Pharms., Inc. v. W.-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018),

Dated: April 22, 2026

/s/ *John F. Bash*
John F. Bash

OVERLOOKED OR MISAPPREHENDED POINTS OF LAW AND FACT

1. The panel erroneously relied on *Genentech, Inc. v. Sandoz Inc.*, 55 F.4th 1368 (Fed. Cir. 2022), when *Genentech* conflicts with prior Federal Circuit precedent and is therefore not controlling.

PRELIMINARY STATEMENT

Under the Hatch-Waxman Amendments, a generic drug manufacturer may piggy-back off the clinical work of brand manufacturers by submitting an Abbreviated New Drug Application (ANDA) to the FDA that copies the brand manufacturer's label. To counterbalance this benefit, Congress deemed submitting the ANDA an "act of infringement" when it covers "a drug claimed in a patent or the use of which is claimed in a patent." 35 U.S.C. § 271(e)(2)(A). Here, Defendant Teva Pharmaceuticals USA, Inc. submitted an ANDA copying Plaintiff Corcept Therapeutics, Inc.'s branded label in all material respects, including dosages subject to Corcept's patents.

Under established precedent, the infringement analysis should have begun and ended with Teva's ANDA because its proposed label indisputably recommends an infringing use. *Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1278-80 (Fed. Cir. 2013). According to the panel, however, a single outlier case, *Genentech, Inc. v. Sandoz Inc.*, 55 F.4th 1368 (Fed. Cir. 2022), permitted the district court to look outside the ANDA to conduct an inquiry into whether infringement is likely to occur in the future. The panel therefore affirmed the district court's holding that Teva's ANDA does not infringe, despite clearly recommending an infringing use. The panel's decision and *Genentech* conflict with prior panel decisions and

with Section 271(e)(2)(A)'s plain text. En banc rehearing or panel rehearing is warranted.

BACKGROUND

A. Legal Framework

Brand manufacturers submit a New Drug Application (NDA) to the FDA containing evidence of drug safety and efficacy. *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 404-09 (2012). In 1984, Congress enacted the Hatch-Waxman Amendments to "allow a generic competitor to file an [ANDA] piggy-backing on the brand's NDA." *Id.* at 405; 21 U.S.C. § 355(j). Brand drugs are typically protected by patents; the Hatch-Waxman Amendments establish mechanisms to resolve disputes over those patents. *Caraco*, 566 U.S. at 405.

Specifically, brand manufacturers need to provide the FDA with information about their patents. 21 U.S.C. §§ 355(b)(1)(A)(viii), (c)(2). The FDA then publishes that information. *Caraco*, 566 U.S. at 405-06. ANDA filers must address these published patents to "assure the FDA that its proposed generic drug will not infringe" them. *Id.* at 406. If the ANDA filer seeks to market its generic drug before the patents expire, it has two options. First, it can make a "paragraph IV certification" stating that a listed patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). This certification often provokes litigation under 35 U.S.C. § 271(e)(2)(A), which

provides that "it shall be an act of infringement to submit" an ANDA "for a drug claimed in a patent or the use of which is claimed in a patent." Second and alternatively, the generic manufacturer can use a "section viii" carve-out statement asserting that it seeks FDA approval to market its drug *only* for uses not claimed by the brand manufacturer's listed method patents. 21 U.S.C. § 355(j)(2)(A)(viii). This case involves a paragraph IV certification.

B. Factual Background

Corcept is a brand manufacturer that sells mifepristone under the trade name Korlym to treat Cushing's syndrome. Op. 2. Because Cushing's syndrome patients are very ill, they typically need other medications. Appx1148-49. One group of often prescribed medications is called "CYP3A inhibitors." Appx10. CYP3A inhibitors suppress activity of CYP3A enzymes, which metabolize most drugs, including mifepristone. Appx10-11. Because of that effect, the 2012 Korlym label warned against co-administering Korlym with strong CYP3A inhibitors, expecting that inhibiting CYP3A activity would lead to a potentially deadly increase in mifepristone blood-plasma concentrations. Op. 2-3. To further ensure patient safety, the FDA mandated that Corcept conduct studies to determine the effects of co-administering Korlym and strong CYP3A inhibitors. *Id*. at 4; Appx13.

