No. 26-___

IN THE

Supreme Court of the United States

CORCEPT THERAPEUTICS, INC.,
Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC.,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Under the Hatch-Waxman Amendments, a generic-drug manufacturer may piggy-back off the clinical work of a brand-drug manufacturer by submitting an Abbreviated New Drug Application (ANDA) to the FDA that copies the brand-drug manufacturer's label. But 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). Such an act of infringement entitles the patentee to an order delaying approval of the ANDA until the patent expires. 35 U.S.C. § 271(e)(4)(A).

The question presented is:

Whether a generic-drug manufacturer seeking approval through an ANDA for a drug or drug use claimed by a valid patent can avoid liability for infringement by presenting evidence that infringement is unlikely to occur in the future.

PARTIES TO THE PROCEEDING

Petitioner Corcept Therapeutics, Inc. was the plaintiff in the district court and the appellant in the Federal Circuit. Corcept's stock ticker symbol is "CORT" (NASDAQ: CORT).

Respondent Teva Pharmaceuticals USA, Inc. was the defendant in the district court and the appellee in the Federal Circuit. Teva's stock ticker symbol is "TEVA" (NYSE: TEVA).

RULE 29.6 DISCLOSURE STATEMENT

Petitioner Corcept Therapeutics, Inc. has no parent corporation. BlackRock, Inc., a publicly held corporation, owns 10% or more of its stock.

RELATED PROCEEDINGS

U.S. District Court for the District of New Jersey:

Corcept Therapeutics, Inc. v. Teva Pharmaceuticals USA, Inc., No. 1:18-cv-3632 (Dec. 29, 2023).

U.S. Court of Appeals for the Federal Circuit:

Corcept Therapeutics, Inc. v. Teva Pharmaceuticals USA, Inc., No. 2024-1346 (Feb. 19, 2026), rehearing denied (July 10, 2026).

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PETITION FOR WRIT OF CERTIORARI

Petitioner Corcept Therapeutics, Inc. respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

INTRODUCTION

This petition seeks this Court's review of the Federal Circuit's longstanding misinterpretation of the Hatch-Waxman Amendments—one of the U.S. Code's most important provisions for fostering drug innovation. Although that misinterpretation dates back to 1997, its practical consequences were limited until the 2022 decision in *Genentech, Inc. v. Sandoz Inc.*, 55 F.4th 1368 (Fed. Cir. 2022), which all but erased the Amendments' central procedural mechanism for protecting drug innovators from infringing generic drugs.

The Hatch-Waxman Amendments allow a patent owner to sue for infringement before the FDA approves a generic drug to be marketed in the United States. Congress amended the infringement provision of the Patent Act, 35 U.S.C. § 271, by adding a subsection (e) stating that it "shall be an act of infringement to submit" an application for approval for a generic drug "claimed in a patent or the use of which is claimed in a patent." 35 U.S.C. § 271(e)(2)(A). That act of infringement entitles the patentee to an order delaying FDA approval of the generic drug until the patent expires. 35 U.S.C. § 271(e)(4)(A).

As the text states and this Court has affirmed repeatedly, Section 271(e)(2)(A) defines the *act of infringement* as filing an abbreviated new drug application (ANDA) that seeks approval for a drug or

drug use that infringes a valid patent. Establishing infringement under Section 271(e)(2)(A)—and obtaining an order delaying approval of the generic drug—thus requires no more than determining whether the ANDA applicant seeks approval for a drug or drug use that infringes a valid patent.

In 1997, however, the Federal Circuit inexplicably held that Section 271(e)(2)(A) is merely "jurisdictional" in that it "provide[s] patentees with a defined act of infringement sufficient to create case or controversy jurisdiction," but that act of infringement does not itself establish the ANDA applicant's liability or entitle the patentee to any remedy. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). Rather, according to the Federal Circuit, to obtain a judgment and remedy, the patentee must further prove that the defendant "will likely market an infringing product" if the drug is approved under the standards that govern other forms of infringement, which depends on a "hypothetical inquiry" about the future. *Id.* at 1569-70.

The Federal Circuit has never provided a coherent textual basis for that view. Its reading adds an element that Section 271(e)(2)(A) does not contain. It treats as "jurisdictional" a provision that never mentions jurisdiction, even though Congress conferred "subject matter jurisdiction" over a different cause of action a few lines later, in Section 271(e)(5). And the Federal Circuit has refused to change its position even after this Court recognized that the Section 271(e)(2)(A) "act of infringement" is a "merits" issue, "not a jurisdictional one." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 412 n.5 (2012).

For decades, however, the Federal Circuit's erroneous interpretation had limited practical reach because a line of Federal Circuit cases had held that where the ANDA unambiguously covers an infringing drug or use, liability is established. See, *e.g.*, *Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1278-79 (Fed. Cir. 2013). But in 2022, *Genentech* held that even when the ANDA clearly covers a method claimed by a valid patent, the defendant can escape liability by pointing to evidence that physicians would not likely practice the patented methods in the future. 55 F.4th at 1378-81. That eviscerates the statutory scheme. Congress intended brand-drug manufacturers to have a streamlined process to delay approval of generic-drug applications claiming a patented drug or use, based on what the ANDA covers and any evidence about the drug's characteristics or how physicians would understand the label. But under the Federal Circuit's approach, brand-drug manufacturers must further prove hypothetical future infringement to obtain a remedy by speculating about whether physicians will employ the methods described on the drug's label in practice were the drug approved.

To compound the problem, the Federal Circuit now has two irreconcilable lines of precedent on whether an unambiguous ANDA alone can establish (or defeat) infringement liability. And it has refused to grant en banc review to rectify the conflict.

Only this Court can now correct that error. It has repeatedly done so when the Federal Circuit has engrafted requirements onto the Patent Act that its text does not contain. See, *e.g.*, *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915, 921-23 (2014);

Octane Fitness, LLC v. ICON Health & Fitness, Inc., 572 U.S. 545, 555 (2014); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391-94 (2006).

This case presents an ideal vehicle to restore the procedural scheme that Congress enacted. In the decision below, the Federal Circuit affirmed the denial of an infringement judgment, despite an unambiguous ANDA covering petitioner's patented methods, because it was "bound by *Genentech*." App.12a. This case therefore squarely presents the question whether *Genentech* properly construed Section 271(e)(2)(A).

The importance of the issue cannot be overstated. *Genentech* provides a blueprint for generic manufacturers to seek regulatory approval to market a drug for a patented use, only to escape liability by telling a court that no physician will actually practice the very method for which it is seeking approval. That renders the Hatch-Waxman scheme all but useless to patentees. And the impact may be most harmful for developing so-called "orphan drugs"—such as the drug at issue in this case—that treat rare diseases. For those drugs, evidence of real-world use is often limited, making it particularly difficult for patentees to prove what will likely happen in the future if the generic drug is marketed. That will in turn reduce incentives to develop these lifesaving drugs in the first place.

The Court should accordingly grant review.

OPINIONS BELOW

The Federal Circuit's opinion is unreported. App.3a-13a. The Federal Circuit's order denying en banc review is unreported. App.1a-2a. The district

court's opinion is reported at 709 F. Supp. 3d 138. App.16a-63a. The district court's judgment is unreported. App.14a-15a.

JURISDICTION

The Federal Circuit entered judgment on February 19, 2026. App.3a-13a. The court denied a timely petition for panel rehearing and rehearing en banc on July 10, 2026. App.1a-2a. On August 31, 2026, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including November 9, 2026. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Section 271(e) of Title 35 provides in relevant part:

> (2) It shall be an act of infringement to submit—
>
> > (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act * * * for a drug claimed in a patent or the use of which is claimed in a patent * * *
>
> if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug * * * claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.
>
> * * *
>
> (4) For an act of infringement described in paragraph (2)—

> (A) the court shall order the effective date of any approval of the drug * * * involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed[.]

Other pertinent statutory provisions are reproduced in the appendix to this petition. See App.64a-75a.

STATEMENT

A. Statutory Background

1. Before a new drug may be sold in the United States, its manufacturer must obtain approval from the Food and Drug Administration (FDA) by filing a new drug application (NDA). The NDA must include "(1) reports setting forth sufficient information to establish the drug's safety and efficacy for its intended uses; (2) 'the labeling proposed to be used for such drug'; and (3) the relevant drug patents, whether they protect the drug itself or the manufacturer's exclusive rights over a particular 'method of using such drug.'" *Hikma Pharms. USA Inc. v. Amarin Pharma, Inc.*, 608 U.S. 580, 584 (2026) (quoting 21 U.S.C. § 355(b)(1)(A)(i), (vi) and (viii)). The FDA publishes the listed patents in a volume known as the Orange Book. *Id.* at 585.

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Amendments, enables a competitor to market a generic version without repeating that work. Pub. L. No. 98-417, 98 Stat. 1585. A generic manufacturer may "file an abbreviated new drug application

(ANDA) piggy-backing on the brand's NDA." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 404-05 (2012); see 21 U.S.C. § 355(j). Rather than furnishing independent evidence of safety and efficacy, "the typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug," *Caraco*, 566 U.S. at 405, which lets the applicant "avoid the costly and time-consuming studies required for a pioneer drug," *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990); see 21 U.S.C. § 355(j)(2)(A)(ii), (iv). Subject to exceptions not relevant here, an ANDA's proposed labeling must be "the 'same' as the brand-name labeling." *Hikma*, 608 U.S. at 588 (quoting 21 U.S.C. § 355(j)(2)(A)(v)).

2. An ANDA applicant must also address the patents listed in the Orange Book, because "the FDA cannot authorize a generic drug that would infringe a patent." *Hikma*, 608 U.S. at 585. While the listed patents remain in force, the ANDA applicant has two choices.

First, the applicant may file 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.'" *Caraco,* 566 U.S. at 407 (quoting 21 U.S.C. § 355(j)(2)(A)(vii)(IV)) (alteration in *Caraco*). If the applicant is wrong about that—if the patent is valid and claims a drug or use for which the applicant seeks approval—the Patent Act defines filing the ANDA itself as an act of patent infringement. Section 271(e)(2)(A) states 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" where "the purpose of such submission is to obtain approval

* * * to engage in the commercial manufacture, use, or sale" of that drug or use before the patent expires.

As a result, when the applicant files an ANDA with a paragraph IV certification, the brand-drug manufacturer will often sue for infringement in federal district court. Filing such an action generally stays the FDA's approval of the ANDA until 30 months pass or until the court finds the patent invalid or not infringed, whichever comes first. *Caraco*, 566 U.S. at 407 (citing 21 U.S.C. § 355(j)(5)(B)(iii)). If the district court concludes that filing the ANDA constituted an "act of infringement" under Section 271(e)(2)(A), the Patent Act provides that "the court shall order the effective date of any approval of the drug * * * involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed." 35 U.S.C. § 271(e)(4)(A). The Act also provides that a court may grant injunctive relief against the commercialization of an approved drug and damages for past commercialization of an approved drug. 35 U.S.C. § 271(e)(4)(B) and (C).

Second, when the applicant believes that method patents are implicated, under certain circumstances, it may instead file a "section viii statement" asserting "that the generic manufacturer will market the drug for one or more methods of use not covered by the brand's patents," and propose a "skinny label" that "'carves out' from the brand's approved label the still-patented methods of use." *Hikma*, 608 U.S. at 585 (quoting *Caraco*, 566 U.S. at 406, and citing 21 U.S.C. § 355(j)(2)(A)(viii)). By taking this route, the generic manufacturer can obtain approval without the 30-month delay that a paragraph IV certification typically entails.

B. Factual Background

1. Cushing's syndrome is a rare endocrine disorder caused by hypercortisolism (overproduction of cortisol). App.23a-24a. Petitioner developed Korlym®, a mifepristone product that reduces the effects of hypercortisolism. In 2012, the FDA approved it to treat Cushing's syndrome. App.27a. Korlym is an "orphan drug" because it treats a condition affecting fewer than 200,000 people in the United States. 21 U.S.C. § 360bb(a)(2); 21 C.F.R. § 316.3. As of 2023, about 1,500 patients were taking Korlym. App.27a-28a.

Cushing's patients are often prescribed strong CYP3A inhibitors, which suppress the enzymes that metabolize mifepristone. It was expected that taking the two together could raise mifepristone levels in the blood to unsafe levels and cause serious harm. App.24a-26a. Accordingly, the FDA required petitioner, as a condition of approval, to study the coadministration of mifepristone and strong CYP3A inhibitors. App.28a.

Those studies yielded an unexpected result: Coadministration produced only a small increase in mifepristone levels such that a physician can safely administer up to 900 mg of mifepristone with a strong CYP3A inhibitor. App.30a. Petitioner obtained two U.S. patents claiming the resulting dosing regimens, U.S. Patent Nos. 10,195,214 (the '214 patent) and 10,842,800 (the '800 patent). App.18a, 30a-31a, 35a-37a. And in November 2019, petitioner secured FDA approval to revise Korlym's label consistent with the claimed methods by raising the ceiling on coadministration from 300 mg to 900 mg and adding a new

subsection setting out dosing instructions for coadministration:

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

App.6a-8a; see also App.32a.

In December 2017, respondent had filed an ANDA seeking approval of a generic version of Korlym. App.37a-38a. Its proposed product label is "identical in all material respects to Korlym's revised 2019 label." App.9a. Respondent did not seek a label carving out petitioner's patented coadministration uses under section viii. Instead, it filed a paragraph IV certification asserting that petitioner's patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of respondent's generic drug. App.13a, 86a-87a.

2. Petitioner asserted the '214 and '800 patents against respondent in two suits in the District of New Jersey, which the court consolidated with an earlier action between the parties involving patents no longer at issue. App.98a-100a; App.101a-106a. In each suit and consistent with Federal Circuit precedent,

petitioner alleged that respondent's submission of its ANDA "constitutes infringement * * * under 35 U.S.C. § 271(e)(2)(A)," that such infringement created a "justiciable controversy," and that unless enjoined, respondent would directly and indirectly infringe the patents when it marketed the generic drug, in violation of Sections 271(a), (b), and (c). App.89a-90a (¶¶ 55-59) ('214 complaint); App.93a (¶¶ 39-42) ('800 complaint). This framing was necessary because under *Glaxo*, *supra*, and other Federal Circuit precedent, Section 271(e)(2)(A) creates a mere jurisdictional hook to assert infringement under other patent-infringement provisions based on what might happen in the future. Petitioner sought "[a]n Order that the effective date of FDA approval of ANDA No. 211436 be a date no earlier than the later of the expiration of each patent-in-suit, or any later expiration of exclusivity to which Corcept is or becomes entitled." App.90a-91a; accord App.95a.