From its trials, Corcept discovered that physicians can safely co-administer up to 900 mg of mifepristone with strong CYP3A inhibitors. Op. 4. Based on that

discovery, Corcept obtained U.S. Patent No. 10,195,214 and continuation No. 10,842,800 for methods for co-administering specific doses of mifepristone to treat Cushing's syndrome patients, including up to 900 mg of mifepristone. *Id*. at 4, 6-7. In 2019, the FDA approved Korlym's revised label. *Id*. at 4. The revised label "included a new subsection on dosage" and, consistent with Corcept's patents, "expressly instructs dosing with up to 900 mg of mifepristone with a strong CYP3A inhibitor." *Id*. at 5.

Teva then filed an ANDA "for a generic version of Korlym with a proposed product label identical in all material respects to Korlym's revised 2019 label." *Id*. at 5-6. Teva did not seek a label carving out Corcept's patented co-administration uses. *Id.* at 9-10. Corcept filed this action against Teva under Section 271(e)(2)(A), arguing that Teva infringed its method patents by filing an ANDA recommending an infringing use. Appx3; Appx22.

After a bench trial, the district court found that Corcept had failed to establish the elements of induced infringement, *i.e.*, direct infringement and specific intent to induce infringement. Op. 7. It so held based on evidence outside the ANDA label—evidence that the court believed demonstrated that physicians had not practiced and would not practice the claimed method. *Id*. at 7-8. The district court separately found that Teva lacked the specific intent to infringe necessary for inducement. *Id*. at 7.

On appeal, the panel recognized that Corcept's patents protect "coadminister[ing] up to 900 mg of mifepristone with a strong CYP3A inhibitor." *Id*. at 4. It acknowledged that Corcept's 2019 revised label "expressly instructs dosing with up to 900 mg of mifepristone along with a strong CYP3A inhibitor." *Id*. at 5. And it recognized that Teva's ANDA label was "identical in all material respects to" Corcept's revised label. *Id*. at 5-6.

Yet despite those facts, the panel affirmed the district court's no-direct-infringement finding. On its account, the district court did not err when it allowed outside-the-label evidence to trump what Teva's ANDA label actually says because doing so was "expressly authorized by this Court's precedents." *Id*. at 7. In particular, the panel felt "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.*" *Id*. at 9 (emphasis added). Because it affirmed the no-direct-infringement finding, the panel did not address specific intent. *Id.*

ARGUMENT

I. THE PANEL'S OUTSIDE-THE-LABEL INFRINGEMENT ANALYSIS WARRANTS EN BANC REVIEW

As the panel recognized, Teva's ANDA label is "identical in all material respects" to Corcept's label for Korlym. Op. 5-6. And Corcept's own label describes a patent-protected method for administering mifepristone with strong

CYP3A inhibitors. *Id*. at 4-5. That should have ended the direct-infringement inquiry. Under established precedent, when an ANDA falls within the scope of the at-issue patent claim, direct infringement exists. Yet the panel here found that a single outlier case, *Genentech*, compelled the conclusion that the district court did not clearly err by considering outside-the-label evidence to find no direct infringement. That decision warrants en banc review.

A. The Panel's Decision Deepened Conflict In This Court's Precedent

Under 35 U.S.C. § 271(e)(2)(A), it is an "act of infringement to submit an [ANDA] . . . for a drug claimed in a patent or the use of which is claimed in a patent." Given that language, this Court has consistently focused Section 271(e)(2)(A)'s infringement analysis on the ANDA.

Take *Sunovion*. There, the asserted claims covered formulations containing less than 0.25% of an isomer. 731 F.3d at 1274. The generic manufacturer's ANDA sought FDA approval for a formulation containing no more than 0.6% (*i.e.*, 0.0-0.6%) of the isomer. *Id.* at 1275. The defendant nonetheless certified before the district court that it would make and sell only non-infringing products containing 0.3-0.6% of the isomer (and thereby avoid the less than 0.25% requirement). *Id.* Based on that certification, the district court found no infringement. *Id.*

This Court reversed. It recognized that "if a product that an ANDA applicant is asking the FDA to approve for sale falls within the scope of an issued patent, a

judgment of infringement must necessarily ensue." *Id.* at 1278. Under that rule, the generic manufacturer's "ANDA specification seeking FDA approval for generic … products with 0.0-0.6% levorotatory isomer mandate[d] a finding of infringement" because it necessarily would have allowed the defendant to sell infringing products containing less than 0.25%. *Id.* The Court rejected the defendant's reliance on its "certification," stating what the defendant "has asked the FDA to approve . . . determines whether infringement will occur." *Id.* at 1278-79.

In *Par Pharm., Inc. v. Eagle Pharms., Inc.*, the Court reaffirmed that the infringement "inquiry is controlled by the ANDA specification." 44 F.4th 1379, 1383 (Fed. Cir. 2022). Put differently, an ANDA "directly resolves the infringement question if it defines a proposed generic product in a manner that either meets the limitations of an asserted patent claim or is outside the scope of such a claim." *Id.* at 1383-84 (quotation omitted). Courts "may look to other relevant evidence," *i.e.*, outside-the-label evidence, only if "the ANDA specification does not speak clearly and directly to the question of infringement." *Id*. at 1384. Applying that rule, *Par* found that the infringement question "beg[an] and end[ed]" with the ANDA because the "ANDA defin[ed] a product outside of the scope of [the patent] claims." *Id*. There is no ambiguity in that holding.

Multiple other panels of this Court have applied the same rule focused on the ANDA to both composition and method patents. *Vanda Pharms., Inc. v. W.-Ward*

Pharms. Int'l Ltd., 887 F.3d 1117, 1130 (Fed. Cir. 2018) (method); *Ferring B.V. v. Watson Lab'ys., Inc.-Fla.*, 764 F.3d 1401, 1408 (Fed. Cir. 2014) (composition); *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1379 (Fed. Cir. 2012) (method); *Bayer AG v. Elan Pharm. Rsch. Corp.*, 212 F.3d 1241, 1250 (Fed. Cir. 2000) (composition). Under that rule, if an ANDA "defines a proposed generic product in a manner that either meets the limitations of an asserted patent claim or is outside the scope of such a claim," then it "directly resolves the infringement question." *Ferring*, 764 F.3d at 1408.

The panel here departed from that well-trodden path. When the panel recognized that Teva's ANDA label "recommends an infringing use" (unsurprising because it is "identical in all material respects" to Corcept's label), it should have found direct infringement. Op. 5-6, 9. Yet it did not. Despite what Teva's label recommends, the panel discerned no clear error in the district court's non-infringement finding—a finding based on "outside-the-label evidence" that physicians had not and would not practice the claimed method. *Id*. at 7-8. That approach conflicts with the numerous cases cited above, which all teach that the ANDA begins and ends the analysis when it meets the claim limitations on its face.

In fairness, the panel reached this conclusion reluctantly. It believed that it "was *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." *Id*. at 9 (emphasis added). In *Genentech*, a divided panel rejected an argument that a "proposed label, which encourages, recommends, and promotes infringement" should be "dispositive." 55 F.4th at 1378. According to *Genentech*, the district court there "did not clearly err by considering physician evidence" and "weighing it against the language" of the label. *Id.* at 1380.