Petitioner moved for summary judgment on the '214 patent (before the '800 patent was asserted), arguing that respondent's proposed label "plainly instruct[s] a physician to perform each and every step of the methods claimed in the '214 Patent" and "does not provide any conflicting or alternate dosing regimens," so that the court could find, "without the need for trial," that respondent "will induce infringement." App.108a, 110a, 113a. The district court denied the motion, deeming it necessary to hear expert testimony about the label's dosing regimens. App.18a.

The district court held a bench trial. In post-trial briefing on both patents, petitioner argued that the expert testimony "uniformly demonstrates" that respondent's label instructs physicians to perform the

patented methods. App.39a. The district court nevertheless found that petitioner's infringement claims failed because petitioner had not established the elements of induced infringement. App.14a, 19a, 39a-63a. For such a claim, the district court required petitioner to prove (1) direct infringement, *i.e.*, that if respondent's generic product were put on the market, it would infringe, and (2) that respondent "possessed the specific intent to encourage another's infringement." App.38a. As to direct infringement, the court—relying on the Federal Circuit's opinion in *Genentech*—rested on evidence outside the proposed label that the court believed demonstrated that physicians would not practice the claimed methods in the future. App.45a-55a (citing *Genentech*, 55 F.4th at 1379-80). The district court separately found that respondent lacked the specific intent to induce infringement. App.55a-63a.

3. On appeal, the Federal Circuit recognized that petitioner's patents are based on the discovery that a physician can "coadminister up to 900 mg of mifepristone with a strong CYP3A inhibitor," App.6a, and that petitioner's 2019 revised label "expressly instructs dosing with up to 900 mg of mifepristone along with a strong CYP3A inhibitor." App.8a. The court further observed that respondent's proposed label was "identical in all material respects to" petitioner's revised label. App.9a.

Despite those facts, the Federal Circuit affirmed the district court's no-direct-infringement finding. The court stated 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." App.12a. On that view, even though Section 271(e)(2)(A) states that filing the ANDA is the act of infringement, a brand-drug manufacturer must still prove that "if a particular drug *were* put on the market" in a "hypothetical" future, "it *would* infringe the relevant patent." App.12a (quotation marks omitted).

Because the court affirmed the no-direct-infringement finding, it did not address specific intent. App.13a.

Petitioner sought panel rehearing and rehearing en banc, arguing that the ANDA controls the infringement analysis and that Section 271(e)(2)(A) creates substantive liability rather than serving as a mere jurisdictional hook. Petitioner asked the court to reconsider its precedents in *Genentech* and *Glaxo*. App.119a-122a. The court of appeals called for a response in less than 24 hours but then denied the petition. App.1a-2a.

REASONS FOR GRANTING THE PETITION

The Patent Act provides that "[i]t 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," entitling the patentee to an order delaying approval of the ANDA until the patent expires. 35 U.S.C. § 271(e)(2)(A), (4)(A). Yet in *Genentech*, *supra*, the Federal Circuit held that such a statutorily defined "act of infringement" does not entitle a plaintiff to that remedy unless the plaintiff can also prove that direct or indirect infringement under other provisions of Section 271 is likely to occur in the future if the generic drug "were put on the market." 55 F.4th at 1379 (quotation marks omitted); see App.12a.

That holding has no basis whatsoever in the statute's text and contradicts this Court's precedents. It stems from a longstanding error of statutory interpretation in which the Federal Circuit deemed the "act of infringement" in Section 271(e)(2)(A) merely a jurisdictional hook to establish a "case or controversy," not a liability-creating event, even though this Court has rejected that very interpretation. *Caraco*, 566 U.S. at 412 n.5. Moreover, *Genentech* has sown confusion within the Federal Circuit's own jurisprudence, because an earlier line of cases held that outside-the-label evidence cannot absolve a defendant from liability where an ANDA unambiguously covers a patented drug or use.

The Federal Circuit's conflicted and erroneous precedent in this area has had a disruptive impact on one of the U.S. Code's most important provisions for protecting drug innovation. This is a prototypical case for this Court's resolution to ensure that U.S. patent laws conform to the statutes that Congress enacted.

I. Infringement Liability Under Section 271(e)(2)(A) Does Not Depend On The Likelihood Of Future Infringement

Section 271(e)(2)(A) establishes that submitting an ANDA seeking approval for a drug or drug use that infringes a valid patent is an act of infringement that entitles the plaintiff to an order delaying approval of the ANDA until the patent expires. The Federal Circuit's contrary reading—that Section 271(e)(2)(A) merely confers jurisdiction on a federal court and a plaintiff must prove likely future infringement under another subsection of Section 271 to prevail—is incorrect.

A. Under Section 271(e)(2)(A), "it shall be an act of infringement to submit * * * an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [an ANDA] * * * for a drug claimed in a patent or the use of which is claimed in a patent." That sentence is not ambiguous. Submitting an ANDA seeking approval for a drug or method claimed by a valid patent is itself an "act of infringement," 35 U.S.C. § 271(e)(2)(A), *i.e.*, "[a]n act that interferes with one of the exclusive rights of a patent * * * owner," *Infringement*, BLACK'S LAW DICTIONARY (12th ed. 2024).

For that reason, to determine whether an act of infringement has occurred under Section 271(e)(2)(A), a court need only determine whether the application seeks approval for a drug or use covered by a valid patent. For a drug, that requires identifying what drug the ANDA covers and determining whether it meets every limitation of at least one claim of a patent, an inquiry that may require evidence about the characteristics of the drug. Likewise, for a drug use, a court must examine the ANDA's proposed label to determine what use is recommended and whether it meets the limitations of at least one claim of a valid method patent, which can be aided by evidence about how physicians would understand the label's statements.

The required remedy for that defined act of infringement is equally clear. Subsection (e)(4)(A) states that "[f]or an act of infringement described in paragraph (2) * * * the court *shall* order the effective date of any approval of the drug * * * involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed" (emphasis added). In other words, a court

must delay FDA approval if submitting the ANDA is "an act of infringement" under Section 271(e)(2)(A).

Those two provisions leave no doubt as to what Congress intended. If an applicant submits an ANDA seeking FDA approval for a drug or drug use that infringes a valid patent, the court must issue an order delaying approval of the ANDA until the patent expires (subject to the affirmative defense of patent invalidity, 35 U.S.C. § 282(b)(2), (3)). Nothing in the statute's text turns on whether the patent is likely to be infringed in the future or whether the requirements for other forms of infringement are met. Courts "ordinarily resist reading words or elements into a statute that do not appear on its face." *Bates v. United States*, 522 U.S. 23, 29 (1997).

Nor does anything in the text suggest that the Section 271(e)(2)(A) "act of infringement" is merely jurisdictional, *i.e.*, that it provides a basis to invoke a federal court's power but does not itself establish liability for infringement. Section 271(e)(2)(A) never mentions jurisdiction and lacks any language "demarcat[ing] a court's power." *Riley v. Bondi*, 606 U.S. 259, 274 (2025) (quoting *Harrow v. Dep't of Def.*, 601 U.S. 480, 484 (2024)). Rather, it defines a particular "act of infringement"—the unmistakable language of liability, not jurisdiction.

B. The structure of Section 271 confirms the plain-text reading. Section 271(e)(2) is listed alongside direct infringement, induced infringement, and contributory infringement (Section 271(a)-(c)) as an independent ground of infringement, 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, about what would likely happen if the drug were put on the market.

Congress also showed, in the same subsection, that it knew how to speak in jurisdictional terms when it wished. Section 271(e)(5) expressly confers "subject matter jurisdiction" over declaratory-judgment actions brought by an ANDA filer whom the patent owner has declined to sue. Section 271(e)(2)(A), by contrast, "does not speak in jurisdictional terms or refer in any way to the jurisdiction of the district courts," *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 515 (2006) (quoting *Zipes v. Trans World Airlines, Inc.*, 455 U.S. 385, 394 (1982)).

In addition, Section 271(e)(4) supplies remedies "[f]or an act of infringement described in paragraph (2)." Jurisdictional provisions do not come with their own remedies. And those remedies are exclusive: They "are the only remedies which may be granted by a court for an act of infringement described in paragraph (2)," apart from attorney's fees. 35 U.S.C. § 271(e)(4).

Further, when Congress wants liability to turn on what would happen in a hypothetical world, it says so. For instance, Section 271(f)(1) reaches a supplier that ships components of a patented invention abroad for assembly. Because assembly occurs outside the United States, no infringement happens here. So Congress wrote the counterfactual into the text: The supplier is liable if it induces the components to be combined "in a manner that *would infringe* the patent if such combination occurred within the United

States." 35 U.S.C. § 271(f)(1) (emphasis added). Section 271(e)(2)(A) contains no comparable condition relating to future infringement were the ANDA approved. And "when Congress includes particular language in one section of a statute but omits it in another, this Court presumes that Congress intended a difference in meaning." *Digital Realty Tr., Inc. v. Somers*, 583 U.S. 149, 161 (2018) (cleaned up).

Finally, the Federal Circuit's approach ignores that Congress already provided the mechanism for a generic manufacturer that does not intend to recommend the patented use. The manufacturer may, in certain circumstances, file a section viii statement and propose a label carving out the patented method. 21 U.S.C. § 355(j)(2)(A)(viii); see *Caraco*, 566 U.S. at 406. The Federal Circuit said as much below, observing that "this suit could have been avoided had [respondent] filed a 'section viii carveout.'" App.13a. The generic manufacturer that instead opts for a paragraph IV certification "wagers that it will eventually be able to 'market its drug for all approved uses,' not just the unpatented ones." *Hikma*, 608 U.S. at 585 (quoting *Caraco*, 566 U.S. at 408). The Federal Circuit's approach distorts that scheme of statutory tradeoffs.

C. This Court has consistently confirmed that Section 271(e)(2)(A) alone establishes liability for patent infringement. In the Court's first decision addressing the Hatch-Waxman Amendments, *Eli Lilly*, *supra*, it explained that because Section 271(e)(1) sets a default rule that immunizes an ANDA from any pre-market infringement claim, "an act of infringement had to be created for the[] ANDA[s]" containing a paragraph IV "certification that is in error." 496 U.S. at 678.

"[T]hat is what is achieved by § 271(e)(2)." *Id.* Although that act of infringement is "highly artificial," it is still the "defined act of infringement." *Id.* And it is artificial only in the sense that, unlike other claims of patent infringement, no "commercial manufactur[ing], use, or sale of the new drug" has "actually occurred." *Id.*

Since *Eli Lilly*, this Court has repeatedly reaffirmed that Section 271(e)(2) makes submitting the ANDA for a patented drug or drug use the liability-producing act of infringement. For instance, this past Term, in *Hikma*, *supra*, the Court explained that filing an ANDA with a paragraph IV certification "is an act of infringement under patent law." 608 U.S. at 585. The Court said the same in *Caraco,* explaining that Section 271(e)(2) treats filing an ANDA with a paragraph IV certification "as itself an act of infringement." 566 U.S. at 407. And in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013), this Court explained that taking the "paragraph IV route * * * automatically counts as patent infringement." *Id.* at 143. All of those statements confirm that the statutory text does not require a plaintiff to prove likely future infringement under a different subsection of Section 271.

More to the point, *Caraco* made clear that Section 271(e)(2)(A) is not jurisdictional. There, the generic manufacturer had first filed a paragraph IV certification, then changed to a section viii statement. In this Court, the brand-drug manufacturer argued that the federal courts had lost subject-matter jurisdiction over the Section 271(e)(2)(A) action and the generic manufacturer's counterclaim because the section viii statement was not an act of infringement under Section 271(e)(2)(A). This Court rejected that argument:

> The want of an infringing act is a merits problem, not a jurisdictional one. Nothing in [Section 271(e)(2)] defining certain filings as acts of infringement suggests anything to the contrary.

566 U.S. at 412 n.5. The Court added that it was "not inclined to interpret statutes as creating a jurisdictional bar when they are not framed as such." *Id.* (quoting *Stern v. Marshall*, 564 U.S. 462, 480 (2011)). And it identified the actual jurisdictional basis of the action—the suit "arose under an Act of Congress relating to patents." *Id.* (quoting 28 U.S.C. § 1338(a)) (brackets omitted).

D. In short, Section 271(e)(2)(A)'s text, the broader statutory structure, and this Court's precedents point in one direction: Submitting an ANDA seeking approval for a patented drug or method alone qualifies as an act of infringement entitling the plaintiff to a delay in FDA approval of the drug. That analysis simply asks whether the ANDA seeks FDA approval "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). It does not require evaluating the likelihood of future infringement were the drug approved.

To be sure, evidence from outside the ANDA can often be relevant to the inquiry required by the statute. For example, the ANDA might not disclose characteristics of the generic drug that are relevant to whether it is "a drug claimed in a patent." *Id.* If not, the plaintiff may bring forward that evidence to prove liability. *E.g.*, *Ferring B.V. v. Watson Labs., Inc.-Fla.*, 764 F.3d 1401, 1409 (Fed. Cir. 2014). Similarly, the language describing a use for which the ANDA seeks

FDA approval might not track the language of a method patent verbatim. In that case, the plaintiff could introduce evidence of how a reasonable practitioner would understand the ANDA's description of the use. Other circumstances may also require evidence and factfinding.

But the statutory standard is whether the applicant has filed 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), not whether infringement is likely to occur in the future if the drug is approved. Thus, for example, evidence that physicians would not practice the use for which approval is sought because they would prefer alternative treatments—the sort of evidence that the Federal Circuit credited here, App.11a-13a—is irrelevant.