That holding—and the panel's reluctant embrace of it—conflicts with *Sunovion, Par*, and the other precedential decisions described above. Indeed, before *Genentech*, no panel had ever held that extrinsic evidence could trump the ANDA's clear statements. *Genentech*'s embrace of outside-the-label evidence even when the label itself recommends an infringing use simply cannot be reconciled with the settled rule that "[w]hat a generic applicant asks for and receives approval to market, if within the scope of a valid claim, is an infringement." *Sunovion*, 731 F.3d at 1279. Nor can *Genentech* be squared with *Par*'s holding that the infringement inquiry "begins and ends with [the] ANDA specification" when the ANDA specification "meets the limitations of an asserted patent claim." 44 F.4th at 1383-84.

That conflict cannot be explained away on the ground that this case and *Genentech* involved method patents, whereas *Sunovion* and *Par* involve patents over drug formulations. Indeed, Section 271(e)(2)(A) states only that "it shall be an act of infringement" to submit an ANDA "for a drug claimed in a patent *or the use of*

which is claimed in a patent." 35 U.S.C. § 271(e)(2)(A) (emphasis added). It does not distinguish between method and drug-formulation patents; it is an act of infringement to submit an ANDA claiming either a patented method or a patented formulation.

Accordingly, this Court has applied the framework of *Sunovion* and *Par* to method patents. For example, in *Vanda*, this Court held that the district court properly found direct infringement based on its "factual findings that the proposed label recommended that physicians perform the claimed steps." 887 F.3d at 1130 (cleaned up). The court cited favorably to the drug-product cases discussed above holding that the "ANDA itself dominates the analysis" in Section 271(e)(2) cases. *Id*. (quotation omitted). Likewise, in *AstraZeneca*, another method patent case, this Court held that "[w]hen considering allegations that an ANDA filing infringes a patented method, § 271(e)(2) directs our analysis to the scope of approval sought in the ANDA—the statute defines the infringing act as filing an ANDA for 'a drug claimed in a patent or the use of which is claimed in a patent.'" 669 F.3d at 1379 (citation omitted). It is therefore clear under this Court's pre-*Genentech* precedents that the analysis is identical for both composition and method patents.

B. The Panel's Outside-the-Label Holding Is Wrong

As explained, the panel here exclusively relied on *Genentech* in affirming the district court's use of outside-the-label evidence. Putting aside that the divided

Genentech panel erred in departing from earlier precedential panel decisions, *Genentech* is wrong on its own terms.

First, *Genentech* misread earlier decisions as allowing courts to consider physician-practice evidence even where the ANDA clearly recommends infringement. 55 F.4th at 1379. The cases that the Court cited in support, *Ferring*, *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997), and *Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625 (Fed. Cir. 2015), do not suggest otherwise. *Id*. at 1379-80 (discussing cases). In *Ferring*, the Court emphasized that the ANDA will "directly resolve[] the infringement question" when it "defines a proposed generic product in a manner that either meets the limitations of an asserted patent claim or is outside the scope of such a claim." 764 F.3d at 1408. That is the opposite of what *Genentech* held. Only because the ANDA in *Ferring* did "not resolve infringement in the first instance" did the Court look to other evidence. *Id.* at 1409. Likewise, as this Court has previously explained, *Glaxo* considered evidence outside of the ANDA specification only "because the ANDA specification itself did not resolve the question of infringement in the first instance." *Sunovion*, 731 F.3d at 1279-80. Likewise, *Takeda* considered outside-the-label evidence only

because the "label language failed to recommend or suggest" an infringing use, and only then to further support a finding of no infringement. 785 F.3d at 634.[1]

Those holdings are a far cry from concluding, as *Genentech* did, that district courts can permissibly allow evidence on what physicians may do in the future to *supersede* a label that unequivocally recommends an infringing use.