II. The Federal Circuit's Precedent Is Wrong And Internally Inconsistent

In *Genentech*, *supra*, the Federal Circuit erroneously held that even where an ANDA recommends an infringing method, a defendant can avoid infringement liability—and the remedy of a delay in approval—if the plaintiff fails to establish that the patented method will likely be performed if the drug is approved. 55 F.4th at 1379-81. That holding conflicts with the text and structure of Section 271(e)(2)(A) and this Court's precedent described above. And it stems from a longstanding error of statutory interpretation in which the Federal Circuit has construed Section 271(e)(2)(A) as merely a "jurisdictional" statute rather than one imposing infringement liability.

Genentech also conflicts with a line of Federal Circuit precedent holding that where an ANDA *unambiguously* recommends an infringing use, the plaintiff has established liability, regardless of any outside-the-label evidence. Those authorities had served to mitigate the worst effects of the Federal Circuit's erroneous jurisdictional interpretation of Section 271(e)(2)(A), but *Genentech* has thrown even that backstop into doubt. Yet the Federal Circuit has refused to grant en banc review to clarify its precedent. This Court should thus intervene.

A. Beginning with *Glaxo, supra*, the Federal Circuit has held that the act of filing an ANDA described in Section 271(e)(2)(A) provides only a "jurisdictional basis" to bring a lawsuit. 110 F.3d at 1569. "Once jurisdiction is established, however, the substantive determination whether actual infringement or inducement will take place is determined by traditional patent infringement analysis" under other provisions of Section 271, "the only difference being that the inquiries now are *hypothetical* because the allegedly infringing product has not yet been marketed." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365 (Fed. Cir. 2003) (emphasis added) (citing *Glaxo*, 110 F.3d at 1567). Based on that erroneous interpretation of Section 271(e)(2)(A), the Federal Circuit has held that the proper inquiry "is whether, if a particular drug *were* put on the market, it *would* infringe the relevant patent" under traditionally defined acts of infringement, such as induced infringement, 35 U.S.C. § 271(b). *Id.* (quotation omitted) (emphasis in original); see *Glaxo*, 110 F.3d at 1569-70; see also *Novartis Pharms. Corp. v. Watson Labs., Inc.*, 611 F. App'x 988, 997 (Fed. Cir. 2015) (similar).

As explained above, that construction is clearly wrong and conflicts with *Caraco* and other precedents of this Court. And the Federal Circuit has never articulated a plausible justification for it. Its only real defense came in *Glaxo*. There, the court reasoned that because a paragraph IV certification asserts that the patent "*will not be infringed* by the manufacture, use, or sale of the drug," a Section 271(e)(2) suit must ask "whether, if the drug were approved based upon the ANDA, the manufacture, use, or sale of that drug would infringe the patent in the conventional sense." *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 submitting an ANDA "for a drug claimed in a patent or the use of which is claimed in a patent" to be "an act of infringement." There is no ambiguity in that congressional directive.

Glaxo also leaned on this Court's description in *Eli Lilly*, *supra*, of the infringing act as "artificial." 110 F.3d at 1569 (quotation omitted). But "artificial" is not a jurisdictional term. As explained, this Court used it to distinguish Section 271(e)(2)(A) from ordinary infringement claims, which focus on products that actually exist. See pp. 18-19, *supra*. The Federal Circuit took a word intended to set Section 271(e)(2)(A) apart from other infringement provisions and used it to build a hypothetical, future-focused framework that reduces Section 271(e)(2)(A) to a mere jurisdictional gateway to Sections 271(a) through (c). That gets *Eli Lilly* backwards.

B. Previously, the Federal Circuit's erroneous jurisdictional construction of Section 271(e)(2)(A) had limited effect because the court had treated the ANDA as controlling when it unambiguously covered a patented drug or method. Only where the ANDA was ambiguous as to whether it covered a patented drug or method did the court hold that the lack of evidence of future infringement could defeat a Section 271(e)(2)(A) claim.

For example, in *Sunovion*, *supra*, 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. It nonetheless certified before the district court that it would make and sell only noninfringing 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.*

The Federal Circuit 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." 731 F.3d 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 Federal Circuit rejected the defendant's reliance on its "certification," stating that what the defendant "has asked the FDA

to approve * * * determines whether infringement will occur." *Id.* at 1278-79.

Likewise, in *Par Pharmaceutical, Inc. v. Eagle Pharmaceuticals, Inc.*, 44 F.4th 1379 (Fed. Cir. 2022), the Federal Circuit reaffirmed that the infringement "inquiry is controlled by the ANDA specification." *Id.* at 1383. It explained that 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.*, evidence outside the ANDA, 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 the scope of [the patent] claims." *Id.*

Multiple other Federal Circuit cases have applied the same rule. See *Vanda Pharms., Inc. v. W.-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1130 (Fed. Cir. 2018), *cert. denied*, 589 U.S. 1132 (2020); *Ferring*, 764 F.3d at 1408; *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1379 (Fed. Cir. 2012); *Bayer AG v. Elan Pharm. Rsch. Corp.*, 212 F.3d 1241, 1250 (Fed. Cir.), *cert. denied*, 531 U.S. 993 (2000).

In each of the Federal Circuit decisions before *Genentech* that looked beyond the ANDA, the ANDA left infringement unresolved. For instance, in *Ferring*, the court looked to evidence outside the ANDA only because the ANDA did "not resolve infringement in the first instance." 764 F.3d at 1409. Likewise,

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 (describing *Glaxo*).

Consistent with the text of Section 271(e)(2)(A), which applies equally to patented drugs and patented drug uses, the Federal Circuit has applied this framework to drug-method patents, not just drug-formulation patents. For example, in *Vanda*, *supra*, the court held that the district court's "analysis of the proposed label to assess potential direct infringement by physicians was proper," given its "factual findings that the proposed label recommended that physicians perform the claimed steps." 887 F.3d at 1130 (cleaned up). The court relied on 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*, *supra*, another method-patent case, the Federal Circuit 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).

This line of precedent limited the practical reach of the Federal Circuit's foundational error in construing Section 271(e)(2)(A) as jurisdictional. Because the circuit held that the ANDA still controlled the infringement inquiry when it unambiguously covered a patented drug or method, in many cases the result was the same as it would be had the circuit correctly

construed Section 271(e)(2)(A) as a liability-defining provision.

C. Then came *Genentech*. In that 2022 decision, the Federal Circuit for the first time held that even where the ANDA clearly recommends an infringing use, the plaintiff still must establish that infringement would likely occur in the future should the drug be approved.

In *Genentech*, the district court had held that a proposed 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." *Genentech*, 55 F.4th at 1375. The Federal Circuit affirmed in a divided decision. *Id.* at 1370. It stated that determining whether a product "*would*" infringe once "put on the market" requires consideration of "all the relevant evidence," including the proposed label's instructions and physician practice. *Id.* at 1379 (emphasis added). It therefore held that the district court "did not clearly err by considering physician evidence, *weighing it against the language in [the defendant's] proposed label*, and finding that [the plaintiff] failed to prove direct infringement." *Id.* at 1380 (emphasis added).

Genentech rested that view on *Glaxo*'s jurisdictional-hook framing, stating that "the filing of an ANDA before a patent covering a compound or a use expires meets the technical jurisdictional requirement of infringement," but proving actual infringement requires a showing that "*if* a particular drug *were* put on the market, it *would* infringe the relevant patent." 55

F.4th at 1379 (emphasis added). Judge Newman dissented without opinion. *Id.* at 1370.

Thus, in *Genentech*, the Federal Circuit's longstanding misconstruction of Section 271(e)(2)(A) produced an extreme rule: Because the Federal Circuit believes that submitting an ANDA seeking approval for a drug or drug use covered by a valid patent does not itself create infringement liability—even though the statute defines such a submission as an "act of infringement"—even an *unambiguous* label can be trumped by a judicial prediction that the method will not be infringed if the label is approved.

That approach not only conflicts with the plain text and structure of Section 271(e)(2)(A) and this Court's precedents, see pp. 14-21, *supra*, but it creates a conflict in the Federal Circuit's own precedent. As explained, see pp. 24-27, *supra*, numerous precedential decisions of that court hold that an unambiguous ANDA resolves the infringement question. But *Genentech* upends that previously settled rule, throwing the Federal Circuit's caselaw into confusion and opening the floodgates to the sort of mischief that earlier cases had largely contained.

D. The Federal Circuit panel here, emphasizing that it was "bound by *Genentech*," App.12a, again allowed outside-the-label evidence of a hypothetical future to relieve a defendant of liability even though the ANDA seeks approval of a label recommending an infringing method. In fact, it recognized that petitioner's patents protect "coadminister[ing] up to 900 mg of mifepristone with a strong CYP3A inhibitor." App.6a. It acknowledged that petitioner's 2019 revised label "expressly instructs dosing with up to 900

mg of mifepristone along with a strong CYP3A inhibitor." App.8a. And it recognized that respondent's proposed label was "identical in all material respects to" petitioner's revised label. App.9a.

Under the plain text of Section 271(e)(2)(A) and this Court's precedent, as well as the Federal Circuit's pre-*Genentech* precedent, that should have been the end of the analysis. The ANDA seeks approval for a label with an infringing use, so respondent committed an "act of infringement" under Section 271(e)(2)(A). Yet the Federal Circuit discerned no clear error in the district court's noninfringement finding based on evidence that physicians had not practiced and would not practice the claimed methods, in part because of asserted safety concerns with the methods and the existence of a noninfringing alternative treatment. App.11a-13a. It reached that holding because it believed 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*." App.12a (emphasis added). That directly applied *Genentech*'s erroneous direction that "[d]etermining what will, or would, happen when a product enters the market requires consideration of all the relevant evidence, including the proposed label's instructions and physician practice." *Genentech*, 55 F.4th at 1379 (quotation omitted).

* * *

The Federal Circuit's muddled jurisprudence in this important area warrants this Court's review. The Federal Circuit has committed two related errors: in the first instance, construing Section 271(e)(2)(A) as

jurisdictional, and then producing conflicting lines of precedent on whether an ANDA that clearly seeks approval for a patented drug or method alone establishes infringement. Petitioner sought rehearing en banc, but even though the Federal Circuit called for a response in less than 24 hours, it declined to grant review to clarify and correct its jurisprudence. This Court should accordingly grant review.

III. The Question Presented Is Exceptionally Important And Cleanly Presented In An Ideal Vehicle

A. The question presented has exceptionally important implications for the regulatory system put in place by the Hatch-Waxman Amendments.

The Amendments were meant to strike "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 development and testing and to submit an ANDA piggy-backing off the brand-drug manufacturer's work without infringing the brand-drug manufacturer's patents. See 35 U.S.C. § 271(e)(1); *Caraco*, 566 U.S. at 404-05. But should the generic manufacturer go further and seek to bring to market a drug or drug use during a patent's life, it must file a paragraph IV certification stating the patent is invalid or will not be infringed, *Eli Lilly*, 496 U.S. at 678, or carve out infringing uses through a section viii statement, *Caraco*, 566 U.S. at 406. A paragraph IV certification entitles a brand-drug manufacturer to sue under Section 271(e)(2)(A). *Eli Lilly*,

496 U.S. at 678. And the whole point of this scheme was to "address [infringement] earlier, generally before ANDA approval." *Sunovion*, 731 F.3d at 1279. That, in turn, also serves generics by ensuring the dispute is resolved before they incur damages. *Eli Lilly,* 496 U.S. at 678.

But by allowing conjecture about likely future infringement to overcome an ANDA that seeks approval for a drug or drug use covered by a valid patent, the Federal Circuit has undermined that goal of early resolution and created perverse incentives.

First, under the Federal Circuit's view, the brand-drug manufacturer must prove, through evidence of how physicians have prescribed and will prescribe the drug, how physicians and others will use a product that has not yet been marketed. Such evidence largely does not exist and requires speculating about how third parties will act in a hypothetical future. The evidentiary burden is particularly heavy for manufacturers of pioneer orphan drugs like Korlym that do not have a large customer base and thus have no ready access to direct infringement evidence. Given those challenges, manufacturers of such drugs may be better off avoiding Hatch-Waxman litigation altogether, waiting for a generic drug to enter the market, and suing under traditional infringement theories once evidence of actual use emerges. That wasteful process is precisely what the Hatch-Waxman Amendments were designed to avoid.

Second, under the Federal Circuit's approach, the brand-drug manufacturer has less incentive to invest in the clinical work that yields new uses in the first place—work that produces safer and more effective

treatments for patients—because a generic can copy the resulting label wholesale and then defend by arguing that physicians will not follow it. This case vividly demonstrates what is at stake. When the FDA approved Korlym in 2012, no one knew how much mifepristone could safely be taken with a strong CYP3A inhibitor. Over the following years, petitioner conducted clinical trials that found that physicians could safely triple the ceiling of coadministration. The district court called the discovery a "breakthrough." App.60a n.8. Petitioner then obtained FDA approval to revise Korlym's label so that physicians treating patients who need both drugs would have instructions for combining them safely.

Respondent, which expended no resources to develop that innovation, then asked the FDA to approve a materially identical label for its own product, patented dosing instructions and all, only to defend against infringement in court by arguing that physicians would not actually follow those instructions. That cannot be what Congress envisioned in passing the Hatch-Waxman Amendments. Rather, Congress created a separate path for generic manufacturers to exclude infringing uses from the label if they did not intend to recommend them—the section viii statement. It is impossible to believe that Congress, when it defined the submission of an ANDA recommending an infringing use as an "act of infringement," meant to allow a generic manufacturer to tell the FDA one thing in its ANDA but then rely on entirely different evidence in court to escape liability.

Third, the Federal Circuit's anti-textual approach will particularly harm orphan drugs. For such drugs, there is often limited evidence of real-world practice.

That will make it that much harder for brand-drug manufacturers to demonstrate how physicians will use the drugs in the future—and therefore to succeed on Section 271(e)(2)(A) claims. That will in turn reduce the incentives to develop and produce such drugs.

B. The question presented is cleanly presented in an ideal vehicle.

First, the underlying material facts are undisputed and straightforward. Respondent's proposed label is identical in all material respects to Korlym's label, App.38a, which "expressly instructs dosing with up to 900 mg of mifepristone along with a strong CYP3A inhibitor," App.8a. And the Federal Circuit treated it as recommending an infringing use, App.8a-9a, 12a. No other facts are material to the question presented. And that question is a pure question of statutory interpretation that will affect many Section 271(e)(2)(A) cases.