Second, *Genentech*'s rule does not square with the statutory language. Section 271(e)(2)(A) states that it "shall be an act of infringement" to submit an ANDA for a patented drug or drug administration method. Put differently, "the statute explicitly defines the act of infringement as the filing of the ANDA," so "[t]he infringement case is therefore limited to an analysis of whether what the generic drug maker is requesting authorization for in the ANDA would be an act of infringement if performed." *Warner-Lambert Co. v. Apotex Corp*., 316 F.3d 1348, 1364 (Fed. Cir. 2003). The text therefore requires a court to determine whether what is sought in the ANDA would infringe. In answering that question, it may be appropriate to consider extrinsic evidence where the ANDA's text is unclear to determine what is being sought, but there is no basis to consider such evidence when

[1] *Genentech* also relied on *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357 (Fed. Cir. 2017). But *Eli Lilly* involved a divided infringement analysis—requiring actions by both patients and physicians—not at issue in *Genentech* or here. *Eli Lilly*, 845 F.3d at 1365-68. Even if *Eli Lilly* did support *Genentech*'s outside-the-label analysis, that would only further show that this Court's caselaw is conflicted.

the ANDA is clear. And that is the rule that this Court has consistently applied for years.

To be sure, this Court has sometimes stated that Section 271(e)(2) creates only a "jurisdictional basis" to bring patent infringement claims. Under that view, a patentee must still prove infringement under other provisions of Section 271—direct infringement under 271(a), induced infringement under 271(b), and contributory infringement under 271(c)—based on what is likely to occur when the ANDA product is marketed. *Glaxo*, 110 F.3d at 1567-70; *Vanda*, 887 F.3d at 1130. Although it is unnecessary to reconsider those statements to resolve this case given the Court's many unambiguous holdings that a clear ANDA forecloses resort to extrinsic evidence, *see* pp. 6-8, *supra*, it would be open to the en banc Court to do so in order to better align the Court's framework with the text, structure, and legislative history of Section 271(e)(2).

Start with the text. Section 271(e)(2)(A) contains no limitation on the phrase "it shall be an act of infringement" to submit an ANDA for "a drug claimed in a patent or the use of which is claimed in a patent." Nothing suggests that the infringement is for jurisdiction-only purposes. That contrasts markedly with a neighboring subsection, which explicitly grants courts "subject matter jurisdiction" over declaratory-judgment actions brought by filers of paragraph IV certifications to declare a patent invalid or not infringed. 35 U.S.C. § 271(e)(5). It is axiomatic that

"when Congress includes particular language in one section of a statute but omits it in another, [courts] presume[] that Congress intended a difference in meaning." *Digital Realty Tr., Inc. v. Somers,* 583 U.S. 149, 161 (2018) (cleaned up).

More generally, Section 271(e)(2) is listed alongside direct infringement, induced infringement, and contributory infringement (Section 271(a)-(c)) as an independent ground for holding that a patent is infringed, in a U.S. Code section entitled "Infringement of patent." Nothing signals that Section 271(e)(2) is merely jurisdictional, requiring a further substantive analysis under one of the other, facially coequal subsections of Section 271. And Section 271(e)(4) then goes on to list the remedies "[f]or an act of infringement described in [(e)(2)]." That subsection is coherent only if Section 271(e)(2) results in substantive infringement, not merely a jurisdictional hook. Moreover, induced infringement, with its unique burdens and *mens rea* requirement, is a particularly awkward fit for Section 271(e)(2), because that section defines "an act of infringement" by the ANDA applicant—not an act of causing someone else to commit an act of infringement.

In reaching a contrary result, *Glaxo* relied on the statutory provision requiring that an ANDA application's paragraph IV certification state that a patent is "invalid or will not be infringed." *Glaxo*, 110 F.3d at 1569 (quoting 21 U.S.C. § 355(j)(2)(A)(vii)(IV)). But that provision—designed to put patent holders on notice of possible infringement—does not address the requirements for establishing

infringement in litigation. Rather, Section 271(e)(2)(A) addresses that question and deems, as "an act of infringement," submitting "an application under [Section 355(j)] . . . for a drug claimed in a patent or the use of which is claimed in a patent." There is no ambiguity in that congressional directive.