Second, the lack of a circuit conflict is no barrier to review because the Federal Circuit hears every patent appeal, 28 U.S.C. § 1295(a)(1), and no other court of appeals will ever decide whether extrinsic evidence about hypothetical future infringement may override an ANDA. "Because the Federal Circuit has exclusive jurisdiction over appeals from all United States District Courts in patent litigation," significant legal rules that it adopts are "matter[s] of special importance to the entire Nation." *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 89 (1993).

This Court has repeatedly granted review of Federal Circuit patent decisions that implicated no conflict among the regional circuits. See, *e.g.*, *eBay Inc.*

v. MercExchange, L.L.C., 547 U.S. 388 (2006) (Federal Circuit's general rule that a permanent injunction issues once infringement is found); *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) (Federal Circuit's rule that a patent licensee must breach its license before seeking declaratory relief); *Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261 (2016) (Federal Circuit's decisions on the claim-construction standard and the reviewability of institution decisions in inter partes review); *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318 (2015) (standard of review of claim-construction findings); *Highmark Inc. v. Allcare Health Mgmt. Sys., Inc.*, 572 U.S. 559 (2014) (standard of review of fee awards). Moreover, like *eBay* and *MedImmune*, the errors in the decision below and in *Genentech* rest on a premise that this Court has already rejected, *i.e.*, that Section 271(e)(2)(A) is a jurisdictional provision. See pp. 19-20, *supra*; *Caraco*, 566 U.S. at 412 n.5.

Third, that the decision below is nonprecedential is no barrier to review. The court of appeals applied *Genentech*'s precedential rule, and the full Federal Circuit declined to revisit that rule. This Court has granted certiorari from an unreported Federal Circuit per curiam order, *Harrow*, 601 U.S. 480, and from a short unreported opinion reasoning that two prior Federal Circuit decisions controlled the outcome, *Feliciano v. Dep't of Transp.*, 605 U.S. 38 (2025).

Fourth, before the Federal Circuit panel, petitioner did not challenge the validity of the Federal Circuit's precedents in *Glaxo* and *Genentech*, and it advanced a good-faith argument for distinguishing *Genentech* on the ground that the ANDA in that case had recommended against the patented method. App.124a-126a, 128a-129a, 131a n.5. But this Court has not

treated a petitioner's failure to raise an argument foreclosed by circuit precedent as a barrier to review, see *Lebron v. Nat'l R.R. Passenger Corp.*, 513 U.S. 374, 379 (1995), and petitioner challenged both *Glaxo* and *Genentech* in its petition for en banc review. App.117a-122a. In addition, at respondent's urging, the panel in this case unanimously rejected petitioner's distinction of *Genentech*, so it is unlikely a future Federal Circuit panel will adopt a different reading. See App.11a-13a, 83a-84a.

Finally, although the decision below did not reach the district court's alternative ground for granting judgment to respondent—that petitioner had failed to prove that respondent specifically intended to induce physicians to infringe petitioner's patents, App.13a—that issue is irrelevant under a proper interpretation of Section 271(e)(2)(A), which asks solely whether the ANDA seeks approval for a drug or drug use that infringes a valid patent. At any rate, should the Court deem the intent question relevant to whatever standard of liability it adopts, it could remand to the Federal Circuit to address that issue in the first instance.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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November 9, 2026

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APPENDIX A

NOTE: This order is nonprecedential.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2024-1346

CORCEPT THERAPEUTICS, INC.,

Plaintiff-Appellant

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Appellee

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.

ON PETITION FOR PANEL REHEARING AND
REHEARING EN BANC

Before MOORE, *Chief Judge*, LOURIE, DYK, PROST, REYNA, TARANTO, CHEN, HUGHES, STOLL, CUNNINGHAM, STARK, *Circuit Judges,*[1] and WANG, *District Judge*.[2]

---

[1] Circuit Judge Newman did not participate.

[2] Honorable Nina Y. Wang, District Judge, United States District Court for the District of Colorado, sitting by designation, participated only in the decision on the petition for panel rehearing.

PER CURIAM.

ORDER

Corcept Therapeutics, Inc. filed a combined petition for panel rehearing and rehearing en banc. A response to the petition was invited by the court and filed by Teva Pharmaceuticals USA, Inc. The petition was referred to the panel that heard the appeal, and thereafter the petition was referred to the circuit judges who are in regular active service.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

The petition for rehearing en banc is denied.

July 10, 2026
Date

FOR THE COURT

/s/ Jarrett B. Perlow
Jarrett B. Perlow
Clerk of the Court

APPENDIX B

NOTE: This disposition is nonprecedential.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2024-1346

CORCEPT THERAPEUTICS, INC.,

Plaintiff-Appellant

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Appellee

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.

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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

[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 300mg. If clinically indicated, titrate to a maximum of 900mg.

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

• Adjust the dose of KORLYM according to Table 1.

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 co-administering 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.

APPENDIX C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

Civil Action No. 18-03632
(RMB) (LDW) (consolidated)

CORCEPT THERAPEUTICS, INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

ORDER

THIS MATTER having proceeded to a three-day bench trial in this "Hatch-Waxman Act" case for patent infringement pursuant to 35 U.S.C. § 271(b) and 271(e)(2)(A); and Corcept Therapeutics, Inc. ("Corcept"), having failed to meet its burden of proof that Teva Pharmaceuticals USA, Inc. ("Teva"), will induce infringement of certain claims recited in United States Patent No. 10,195,214 ("the '214 Patent") and United States Patent No. 10,842,800 ("the '800 Patent") given the submission of Teva's Abbreviated New Drug Application ("ANDA") No. 211436 to the United States Food and Drug Administration for commercial approval of Teva's generic version of Korlym® (mifepristone); and for the reasons set forth in the Opinion of today's date; and for good cause appearing,

IT IS, on this 29th day of December 2023, hereby:

1. ORDERED that judgment is entered in Teva's favor as to Corcept's § 271(b) claim for inducement of patent infringement; and it is further

2. ORDERED that Teva's ANDA No. 211436 does not infringe the '214 Patent or the '800 Patent; and it is finally

3. ORDERED that Teva has not infringed, and that Teva's making, using, offering to sell, selling, or importing Teva's generic mifepristone product will not infringe, claims 10–13 of the '214 Patent or claims 1, 6, 7, and 9 of the '800 Patent.

s/Renée Marie Bumb
Renée Marie Bumb
Chief United States District Judge

APPENDIX D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

———

Civil Action No. 18-03632
(RMB) (LDW) (consolidated)

———

CORCEPT THERAPEUTICS, INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

———

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On behalf of Defendant
Teva Pharmaceuticals USA, Inc.

OPINION

RENÉE MARIE BUMB, Chief United States District Judge:

This is a "Hatch-Waxman Act" case for patent infringement brought by Plaintiff Corcept Therapeutics, Inc. ("Corcept") against Defendant Teva Pharmaceuticals USA, Inc. ("Teva") pursuant to 35 U.S.C. § 271(b) and 271(e)(2)(A). Teva seeks to market and sell a generic version of Corcept's 300 mg branded drug, Korlym® (mifepristone), prior to the expiration of certain

Corcept patents. Following Teva's submission of Abbreviated New Drug Application No. 211436 to the United States Food and Drug Administration for commercial approval of its generic drug product, Corcept initiated this suit seeking, *inter alia*, a declaration of patent infringement and a permanent injunction restraining Teva from launching its generic mifepristone product prior to the expiration of the Patents-in-Suit (defined below).

On February 27, 2023, the Court denied the parties' cross-motions for summary judgment, observing that it was critical to hear "expert testimony regarding [Teva's] label's dosing regimens available when healthcare providers co-administer mifepristone with strong CYP3A inhibitors." [Docket No. 229.] This action proceeded to a three-day bench trial on September 26, 2023. [Transcript of Bench Trial, Docket Nos. 284, 285, 286 ("Tr.").] The sole issue presented to the Court was whether Teva induced infringement of claims 10–13 of United States Patent No. 10,195,214 ("the '214 Patent") and claims 1, 6, 7, and 9 of United States Patent No. 10,842,800 ("the '800 Patent") (the "Patents-in-Suit"). [*See generally* Def.'s Pretrial Br., Docket No. 269; Pl.'s Pretrial Br., Docket No. 270.] Claim 10 of the '214 Patent and claims 1 and 6 of the '800 Patent are the only independent claims asserted. The Court heard evidence, including live testimony from the parties' respective expert wit-

nesses,[1] and thereafter directed the submission of post-trial briefing.[2]

Having considered the parties' briefs, the evidence of record, and the applicable law, the Court concludes that Corcept has not met its burden of proof: it has not demonstrated that there is a likelihood of direct infringement of the asserted claims in the future because it has not established that physicians are likely to coadminister mifepristone with a strong CYP3A inhibitor at an infringing sequence and/or dosage now or in the future. Indeed, Corcept failed to introduce credible record evidence that anyone has ever previously infringed the asserted claims. *See Genentech, Inc. v. Sandoz Inc.*, 55 F.4th 1368, 1380 (Fed. Cir. 2022). Additionally, Corcept failed to demonstrate that Teva possesses the specific intent to encourage physicians to infringe the asserted claims because Teva's proposed product label does not clearly "encourage, recommend, or promote" infringement. *See Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015). Accordingly, the Court will enter judgment in Teva's favor. This Opinion constitutes the Court's findings of fact and

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[1] The Court heard live testimony from Dr. Joseph Belanoff (co-founder, CEO, and President of Corcept, and the inventor associated with the Patents-in-Suit); Dr. Ty Carroll (Corcept's expert witness); and Dr. Peter Snyder (Teva's expert witness). The Court also heard deposition testimony via video from Dr. Adrian Dobs, Mr. Gregg DeRosa, Mr. Craig Jones, Mr. Sean Maduck, and Dr. Andreas Moraitis.

[2] The parties submitted their briefs accordingly. [Def.'s Post-Trial Br., Docket No. 288; Pl.'s Post-Trial Br., Docket No. 289; Def.'s Post-Trial Reply Br., Docket No. 294; Pl.'s Post-Trial Reply Br., Docket No. 295.]

conclusions of law pursuant to Federal Rule of Civil Procedure 52(a).

I. BACKGROUND

A. The Parties, Standing, and Jurisdiction.

Corcept is a publicly traded corporation organized under the laws of the State of Delaware, with a principal place of business in Menlo Park, California. [Final Pre-Trial Order ("FPTO"), Tab 2, Stipulated Facts ¶ 2, Docket No. 273.] Teva is a corporation organized under the laws of the State of Delaware, with a principal place of business in Parsippany, New Jersey. [*Id.* ¶ 1.] (Teva's global headquarters is located in Tel Aviv, Israel.)

As the assignee of the Patents-in-Suit, [Tr. at 127:4–10 (Dr. Belanoff) (citing PTX-001, PTX-003)], Corcept has standing to maintain this litigation. *See Enzo APA & Son, Inc. v. Geapag A.G.*, 134 F.3d 1090, 1093 (Fed. Cir. 1998) ("[A]n assignee is the patentee and has standing to bring suit for infringement in its own name.") (citing 35 U.S.C. § 100(d)).

Because this action arises under the patent laws of the United States, this Court exercises subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

B. The Hatch-Waxman Act.

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, the United States Food and Drug Administration ("FDA") must approve a new drug prior to its introduction on the market. 21 U.S.C. § 355(a). To secure the FDA's approval, a drug applicant may file a New Drug Application ("NDA") that includes certain specified information, including examples of the proposed label for the drug and any

patents that claim the drug, or a method of using the drug, if an infringement claim could reasonably be asserted. *Id.* § 355(b)(1)(A)(vi), (viii). "The FDA publishes the names of approved drugs and their associated patent information in the *Approved Drug Products with Therapeutics Equivalence Evaluations* list, commonly referred to as the 'Orange Book.'" *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1045 (Fed. Cir. 2010).

Where a drug applicant seeks the FDA's approval to introduce a generic version of an approved drug, the drug applicant may file an Abbreviated New Drug Application ("ANDA"). 21 U.S.C. § 355(j). An ANDA is a more streamlined submission than an NDA, allowing the applicant to rely on the safety and efficacy information of a drug listed in the Orange Book if the applicant can demonstrate "bioequivalence." *See AstraZeneca*, 633 F.3d at 1045; *see also* 21 U.S.C. § 355(j)(2)(A). Congress permitted the submission of ANDAs, rather than full NDAs, under the Hatch-Waxman Act,[3] as part of a deliberate and carefully constructed scheme to balance competing policy priorities in the pharmaceuticals industry. On the one hand, Congress sought to encourage "pioneering research and development of new drugs," while on the other hand, "enabling competitors to bring low-cost, generic copies of those drugs to market." *Andrx*

[3] The "Hatch-Waxman Act" is the more common referent for the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360(c), 35 U.S.C. §§ 156, 271, 282), as amended by the Medicare Prescription Drug Improvement and Modernization act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. Sometimes the law is referred to as the "Hatch Waxman Amendments" to the FDCA. *See, e.g.*, *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1370–71 (Fed. Cir. 2002).

Pharms., Inc. v. Biovail Corp., 276 F.3d 1368, 1371 (Fed. Cir. 2002); *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990) (explaining that Congress authorized ANDAs, substantially shortening the time and effort needed to obtain marketing approval, to eliminate the *de facto* extension of a patent's term, and to enable new drugs to be marketed more quickly and cheaply).

Under a safe harbor provision, it is not an act of patent infringement to research, develop, test, and collect information for submission of a drug application to the FDA. *See* 35 U.S.C. § 271(e)(1) ("It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under [applicable law]."); *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997). Under § 271(e)(2)(A), however, it is an act of patent infringement for a generic drug applicant to file an ANDA seeking approval of a generic drug product claimed by a valid and unexpired patent. *Glaxo Grp. Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1351 (Fed. Cir. 2004); *Andrx Pharms.*, 276 F.3d at 1371. This provision, based on a somewhat "artificial" act of infringement, has been considered a "jurisdictional-conferring statute" invoked to establish a case or controversy in a declaratory judgment action. *Glaxo Grp.*, 376 F.3d at 1351 (citing *Allergan, Inc. v. Alcon Labs.*, 324 F.3d 1322, 1330 (Fed. Cir. 2003)); *see also Eli Lilly & Co.*, 496 U.S. at 676 (explaining that § 271(e)(2) is based on a "somewhat artificial[] act of infringement for a very limited and technical purpose").