That clear meaning is consistent with the statute's legislative history. The Hatch-Waxman Amendments struck "a balance among the varying interests of research drug firms, generic firms and consumers." *Hearing on S. 2748 Before the S. Comm. on Lab. and Hum. Res.*, 98th Cong. 1 (1984) (statement of Sen. Orrin Hatch, Chairman). That balance allowed generic manufacturers to use patented drugs during the generic's product testing and to submit an ANDA piggy-backing off the brand manufacturer's work. *Warner-Lambert*, 316 F.3d at 1356-59 (summarizing history). The counterweight to those benefits was that it "shall be a *patent infringement* to submit an [ANDA] for a drug claimed, or whose use is claimed, in a patent if [it] is to obtain approval to engage in the commercial manufacture, use, or sale of such a drug before the patent expires." *Drug Price Competition and Patent Term Restoration Act of 1984*, H.R. 3605, 98th Cong. (1984) (emphasis added). That basic tradeoff was codified as Section 271(e)(2)(A) with the submission of the ANDA itself being the act of infringement.

In short, the panel decision and *Genentech* conflict with numerous precedents of this Court and are inconsistent with Section 271. En banc review is warranted.

C. Reasserting the Primacy Of The ANDA Is Exceptionally Important

For two reasons, it is exceptionally important to correct *Genentech*'s departure from this Court's precedents.

First, the Hatch-Waxman Amendments were meant to encourage early resolution of patent-infringement disputes over generic drugs and their uses. *Caraco*, 566 U.S. at 405; *Sunovion*, 731 F.3d at 1279. But by allowing evidence outside the ANDA over the possibility and extent of future infringement, *Genentech* undermines that goal. Indeed, Section 271(e)(2)'s point was to resolve patent-infringement disputes ***before*** the generic enters the marketplace, making it difficult for brand manufacturers to adduce evidence of actual infringement.

Genentech's burden is especially difficult to meet for orphan drugs like Korlym that do not have a large customer base and thus no ready access to direct-infringement evidence. *Genentech* creates a perverse incentive that brand manufacturers may be better off avoiding Hatch-Waxman litigation, waiting for the generic to begin selling, and then suing for conventional patent infringement under Sections 271(a) and (b) when better evidence emerges. That outcome is the opposite of the Hatch-Waxman Amendments' goal.

Second, reaffirming this Court's pre-*Genentech* precedent does not leave generic manufacturers without options when they believe physicians may not prescribe the patent-protected use. On the contrary, they have a readily available

statutory pathway to seek the FDA's approval by carving out the infringing uses from the generic drug's label. *See* pp. 2-3, *supra*; 21 U.S.C. § 355(j)(2)(A)(viii); Op. 9-10.

But when, as here, a generic manufacturer's ANDA seeks approval for the ***entire*** label with uses expressly claimed in a patent and piggy-backs on the brand manufacturer's prior work, the ANDA is binding. It would be incongruous to let the generic manufacturer tell the FDA one thing in its ANDA but then rely on entirely different evidence in ANDA litigation. *Sunovion* and *Par*'s rule avoids that incongruity; *Genentech* promotes it. And by doing so, *Genentech* will discourage brand manufacturers from investing in clinical trials that lead to new treatments.

II. PANEL REHEARING IS WARRANTED BASED ON PRECEDENT PRIOR TO *GENENTECH*

When this Court's panel decisions conflict, "the earlier panel decision controls unless overruled en banc." *Ateliers de la Haute-Garonne v. Broetje Automation USA Inc.*, 717 F.3d 1351, 1358 (Fed. Cir. 2013). Here, the panel held that it was "bound by *Genentech*," but it overlooked that *Genentech* conflicts with earlier precedential decisions discussed in Section I.A. Panel rehearing is appropriate.

CONCLUSION

For these reasons, Corcept respectfully requests that this petition be granted.

Respectfully submitted,

DATED: April 22, 2026

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Attorneys for Appellant Corcept Therapeutics, Inc.

Addendum

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

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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.

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing complies with the word limitation of Fed. R. App. P. 40 (b) because it contains 3,899 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 in 14-point font.

Dated: April 22, 2026

/s/ *John F. Bash*
John F. Bash