As part of the approval process, an ANDA applicant must file one of four certifications concerning every patent that claims the listed drug that is the subject of the application, or a method of using the drug: (I) "that such patent information has not been filed," (II) "that such patent has expired," (III) "the date on which such patent will expire," or (IV) "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV). An applicant who files a "Paragraph IV" certification must give notice to the holder of the patents at issue that an ANDA has been filed, and the applicant must state the basis for its belief that the patents are not valid or will not be infringed. *Id.* § 355(j)(2)(B)(i), (ii). The ANDA becomes effective 45 days thereafter unless the patentee commences suit. *Id.* § 355(c)(3)(C). Subject to certain exceptions, if a patent infringement suit is commenced, then the ANDA will not become effective until the expiration of an automatic 30-month stay. *Id.*; *see also Eli Lilly & Co.*, 496 U.S. at 677–78 (explaining certification process).

C. Cushing's Syndrome and Treatment.

Relevant to the dispute before the Court is the rare and debilitating endocrine disorder, Cushing's syndrome. Endogenous Cushing's syndrome is characterized by excessive production of the adrenal hormone cortisol. [Tr. at 120:15–16 (Dr. Belanoff); Tr. at 382:1–3 (Dr. Snyder); *see also* Tr. at 52:18–53:2 (Dr. Dobs) (differentiating endogenous and exogenous Cushing's syndrome, the latter signifying a cause outside of the body).] Endogenous Cushing's syndrome often results from the presence of a tumor in the adrenal or pituitary glands that stimulates, either directly or indirectly, the overproduction of cortisol. [Tr. at

120:16–19 (Dr. Belanoff); Tr. at 382:3–8 (Dr. Snyder).] As Dr. Snyder put it, excess cortisol is "really bad." [Tr. at 382:12.] It can lead to hyperglycemia (*i.e.*, high blood sugar), hypertension, obesity, osteoporosis, depression, sexual dysfunction, menstrual disorders, and infertility, among other problems and complications. [Tr. at 382:11–17 (Dr. Snyder); *see also, e.g.*, Rosario Pivonello *et al.*, *The Treatment of Cushing's Disease*, Endocrine Rev., Aug. 2015, at 385, 386 (describing manifestations of Cushing's syndrome) (PTX-015.01).]

The first-line treatment for a patient suffering from Cushing's syndrome is surgery. [Tr. at 53:15–54:11 (Dr. Dobs); Tr. at 120:22–25 (Dr. Belanoff); Tr. at 382:21–24 (Dr. Snyder).] Excising the "offending tumor" is preferred for multiple reasons, not least of which is that it is the most efficient option from a medical and financial "point of view." [Tr. at 53:21–54:1 (Dr. Dobs); *see also* Tr. at 382:23–24 (Dr. Snyder).] A majority of those who suffer from hypercortisolism undergo surgery and are cured. [Tr. at 236:12–18 (Dr. Carroll); *see* Tr. at 120:24–121:4 (Dr. Belanoff) (explaining that surgery is only possible "about half the time").] However, if surgical intervention is not an option for the patient or surgery has already yielded an unsuccessful result, physicians will consider medical therapies (*i.e.*, medication). [Tr. at 382:25–383:3 (Dr. Snyder); Tr. at 54:22–55:3 (Dr. Dobs); *see also, e.g.*, Pivonello *et al.*, *supra*, at 396 (Fig. 2) (depicting schematic algorithm for treating Cushing's disease, prioritizing surgery followed by medical therapy) (PTX-015.12).]

Today, there are a few medications available to treat Cushing's syndrome when surgery is not an option. [*See* Tr. at 55:24–56:2 (Dr. Dobs).] One group of medications that is often prescribed—called "CYP3A

inhibitors"—impedes the synthesis of cortisol in the adrenal glands, thereby "blocking" excessive cortisol at its source. This group includes ketoconazole and metyrapone, among others. [Tr. at 383:6–12 (Dr. Snyder).] CYP3A inhibitors are a broad therapeutic class of drugs that target multiple different diseases, often addressing specific manifestations of Cushing's syndrome. [*See* Tr. at 129:6–131:6 (Dr. Belanoff) (explaining that CYP3A inhibitors, such as ketoconazole, itraconazole, nefazodone, ritonavir, nelfmavir, and clarithromycin, are often the "best choice" for addressing a particular manifestation of Cushing's syndrome).] However, these medications also suppress the activity of CYP3A enzymes, which are the enzymes that metabolize most drugs. [*See* Tr. at 127:19–24 (Dr. Belanoff).] As a result, there is the potential for adverse drug-drug interactions. [*See* Tr. at 127–28 (Dr. Belanoff); *see also generally* Lynette K. Nieman, *Medical Therapy of Hypercortisolism (Cushing's Syndrome)*, UpToDate (last updated Aug. 29, 2022) [DTX-034]).]

Another medication is mifepristone, which "antagonizes the effects of cortisol," [Tr. at 121:5–6 (Dr. Belanoff)], by blocking cortisol from binding to a glucocorticoid receptor, [Tr. at 383:9–12 (Dr. Snyder); *see generally* Pivonello *et al.*, *supra*, at 455–58 (PTX-015.71–74)]. Unlike a CYP3A inhibitor that prevents production of cortisol, mifepristone manages cortisol's effects. [*See, e.g.*, Tr. at 121:5–6 (Dr. Belanoff).] The major benefit of mifepristone is that it acts quickly and can be used to stabilize a very sick patient, while that patient waits for surgery, for instance. [Tr. at 385:6–13 (Dr. Snyder); Tr. at 57:15–58–12 (Dr. Dobs).] The major drawback, however, is inherent in mifepristone's function: by blocking cortisol's "action," mifepristone does not actually inhibit cortisol production. Cortisol

levels can thus increase even though mifepristone is being used. This can lead to dosing problems because a prescribing physician cannot use cortisol levels to determine the right dose. [*See* Tr. at 385–86 (Dr. Snyder).]

Mifepristone is rarely, if ever, prescribed in combination with a strong CYP3A inhibitor, such as ketoconazole, to treat Cushing's syndrome. [*See, e.g.*, Tr. at 58:19– 25 (Dr. Dobs) (explaining generally that she has prescribed mifepristone with ketoconazole only "about two to three times" where a patient was "extremely ill"); Tr. at 410:9–22 (Dr. Snyder) (noting that he has never co-administered mifepristone with a strong CYP3A inhibitor and "can't think of any situation where it would be necessary," where the benefits would outweigh the risk).] As will be discussed herein, co-administration can be risky because it can increase mifepristone levels in the blood and cause resulting health consequences, as strong CYP3A inhibitors block CYP3A enzymes from metabolizing mifepristone. [Tr. at 212:1–7 (Dr. Carroll); Tr. at 127–28, 131 (Dr. Belanoff).]

In this regard, Dr. Snyder testified that a newer drug, osilodrostat, is now being used to treat Cushing's syndrome. [Tr. at 384, 386, 393 (Dr. Snyder).] It is a powerful drug that acts quickly by inhibiting the synthesis of cortisol. [Tr. at 386 (Dr. Snyder).] While osilodrostat's branded version (Isturisa®) is only indicated for the treatment of Cushing's disease, Dr. Snyder testified that it is now widely used off-label for the treatment of Cushing's syndrome. [Tr. at 474, 476 (Dr. Snyder).] Its principal advantage in this context is that physicians can rely on cortisol levels to determine the proper dose. [Tr. at 384, 386 (Dr. Snyder).]

D. Korlym® and Discovery of the Claimed Invention.

In the years after Corcept was founded (in 1998), Dr. Belanoff and the company focused on developing a treatment for psychotic depression. [Tr. at 117–120 (Dr. Belanoff).] Because of cortisol's systemic bodily effect, Dr. Belanoff was particularly interested in, and focused Corcept's research and development activities on, cortisol modulation. [Tr. at 120 (Dr. Belanoff).] Corcept became aware that researchers had reported the successful treatment of Cushing's syndrome with mifepristone—a drug that had been around since 1985—but that there was not an FDA-approved medication on the market. [Tr. at 120–21, 123, 157 (Dr. Belanoff).] In 2007, Corcept filed an Investigational New Drug Application to evaluate a mifepristone product for the treatment of Cushing's syndrome, and it soon designed a clinical study that produced "potent and positive" results. [Tr. at 122 (Dr. Belanoff).] Corcept named its efficacy study "SEISMIC." [Tr. at 121–22 (Dr. Belanoff).] These results supported Corcept's NDA No. 202107 for approval of its product. [Tr. at 122 (Dr. Belanoff).]

In 2012, the FDA approved Corcept's mifepristone product, Korlym®, for the following indication: "for the control of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery." [FPTO, Tab 2, Stipulated Facts ¶¶ 31, 33; *see* Tr. at 123:9–12 (Dr. Belanoff); JTX-015.] When the drug was approved, it qualified for orphan status, with an estimated market of 5,000 patients. [Tr. at 123:15–18 (Dr. Belanoff).] More than ten years on,

Korlym® is today prescribed to about 1,500 patients. [Tr. at 123:17–18 (Dr. Belanoff).]

In connection with the product's initial approval, the FDA required Corcept to conduct drug-drug interaction studies to determine the effect of coadministration of mifepristone with a strong CYP3A inhibitor. [Tr. at 136–37 (Dr. Belanoff).] The FDA's directive is reflected as a post-marketing requirement in its initial approval letter. [PTX-012.3 (approval letter).] The FDA required post-marketing studies to be conducted because it recognized that ketoconazole (an exemplary CYP3A inhibitor) was widely used off-label to treat Cushing's syndrome and that increased exposure to mifepristone might result from coadministration, potentially leading to severe hypokalemia and adrenal insufficiency. [Tr. at 136–39 (Dr. Belanoff); *see* PTX-012.3–4.] Dr. Belanoff agreed with the FDA's directive to conduct "rigorous" and "robust" studies to quantify the effects of coadministration on mifepristone blood levels, as he was fearful that concomitant use could lead to severe effects, including death. [Tr. at 131:20–25, 137:13–139:4.] He also testified that there was an awareness at the time of approval that physicians were already administering mifepristone with a strong CYP3A inhibitor in very sick patients in isolated cases. [Tr. at 132:6–11, 138:14–20; PTX-012.4.] According to Dr. Belanoff and Dr. Carroll, doctors desired to coadminister the drugs but avoided doing so, unless medically necessary, due to safety concerns. [Tr. at 143:13–144:12, 146:8–22 (Dr. Belanoff); Tr. at 211:8–11, 211:21–212:7 (Dr. Carroll).]

Corcept's initial 2012 Korylm® label was approved with the following warnings regarding coadministration of mifepristone and strong CYP3A inhibitors:

- Warnings & Precautions – *Use of Strong CYP3A Inhibitors:* Concomitant use can increase mifepristone plasma levels significantly. Use only when necessary and limit mifepristone dose to 300 mg (5.6). [JTX-015.1.]
- Drug Interactions – 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. (5.6, 7.2). [JTX-015.1.]
- 5.6 Use of Strong CYP3A Inhibitors – Korlym should be used with extreme caution in patients taking ketoconazole and other strong inhibitors of CYP3A, such as itraconazole, nefazodone, ritonavir, nelfinavir, indinavir, atazanavir, amprenavir, fosamprenavir, boceprevir, clarithromycin, conivaptan, lopinavir, nefazodone, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, or voriconazole, 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. [*See Warnings & Precautions (5.4), Drug Interactions (7.2), and Clinical Pharmacology (12.3)*.] [JTX-015.6.]
- 7.2 CYP3A Inhibitors – Medications that inhibit CYP3A could increase plasma mifepristone concentrations and dose reduction of Korlym may be required. [¶] Ketoconazole and other strong inhibitors of CYP3A, such as itraconazole, nefazodone, ritonavir, nelfinavir, indinavir,

> atazanavir, amprenavir and fosamprenavir, boceprevir, clarithromycin, conivaptan, lopinavir, mibefradil, nefazodone, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, or voriconazole 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. [*See Warnings & Precautions (5.6)*]. [JTX-015.9–10.]

[JTX-015 (Corcept's 2012 Korlym® Label).] Dr. Belanoff testified that the 2012 label represented a "forceful[]" warning to physicians not to coadminister mifepristone with strong CYP3A inhibitors. [*See* Tr. at 145–48, 149–50 (Dr. Belanoff) (citing prior declaration to Patent Office, characterizing 2012 product label as "forcefully" warning that coadministration might be dangerous).]

In the years that followed, as required, Corcept conducted a series of clinical trials under a variety of conditions, hypothesizing that mifepristone blood levels would "skyrocket" if mifepristone and a strong CYP3A inhibitor were taken together. [Tr. at 128, 131 (Dr. Belanoff).] Rather, Corcept discovered that mifepristone blood levels only increased marginally and that a physician could prescribe up to 900 mg of mifepristone with a strong CYP3A inhibitor if dosed appropriately. [Tr. at 128–31, 151–55 (Dr. Belanoff).] Based on this discovery, Corcept filed a patent application in March 2017 that led to the issuance of

the '214 Patent and '800 Patent. Corcept also asked the FDA to approve modifications to its original product label. [Tr. at 151 (Dr. Belanoff).] The current label, revised in November 2019, includes the following language regarding coadministration (with modifications noted in-line):

- Warnings and Precautions – *Use of Strong CYP3A Inhibitors:* Concomitant use can increase mifepristone plasma levels [~~significantly~~]. Use only when necessary and limit mifepristone dose to *900 mg* (5.6). [JTX-016.1 (Corcept's 2019 Korlym® Label) (strikethrough and emphasis added).]

- Drug Interactions – 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 (7.2). [JTX-016.1 (emphasis added).]

- 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

[JTX-016.4 (new instruction regarding coadministration).]

- 5.6 Use of Strong CYP3A Inhibitors – KORLYM should be used with [~~extreme~~] caution in patients taking ketoconazole and other strong inhibitors of CYP3A, such as itraconazole, nefazodone, ritonavir, nelfinavir, indinavir, atazanavir, amprenavir, fosamprenavir, clarithromycin, conivaptan, lopinavir/ritonavir, posaconazole, saquinavir, telithromycin, or voriconazole, 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. 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. [*See Warnings & Precautions (5.4), Drug Interactions (7.2), and Clinical Pharmacology (12.3)*]. [JTX-016.6 (strikethroughs and emphasis added).]

- 7.2 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 [~~significantly~~]. [~~The clinical impact of this interaction has not been studied.~~] [~~Therefore, extreme~~] 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. [*See Dosage and Administration (2.4), Warnings & Precautions (5.6), and Clinical Pharmacology (12.3)*]. [JTX-016.11 (strikethroughs and emphasis added).]

[JTX-016 (Corcept's 2019 Korlym® Label); *see also* Tr. at 151–55 (Dr. Belanoff) (describing changes to label).] The Clinical Pharmacology section of the 2019 Korlym® label (Section 12.3) now includes data from Corcept's clinical trials reflecting the drug-drug interaction effects of coadministering mifepristone with a strong CYP3A inhibitor. [JTX-016.16–17.]

Specifically, Table 3 lists the average ratios of blood concentrations of mifepristone with and without coadministration of a variety of drugs. [Tr. at 403–04 (Dr. Snyder) (summarizing purpose of, and information contained in, table).] Table 3 is reproduced in full below:

Table 3. Summary Table of KORLYM Drug-Drug Interaction Effects

Dosing of Mifepristone	Coadministered Drug	Dosing of Coadministered Drug	Geometric Mean Ratio (analyte ratio with/without drug coadministration)		
			Analyte	AUC	Cmax
Effect of KORLYM on Coadministered Drug					
Contraindicated with mifepristone *[See Contraindications (4)]*					
1200 mg once daily for 10 days	simvastatin[1]	80 mg single dose	simvastatin acid simvastatin	15.70 10.40	18.20 7.02
Use lowest dose of coadministered drug, based on clinical experience and/or use of therapeutic drug monitoring					
1200 mg once daily for 10 days	alprazolam[2]	1 mg single dose	alprazolam 4-hydroxy-alprazolam	1.80 0.76	0.81 0.39
1200 mg once daily for 7 days	fluvastatin[3]	40 mg single dose	fluvastatin	3.57	1.76
1200 mg once daily for 10 days	digoxin[4]	0.125 mg once daily	digoxin	1.40	1.64
Effect of Coadministered Drug on KORLYM					
Dose adjustment required					
600 mg once daily for 17 days	ketoconazole	200 mg bid on days 13-17	mifepristone Metabolite 1† Metabolite 2† Metabolite 3†	1.38 1.02 1.67 0.95	1.28 1.06 1.69 0.96
900 mg once daily for 14 days	itraconazole	200 mg daily for 14 days	mifepristone Metabolite 1† Metabolite 2† Metabolite 3†	1.10 1.04 1.23 0.97	1.20 1.00 1.19 0.94
Effect of Coadministered Drug on KORLYM					
No dosing adjustment required					
300 mg once daily for 14 days	cimetidine[5]	800 mg once daily	mifepristone	0.85*	0.75

* No effect = 90% Cl within range *0.80* - 1.25

† See Section 12.2 for the relative potencies of the three metabolites

[1] Simvastatin 40 mg dose used as reference for the comparison. Result could be representative of other

oral drugs with CYP3A metabolism and high first pass effect: cyclosporine, midazolam, triazolam, pimozide, sildenafil, sirolimus, and tacrolimus

[2] Result could be representative of other oral drugs with CYP3A metabolism and low first pass effect. Clinical significance of any interaction will depend on the therapeutic margin of the drug.

[3] Result could be representative of other oral drugs with CYP2C8/C9 mifepristone

[4] Plasma digoxin concentration should be measured after 1 to 2 weeks of concomitant use and following usual clinical practice at appropriate intervals thereafter.

[5] Result could be representative of other mild inhibitors of CYP3A

[JTX-016.16-17.]

E. The Patents-in-Suit.

There are two remaining patents in this litigation: the '214 Patent and the '800 Patent. Both involve methods of controlling hyperglycemia in certain patients who have Cushing's syndrome. [*See generally* JTX.001 ('214 Patent); JTX.003 ('800 Patent).] The claims embodied in these patents are based on Corcept's findings following the post-marketing studies that the FDA required, as summarized above.

The only asserted independent claim of the '214 Patent is claim 10, which involves coadministering 600 mg of mifepristone with a strong CYP3A inhibitor, after titrating down from 1200 mg or 900 mg of mifepristone:

> 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, itraconazole, nefazodone, ritonavir, nelfmavir, indinavir, boceprevir, clarithromycin, conivaptan, lopinavir, posaconazole, saquinavir, telaprevir, cobicistat, troleandomycin, tipranavir, paritaprevir and voriconazole.

[JTX-001.37 ('214 Patent, 68:47–63) (Claim 10).] Claim 1 of the '800 Patent is nearly identical to claim 10 of the '214 Patent, except that it requires concomitant administration of 900 mg of mifepristone with a strong CYP3A inhibitor, after titrating down from 1200 mg of mifepristone:

> 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, itraconazole, nefazodone, ritonavir, nelfinavir, boceprevir, clarithromycin, conivaptan, lopinavir, saquinavir, telaprevir, cobicistat, troleandomycin, tipranavir, and paritaprevir.

[JTX-003.41 ('800 Patent, 67:30–68:2) (Claim 1).]

Independent claim 6 of the '800 Patent is practiced when 900 mg of mifepristone is administered to a patient who is already taking a strong CYP3A inhibitor:

> 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, itraconazole, nefazodone, ritonavir, nelfinavir, indinavir, boceprevir, clarithromycin, conivaptan, lopinavir, posaconazole, saquinavir, telaprevir, cobicistat, troleandomycin, tipranavir, paritaprevir and voriconazole, the method comprising administering to the patient a once-daily dose of mifepristone of 900 milligrams (mg) per day.

[JTX-003.41 ('800 Patent, 68:15–24) (Claim 6).]

F. Teva's ANDA and Generic Mifepristone Product.

Teva filed ANDA No. 211436 with the FDA in December 2017 seeking FDA approval to market,

make, use, offer to sell, sell, and/or import a generic version of Korlym® prior to the expiration of the '214 Patent and '800 Patent. [FPTO, Tab 2, Stipulated Facts ¶ 37.] Teva's proposed package insert is identical in all material respects to Corcept's 2019 Korlym® label. [*Compare* JTX-016 (Corcept's 2019 label), *with* JTX-011 (Teva's proposed product label)], and Teva's generic product is bioequivalent to Korlym®, [FPTO, Tab 2, Stipulated Facts ¶ 41]. On August 2, 2020, the FDA granted Teva's ANDA final approval. [*Id.* ¶ 40.] As of the date hereof, Teva has not yet launched its product.

II. LEGAL STANDARDS

Patent law provides that whoever actively induces infringement "shall be liable as an infringer." 35 U.S.C. § 271(b). To prevail on a theory of induced infringement in the Hatch-Waxman context, a plaintiff must prove two elements: (1) direct infringement, *i.e.*, "if defendant's drug [were] 'put on the market, it would infringe the relevant patent'"; and (2) specific intent, *i.e.*, that the defendant "possessed the specific intent to encourage another's infringement." *Genentech v. Sandoz Inc.*, 55 F.4th 1368, 1376 (Fed. Cir. 2022) (quoting *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1129–30 (Fed. Cir. 2018)).[4]

In a Hatch-Waxman Act case involving a method-of-treatment patent, the "mere existence of direct infringement by physicians, while necessary to find liability for induced infringement, is not sufficient for

[4] A patent is directly infringed when a person "without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent." 35 U.S.C. § 271(a).

inducement." *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015). Rather, where it is alleged that the ANDA applicant's proposed label induces physicians to infringe, the label must "encourage, recommend, or promote infringement." *Id.* (citations omitted); *see also Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1329 n.2 (Fed. Cir. 2009) ("The question is not . . . whether a user following the instructions may end up using the device in an infringing way. Rather, it is whether [the] instructions teach an infringing use of the device such that we are willing to infer from those instructions an affirmative intent to infringe the patent."). If 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." *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010).

The plaintiff, as patentee, bears the burden of proving induced infringement by a preponderance of the evidence. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1366 (Fed. Cir. 2003) (citing *Bristol-Myers Squibb Co. v. Royce Lab'ys, Inc.*, 69 F.3d 1130, 1135 (Fed. Cir. 1995)); *SmithKline Diagnostics, Inc. v. Helena Lab'ys Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988).

III. DISCUSSION

Before proceeding to its analysis, the Court summarizes the parties' arguments. Corcept argues that it has met its burden of establishing Teva's liability for induced infringement under 35 U.S.C. § 271(b). [*See* Pl.'s Post-Trial Br., Docket No. 289.] First, it contends that the expert testimony elicited at trial uniformly demonstrates that Teva's label instructs physicians to perform the patented method when coadministering mifepristone with a strong

CYP3A inhibitor. [*Id.* at 2–5.] Corcept next claims that physicians have previously administered mifepristone and a strong CYP3A inhibitor concomitantly for seriously ill Cushing's syndrome patients and that they are likely to do so in an infringing way in the future. [*Id.* at 5–11.] To this end, it characterizes Dr. Snyder's testimony concerning osilodrostat as a "red herring." [*Id.* at 11–13.]

Second, Corcept argues that Teva's specific intent to induce is clear from Teva's label. Claiming that *HZNP Medicines v. Actavis Laboratories UT, Inc.*, 940 F.3d 680 (Fed. Cir. 2019) is distinguishable, Corcept contends that Teva's label does not merely describe infringing activity in an "if/then" manner, but rather instructs physicians to perform the patented method when prescribing Teva's generic mifepristone product. [Pl.'s Post-Trial Br. at 13–17.] It argues that Dr. Synder's opinions regarding encouragement are not credible and that the weight of the evidence supports a finding of intent to induce. [*Id.* at 17–19.] Corcept also submits that Teva's inducement argument does not apply to claim 6 of the '800 Patent because all a physician must do to practice the claim is administer 900 mg of mifepristone to a patient already taking a strong CYP3A inhibitor. [*Id.* at 19–20.] Finally, Corcept asserts that Teva's intent to induce is evidenced by its failure to seek approval of alternative labeling. [*Id.* at 20.]

In opposition, Teva argues that Corcept has failed to meet its burden of demonstrating inducement. [Def.'s Post-Trial Br., Docket No. 288.] Teva contends that there is no record evidence that anyone has ever practiced the patented method, and that the weight of the evidence suggests that coadministration of mifepristone and a strong CYP3A inhibitor in the

future is not likely. [*Id.* at 2–9.] In particular, Teva stresses that the introduction of osilodrostat, a recently approved drug that inhibits the synthesis of cortisol, makes coadministration of mifepristone and strong CYP3A inhibitors obsolete. [*Id.* at 4–5.] Moreover, Teva maintains that its label does not actively induce performance of the patented methods because it discourages the concomitant use of mifepristone with a strong CYP3A inhibitor. [*Id.* at 9–14.] Teva contends that *HZNP* is dispositive of Corcept's inducement argument because Teva's label, like the generic label in *HZNP*, is permissive without encouraging the infringing activity. [*Id.* at 14–17.] Next, it devotes much of the remainder of its submission to distinguishing the cases on which Corcept relies. [*Id.* at 17–20.] In closing, Teva opposes Corcept's "carve-out" argument regarding alternative labeling. [*Id.* at 20.]

The Court discusses each of these arguments, to the extent relevant, below.

A. Direct Infringement.

The asserted claims of the '214 Patent and the '800 Patent are quite similar. Claim 10 of the '214 Patent has the following limitations: (1) it applies to a patient who is taking a once-daily dose of 1200 mg or 900 mg of mifepristone to treat endogenous Cushing's syndrome; (2) the patient's dose is reduced to 600 mg of mifepristone; and (3) the patient is simultaneously administered a strong CYP3A inhibitor. [*See* JTX-001.37.] Claim 1 of the '800 Patent has the following limitations: (1) it applies to a patient who is taking a once-daily dose of 1200 mg of mifepristone to treat endogenous Cushing's syndrome; (2) the patient's dose is reduced to 900 mg of mifepristone; and (3) the patient is simultaneously administered a strong

CYP3A inhibitor. [*See* JTX-003.41.] Claim 6 of the '800 Patent has the following limitations: (1) it applies to a patient who is taking a strong CYP3A inhibitor; and (2) the patient is simultaneously administered a once-daily dose of 900 mg of mifepristone. [*See* JTX-003.41.]

As noted above, to prove direct infringement, Corcept must establish that, if Teva's mifepristone drug product were put on the market, it would infringe the asserted claims of the '214 Patent and the '800 Patent. *See Vanda*, 887 F.3d at 1129–30 (explaining that the inquiry is hypothetical and asks whether the generic drug maker is likely to market an infringing product). A court may consider all relevant evidence in this regard. *See, e.g.*, *Ferring B.V. v. Watson Lab'ys, Inc.-Fla.*, 764 F.3d 1401, 1409 (Fed. Cir. 2014) ("The infringement determination is . . . based on consideration of all the relevant evidence[.]"); *Glaxo*, 110 F.3d at 1570 (noting that district court "properly considered the ANDA itself, the materials submitted by Novopharm to the FDA, and other pertinent evidence" in conducting its infringement analysis). Though "a patentee does not need to prove an actual past instance of direct infringement" to establish liability for inducement, *Vanda*, 887 F.3d at 1129, 1129–30, "past conduct is relevant to what will happen in the future," *Genentech*, 55 F.4th at 1379, 1379–80.

1. Evidence of Prior Infringement.

The Court begins with the lack of record evidence demonstrating that anyone has ever practiced the claimed methods, including during the ten-year span since Korlym® was approved. Teva contends that *Genentech* "dismantles Corcept's infringement case" for this reason. [Def.'s Post-Trial Br. at 8–9; *see also* Def.'s Pre-Trial Br. 9–10.] Corcept asserts that Teva's reliance on *Genentech* is misplaced because it did not

"change[] the law" to "*require*" the Court to consider past conduct in determining whether infringement will likely occur in the future. [Pl.'s Post-Trial Br. at 5–6; *see also* Pl.'s Pre-Trial Br. 27–30.] The *Genentech* court looked outside of the generic manufacturer's proposed product label to prior physician conduct only because it found that the label did not recommend practice of the claimed methods, Corcept argues. [Pl.'s Post-Trial Br. at 5; *see also* Pl.'s Post-Trial Reply Br. at 4.]

In *Genentech*, the Federal Circuit considered certain patented methods for avoiding adverse drug interactions between pirfenidone, a medication to treat idiopathic pulmonary fibrosis, and fluvoxamine, a strong CYP1A2 inhibitor. 55 F.4th at 1371, 1374. The drug-drug interaction patents at issue involved administering pirfenidone to a patient already taking fluvoxamine by either discontinuing fluvoxamine or titrating the pirfenidone dose and continuing fluvoxamine. *Id.* at 1374–75. The generic manufacturer's proposed label warned about the drug-drug interactions, specifically stating that "concomitant administration" is "*not recommended*" and "[u]se of fluvoxamine . . . should be discontinued prior to administration of pirfenidone and avoided during pirfenidone treatment." *Id.* at 1375 (emphasis added). Still, the label permitted coadministration of the two agents when necessary and provided dosing instructions in such case. *See id.* ("In the event that fluvoxamine or other strong CYP1A2 inhibitors are the only drug of choice, dosage reductions are recommended. Monitor for adverse reactions and consider discontinuation of pirfenidone as needed *[see Dosage and Administration (2.4)]*.") (brackets and emphasis in original).

The district court determined that the patentee had not met its burden of establishing direct infringement, and the Federal Circuit affirmed for two principal reasons. *Id.* First, there was no record evidence that any physicians had ever practiced the patented methods, and "past conduct is relevant to what will happen in the future." *Id.* at 1379. Second, the generic manufacturer had presented evidence from physicians who testified that "they had never prescribed pirfenidone to an [idiopathic pulmonary fibrosis] patient taking fluvoxamine" and that they would prescribe a noninfringing alternative (*i.e.*, nintedanib) if placed in that situation. *Id.* at 1380. "The court did not clearly err by considering all relevant evidence, including Sandoz's proposed label and physician practice." *Id.*

Here, Corcept's attempt to discredit *Genentech* is unavailing. Teva is not claiming that a "split-panel decision" changed the law, as Corcept says [*see* Pl.'s Post-Trial Br. at 5], nor that this Court *must* credit the lack of evidence of past infringement. Rather, Teva correctly contends that such evidence is relevant. There is nothing new about the proposition for which the case is cited. *See, e.g.*, *Takeda*, 785 F.3d at 634 (affirming district court finding of no inducement based on insufficient evidence that healthcare provider had actually practiced claimed methods and patentee had not otherwise met threshold element of direct infringement) (citing *Ricoh Co. v. Quanta Computer Inc.*, 550 F.3d 1325, 1341 (Fed. Cir. 2008)); *accord Limelight Networks, Inc. v. Akamai Techs. Inc.*, 572 U.S. 915, 921–22 (2014) (explaining that inducement liability can arise "if, but only if, there is direct infringement") (citation omitted) (cleaned up). Moreover, the Federal Circuit in *Genentech* did not hold that evidence of physician practice is only relevant if the

product label fails to recommend an infringing use. Corcept's reading of *Genentech* would collapse the distinct elements of induced infringement into one inquiry focused exclusively on the language of the product label. That is not the law. As the trial court explained,

> The presence of language that "encourages, recommends or promotes" an infringing use on a proposed label, without any additional evidence showing such an infringing use will in fact occur, especially where there is evidence that an infringing use likely will not occur, is insufficient for a finding of induced infringement.

Genentech, Inc. v. Sandoz, Inc., 592 F. Supp. 3d 355, 376 (D. Del.), *aff'd*, 55 F.4th 1368 (Fed. Cir. 2022).[5]

Just as the *Genentech* courts concluded, and mindful of Corcept's burden, this Court finds the lack of record evidence that any physician has ever practiced the asserted claims to be persuasive—here, as a starting point to its analysis. Neither Dr. Carroll (Corcept's expert) nor Dr. Snyder (Teva's expert) has ever prescribed mifepristone with a strong CYP3A inhibitor to treat Cushing's syndrome. [Tr. at 266:9–12, 266:18–23, 270:3–9, 273:17–19 (Dr. Carroll); Tr. at 410:9–22 (Dr. Snyder).] Though Dr. Carroll testified regarding other physicians' occasional coadministration of mifepristone with strong CYP3A inhibitors to treat especially ill patients, [*see, e.g.*, Tr. at 236:22–238:2 (referencing Dr. Hamrahian)], it is critical to note that

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[5] The trial court did not reach the question whether the patentee had demonstrated specific intent to induce infringement because it concluded that the patentee had failed to prove direct infringement.

Dr. Carroll did not provide evidence that any physician had ever prescribed the drugs together at an infringing sequence and/or dosage, [*see* Tr. at 270:20–23, 285:2–19.] Dr. Snyder also did not identify any instances of past practice of the asserted claims. [Tr. at 392:22–393:5.] The parties' experts thus did not testify regarding prior direct infringement.

Similarly, the other Corcept (as well as Teva) witnesses did not provide testimony that they had ever practiced Corcept's patented methods. Dr. Dobbs, for instance, indicated that she had combined ketoconazole with mifepristone "two to three times" in her career to take advantage of their "different mechanisms of action" for "extremely ill" patients, [Tr. at 58:16–25], but she did not provide testimony concerning the dosage or sequence employed. The other witnesses are no different. [*See, e.g.*, Tr. at 96:18–23, 97:23–98:15 (Dr. Moraitis indicating that he has never treated a Cushing's syndrome patient with a combination of mifepristone and ketoconazole and is not aware of any who have).] While the record undisputedly reveals that physicians have coadministered mifepristone with a strong CYP3A inhibitor in rare cases, [*see, e.g.*, Tr. at 244:25–245:14 (Dr. Carroll crediting case report of patient who both ketoconazole and mifepristone for treatment of Cushing's syndrome)], Corcept did not present the Court with any specific evidence where a physician practiced the patented methods. This is notwithstanding the fact that Korlym® has been commercially available since April 2012. The absence of this relevant information leads to the conclusion that future direct infringement is not

likely.[6] *See Genentech*, 55 F.4th at 1379–80; *Takeda*, 785 F.3d at 634.

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[6] On November 2, 2023, the Court observed in a Letter Order that Corcept had not pointed to record evidence of prior instances of coadministration at an infringing sequence or dosage. [Docket No. 292, at 2.] While not required, the Court emphasized that "the existence—or absence—of such prior infringement evidence" was important to its analysis. [*Id.*] The Court reminded Corcept that it had invited this evidence during and after trial. [*Id.*] In its Post-Trial Reply Brief, Corcept interpreted the Court's letter as an opportunity to reopen the trial record to include a set of belated declarations from medical professionals attesting, in summary fashion, that each has practiced one or more of the claimed methods in the past. [Pl.'s Post-Trial Reply Br. at 5 & Exs. A–F, Docket No. 295.] This is not what the Court invited, nor will the Court grant Corcept's request at this stage. Courts have considerable discretion in deciding whether to reopen the trial record to permit additional evidence. *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 331 (1971). In making this decision, courts consider several factors, including (1) the burden on the parties and their witnesses, (2) any undue prejudice that may result to the nonmoving party, and (3) the impact on judicial economy. *See Rochez Bros., Inc. v. Rhoades*, 527 F.2d 891, 894 n.6 (3d Cir. 1975). The trial record may be reopened when the failure to adduce sufficient evidence is based on a reasonable misunderstanding or when it is to ensure substantial justice. *See id.* at 894–95. Here, Corcept has had ample opportunity during this litigation to introduce specific evidence that physicians have practiced the patented methods. Indeed, courts routinely consider this evidence when assessing whether a patentee has made a threshold showing that future direct infringement is likely. *See, e.g.*, *Takeda*, 785 F.3d at 634. It would be too prejudicial now to consider Corcept's hearsay declarations over Teva's objection, and it would be inappropriate and burdensome to delay resolution of this matter to further examine this issue. Corcept has not persuaded the Court that its lack of prior infringement evidence stems from a reasonable misunderstanding, or that reopening the trial record is necessary to ensure substantial justice. Therefore, Corcept's request must be denied.

2. Evidence of Future Infringement.

Next, the Court addresses whether Corcept has met its burden of proof that it is more likely than not that direct infringement of the asserted claims will occur in the future based on other record evidence. Crediting Dr. Snyder's testimony, this Court finds that, while clinicians may exercise their medical judgment to coadminister mifepristone with a strong CYP3A inhibitor in isolated instances "when necessary," it is highly unlikely that physicians will practice the claimed methods.

First, the record evidence demonstrates that physicians generally avoid coadministering mifepristone and strong CYP3A inhibitors. They avoid doing so because of the challenges of dosing mifepristone and the dangers associated with coadministering the two substances.

The evidence established that mifepristone does not inhibit the production of cortisol, but rather blocks its effects. [Tr. at 121:5–6 (Dr. Belanoff); Tr. at 383:9–12 (Dr. Snyder).] As a result, mifepristone can cause a patient's cortisol blood concentrations to increase. [Tr. at 384:24–385:5 (Dr. Snyder).] Physicians thus cannot rely on circulating blood levels of ACTH and/or cortisol to reflect therapeutic efficacy of mifepristone when treating Cushing's syndrome patients. [*See* Tr. at 158:25–163:20 (Dr. Belanoff); *see also* James W. Chu *et al.*, *Successful Long-Term Treatment of Refractory Cushing's Disease with High-Dose Mifepristone (RU 486)*, 86 J. Clinical Endocrinology & Metabolism 3568, 3570, 3572 (2001) (explaining that difficulty in monitoring therapeutic efficacy of mifepristone stems from lack of objective measure of receptor activity) [DTX-043.0004].] This is mifepristone's principal disadvantage in this context. [*See* Tr. at 385:16–20

(Dr. Snyder) ("[T]he major drawback is that because it doesn't block the production of cortisol, one cannot use cortisol to determine if one is giving the right dose. So one doesn't know if one's giving the right dose or too much or too little.").]

Strong CYP3A inhibitors, such as ketoconazole, impede the synthesis of cortisol in the adrenal glands, thereby "blocking" excessive cortisol at its source. [Tr. at 383:6–12 (Dr. Snyder).] Because these medications suppress the activity of CYP3A enzymes, they can raise mifepristone blood concentrations and increase the chances of severe side effects when taken together. [Tr. at 127:19–24 (Dr. Belanoff); Tr. at 303:9–22 (Dr. Carroll); Tr. at 395:5–8 (Dr. Snyder).] Partly on this basis, Dr. Moraitis reported that he strongly prefers monotherapy because of the possibility of adverse drug-drug interactions. [*Cf.* Tr. at 96–97 (explaining that he avoids combining agents because combination usually fails and requires more aggressive intervention).]

Given this context, and opining on Teva's label, Dr. Snyder persuasively testified that physicians should "be very afraid" of coadministration, that it could cause a "problem." [*See* Tr. at 394:11, 397:22.] He explained that he would not likely use mifepristone today to treat Cushing's syndrome because of the dosing problem outlined above. [Tr. at 386:9–11.] And the problem is not without consequence: too little mifepristone, and the patient continues to have Cushing's syndrome, with all its attending consequences; too much mifepristone, and the patient's blood pressure could drop, even causing death. [Tr. at 385:21–25, 386:1–8 (Dr. Snyder).] "I am not aware of any authority in the area of Cushing's syndrome who *recommends* combining mifepristone with another medication." [Tr. at 413:10–12 (Dr. Snyder) (emphasis added).] The

Court finds Dr. Snyder's testimony credible. It is significant that Dr. Lynette Nieman, a leading authority on the treatment of Cushing's syndrome, did not mention combining mifepristone with other drugs in a topic review of hers published in UpToDate®, a medical periodical for which Dr. Snyder serves a co-editor-in-chief. [*See* Tr. at 413:21–418:20 (discussing Lynette K. Nieman, *Medical Therapy of Hypercortisolism (Cushing's Syndrome)*, UpToDate (last updated Aug. 29, 2022) [DTX-034]).[7]] Dr. Snyder suggests that the absence of any such discussion in sections of the topic review addressing combination therapy is telling, [*see* Tr. at 418:7–10], and this Court agrees. Indeed, Corcept had no real response.

Second, and relatedly, the existence of at least one non-infringing alternative treatment to mifepristone suggests that physicians are not likely to directly infringe the asserted claims in the future. As Dr. Snyder testified, the recent introduction of osilodrostat has "changed" the "landscape." [Tr. at 386:13–17.] Osilodrostat is a "powerful" and "effective" drug that "acts rapidly." [Tr. at 386:19–22.] Unlike mifepristone, osilodrostat blocks cortisol production, so physicians can use cortisol blood concentrations to determine effective dosage. [Tr. at 384:9–12, 386:17–22, 484:10–20.] Dr. Snyder opined that physicians are unlikely to coadminister mifepristone and strong CYP3A inhibitors in the future because osilodrostat is a better drug to

[7] Still, the Court notes that the article refers to the danger of combining ketoconazole with CYP3A4 substrates: "Ketoconazole is a strong inhibitor of CYP3A4. Coadministration of CYP3A4 substrates should be avoided if possible and may result in increased plasma concentrations of these drugs, with increased or prolonged therapeutic or adverse effects." Nieman, *supra*, at 4 (Initial Therapy – Ketoconazole) [DTX-034.0004].

treat Cushing's syndrome. [Tr. at 393:11–18; *see also* Tr. at 489:22–24 ("So it is safer to give osilodrostat than to give mifepristone, in spite of the fact that the blood concentration has changed more with osilodrostat."] This is so even though, as Corcept elicited on cross-examination, osilodrostat is only indicated for the treatment of Cushing's disease. [*See* Tr. at 474:2–15 (Dr. Snyder) (explaining that Isturisa®, or osilodrostat, while only FDA-approved for treatment of Cushing's disease, is widely used off-label for Cushing's syndrome); Tr. at 476:21–25 (Dr. Snyder) ("[I]t is, I'd say, even desirable to use osilodrostat for any form of Cushing's syndrome, and preferable to use it compared to mifepristone. I think it's medically preferrable.").] In summary, Dr. Snyder concluded that in his personal experience, the benefits of coadministering mifepristone and ketoconazole never outweigh the risks, especially since the introduction of osilodrostat. [Tr. at 410:9–14.] The Court finds this testimony credible and persuasive.

Corcept's arguments are not to the contrary. For instance, Corcept argues that Teva presented no evidence that "even a single prescription" of Korlym® has been lost to osilodrostat. [Pl.'s Post-Trial Br. at 11, 11–12.] Corcept points to Dr. Belanoff's testimony that since the FDA approved Isturisa® (osilodrostat) in 2020, Corcept has actually experienced increased sales. [*See* Tr. at 123:23–124:3.] He attributes the increase in sales to heightened visibility of hypercortisolism treatments and better screening by physicians. [Tr. at 124:7–125:1.] In other words, Dr. Belanoff claims that the introduction of a competing drug, with a different mechanism of action, has had a positive impact for the company. [*See* Tr. at 124:21–125:1.] While the Court has no reason to disbelieve that greater awareness about hypercortisolism has certain

salubrious effects, Dr. Belanoff's explanation about increased sales was by no means a causal analysis. And Corcept failed to prove that the increase is *because of* the introduction of osilodrostat. Dr. Belanoff's testimony left more questions in the Court's mind than answers. [*See* Tr. at 412:20–21 (Dr. Synder stating that he was "puzzled" by the suggestion that osilodrostat has increased Corcept's sales of Korlym®).] Therefore, based on the evidence elicited at trial, the Court cannot conclude that osilodrostat will *not* be preferred to Korlym® in the future, as Dr. Snyder persuasively testified.

Third, Corcept has not met its burden of demonstrating that direct infringement is likely to occur even if a physician consults Teva's proposed label to coadminister mifepristone and a strong CYP3A inhibitor. As will be discussed further below, Teva's label does not induce physicians to administer the drugs together. Rather, the label cautions against coadministration, providing dosing instructions if a physician independently determines that it is medically necessary to prescribe mifepristone and a strong CYP3A inhibitor together. Corcept has maintained that physicians will infringe the asserted claims by following Teva's label because the label's instructions are not "optional." [Pl.'s Post-Trial Br. at 9–11, 13–17.] But this position ignores that a physician could follow the instructions on Teva's label and not infringe the claims. As Corcept's own expert, Dr. Carroll, acknowledged, administering 300 mg of mifepristone to a patient who is already taking a strong CYP3A inhibitor *would not infringe* claim 6 of the '800 Patent. [Tr. at 267:5–9, 268:5–12.] *Nor would administering 600 mg of mifepristone*. A physician infringes claim 6 only by administering 900 mg of mifepristone to a

patient who is already taking a strong CYP3A inhibitor. [JTX-003.41.]

Similarly, a physician who administers a strong CYP3A inhibitor to a patient who is already taking 300 mg or 600 mg of mifepristone *would not infringe* claim 10 of the '214 Patent or claim 1 of the '800 Patent. [*See* Tr. at 261:14–264:8 (Dr. Carroll) (acknowledging that these scenarios, and others, fall outside the claimed methods).] Claim 10 is only practiced when a Cushing's patient is already taking 1200 mg or 900 mg of mifepristone, and the physician lowers the patient's dose to 600 mg of mifepristone and administers a strong CYP3A inhibitor. [JTX-001.37.] Claim 1 is only practiced when a Cushing's patient is already taking 1200 mg of mifepristone, and the physician lowers the patient's dose to 900 mg and administers a strong CYP3A inhibitor. [JTX-003.41.]

Corcept largely ignores these non-infringing possibilities. Instead, it contends that infringement will occur because most patients require 900 mg or 1200 mg of mifepristone to achieve an efficacious result. [Pl.'s Post-Trial Br. at 9–10.] The Court does not find this argument to be compelling. First, the testimony elicited on this score from Dr. Belanoff and Dr. Carroll focused on the optimal dose reported in the SEISMIC study that supported the FDA's initial approval of Korlym® in 2012. [*See* Tr. at 147:4–6 (Dr. Belanoff); Tr. at 320:23–321:2 (Dr. Carroll).] Only 34 patients participated in this study. [Tr. at 333:6–9 (Dr. Carroll).] Despite years of discovery, Corcept did not introduce any evidence regarding the average dose of Korlym® that patients receive in practice, or the number of patients who have taken 300 mg, 600 mg, 900 mg, or 1200 mg of Korlym®, or the number of patients who have taken Korlym® together with ketoconazole. The

logical conclusion is that Corcept does not know this information. [*See* Tr. at 83:19–21, 81:19–82:3, 82:10–14 (Mr. Maduck, Corcept's Chief Commercial Officer).] As a result, Corcept has not persuaded this Court that today most patients who receive a strong CYP3A inhibitor are already taking at least 900 mg of Korlym® or that patients who are already receiving a strong CYP3A inhibitor will be prescribed at least 900 mg of Korlym®. Therefore, the Court concludes that physicians are not likely to titrate Cushing's syndrome patients' dosage of mifepristone in an infringing manner. Accordingly, Corcept has not demonstrated that physicians, following Teva's label, would necessarily infringe the asserted claims.

Corcept's other arguments fail to persuade the Court that direct infringement is likely. For instance, Corcept contends that physicians will infringe the asserted claims because ketoconazole remains the most commonly used medication to treat manifestations of Cushing's syndrome. [Pl.'s Post-Trial Br. at 7.] Corcept also argues that patients taking mifepristone may require ketoconazole if they develop an opportunistic infection, such as aspergillosis. [*Id*. at 8.] Even crediting the testimony on which Corcept's argument is based, [*see, e.g.*, Tr. at 229:18–234:16 (Dr. Carroll) (opining that it might be "medically necessary" to coadminister mifepristone with a strong CYP3A inhibitor where certain infections occur in a patient with Cushing's syndrome) (first citing J.K. Oosterhuis *et al.*, *Life-Threatening* Pneumocystis Jiroveci *Pneumonia Following Treatment of Severe Cushing's Syndrome*, 65 Netherlands J. Med. 215 (2007) [PTX-016]); then citing Pivonello *et al.*, *supra*), the Court does not find that infringement will likely result. As the Court has already explained, Dr. Carroll's testimony is not supported by any credible

instances in which a physician practiced the claimed method, and a physician can faithfully follow Teva's label and avoid infringement. Given these reasons, and Dr. Snyder's testimony, the Court must reject Corcept's conclusion that infringement will occur.

Therefore, for the above reasons, the Court finds that Corcept has not met its burden of demonstrating that direct infringement of the '214 Patent and the '800 Patent is likely. *See Takeda*, 785 F.3d at 635 (finding that court permissibly concluded direct infringement was unlikely based on testimony from physicians that they try to avoid coadministration of drugs and lack of evidence that claimed method would actually be practiced).

B. Specific Intent.

Next, the Court addresses whether Teva's label "instructs users to perform the patented method." *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010). To answer the question, the Court asks whether the label "encourage[s], recommend[s], or promote[s] infringement." *Takeda*, 785 F.3d at 631. "[M]ere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce must be proven." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003) (citation omitted). The Court reaches this question for the sake of completeness, even though it has concluded that Corcept has not shown a likelihood that Teva's generic product would directly infringe the asserted claims if marketed. *See Limelight Networks*, 572 U.S. at 921–22 (explaining that likelihood of direct infringement is a threshold requirement for inducement liability).

Corcept contends that Teva's intent to induce infringement can be inferred from Teva's product label. [*See* Pl.'s Post-Trial Br. at 13–17.] Corcept maintains that the label instructs physicians to follow dosage adjustment steps that infringe the asserted claims, and it submits that the appropriate test is not whether the label recommends coadministration, but whether the label recommends that physicians follow the claimed method once it has been decided to administer the drugs together. [*Id*.] Relying on *HZNP*, 940 F.3d at 702, Teva counters that "an instruction *how* to do something is not an instruction *whether* to do it in the first place." [Def.'s Post-Trial Br. at 10, 14–17.]

In *HZNP*, the Federal Circuit considered whether Horizon had met its burden of showing that Actavis's product label induced a use of Actavis's proposed product that would infringe Horizon's method-of-use patents. 940 F.3d at 699. The product at issue was a topical solution for the treatment of osteoarthritis pain of the knees, and Horizon's patents addressed its method of application. *Id.* As the court summarized, the patented method required three steps: (1) applying the topical solution; (2) waiting for the area to dry; and (3) applying sunscreen, insect repellant, or a second topical medication. *Id.* at 702. Actavis's proposed label, materially identical to Horizon's label for its branded product, recommended a specified dosage of the solution and instructed users to apply the solution to the clean, dry skin of the knee twice a day. *Id.* at 699. It also warned that users should wait until the treated area was completely dry before covering with clothing, applying sunscreen, insect repellent, or other substances. *Id.* at 699–700.

Horizon argued that Actavis's label reflected its specific intent to induce infringement because it tracked, nearly exactly, Horizon's three-step, patented method of applying the topical solution. *Id.* at 701. Horizon contended that if a user sought to apply sunscreen, insect repellant, or another substance, then direct infringement would occur, as the user would follow the patented method and wait until the user's skin was dry before applying the other substance to the treated area. *Id.*

The Federal Circuit rejected Horizon's argument. It explained that Actavis's label, properly construed, only *required* step one, *i.e.*, application of the topical solution. *Id.* at 702. Post-product application of sunscreen or another substance was not required by the label. Rather, the label's warning operated 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.* This construction, the Federal Circuit explained, does not "encourage, recommend, or promote" infringement; the label "merely provided guidance to patients about what to do if the pat[i]ent desired to have anything come into contact with the knee after application of the medication." *Id.* While a user may infringe Horizon's method-of-use patents, the court reaffirmed that evidence of direct infringement is not sufficient to establish that a proposed label instructs the user to perform the patented method. *Id.*

HZNP is instructive here. Just as the product label in *HZNP* did not encourage, promote, or recommend the specified steps of the patented method because nothing required post-product application of sunscreen or another substance, 940 F.3d at 702, Teva's label does not encourage physicians to practice the asserted

claims because the label does not encourage coadministration of mifepristone and a strong CYP3A inhibitor. The label only provides instructions *how* to coadminister the substances to achieve an efficacious result *if* a physician determines that it is medically necessary. In this context, the label only provides "guidance" for physicians; it does not teach an infringing use "such that we are willing to infer from those instructions an affirmative intent to infringe the patent." *Vita-Mix*, 581 F.3d at 1329 n.2.

The Court thus rejects Corcept's attempts to distinguish *HZNP*. For instance, Corcept argued that a recent decision by another court in this District demonstrates why *HZNP* is distinguishable. [*See* Pl.'s Post-Trial Br. at 16–17 (discussing *Janssen Pharms., Inc. v. Mylan Labs. Ltd.*, 2023 WL 3605733 (D.N.J. May 23, 2023) (Padin, J.).] In *Janssen*, the court confronted a patented method for reinitiating treatment of schizophrenia in patients who had missed their last dose of a three-month paliperidone palmitate extended-release injectable medication within a four-to-nine-month window. 2023 WL 3605733, *5–7. The patent specifications described a "reinitiation dosing regimen." *Id.* at *7. The generic label at issue instructed clinicians to apply the regimen in the "inevitable" situation that a patient returns between four and nine months after a missed dose. *Id.* at *15–16. Rejecting the generic manufacturer's argument that its label did not induce infringement because a warning discouraged missing a dose, the court explained that the label does not "discourage or make optional the practice of the Asserted Claims (or any claimed steps) in the inevitable situation that doses *are* missed." *Id.* at *17. The *Janssen* court also suggested that *HZNP* supported its finding of induced

infringement because there "one of the claimed steps was optional." *Id.* (citing *HZNP*, 940 F.3d at 702).

Here, Corcept has failed to demonstrate that a similarly "inevitable" situation is present. Unlike the missed doses in *Janssen* that were likely to occur based on the credible record evidence that more than 50 percent of patients miss a dose, *see Janssen*, 2023 WL 3605733, at *15, there is no external trigger here that is likely to convince a physician to coadminister mifepristone and a strong CYP3A inhibitor. The record evidence reveals that physicians are unlikely to coadminister the two substances, and even less likely to do so in an infringing manner. Furthermore, contrary to *Janssen*, a physician here can faithfully follow Teva's label and not infringe the asserted claims. There are non-infringing options available. Therefore, Corcept's efforts to differentiate *HZNP* are unconvincing.

Two additional points bear emphasizing. First, Teva's label does not affirmatively encourage the coadministration of mifepristone with a strong CYP3A inhibitor. The label does not outline any benefits of coadministration or indicate the circumstances in which the agents should be coadministered. [Tr. at 399:16–22 (Dr. Snyder).] Rather, Teva's label warns physicians *against* coadministration, advising the exercise of caution if they choose to do so.[8] [*See, e.g.*,

[8] Dr. Belanoff acknowledged that Corcept's 2012 label represented a "forceful[]" warning against coadministration, that physicians were taught to avoid the use of mifepristone with a strong CYP3A inhibitor. [JTX-005.682 (Dr. Belanoff Decl. to Patent Office); Tr. at 169:24–170:12, 171:12–15 (Dr. Belanoff).] After additional study of mifepristone, Corcept discovered that coadministration did not raise the blood concentration of mifepristone as much as was previously believed. Accordingly,

JTX-011.1 (WARNINGS AND PRECAUTIONS – "*Use of Strong CYP3A Inhibitors*: Concomitant use can increase mifepristone plasma levels. Use only when necessary and limit mifepristone dose to 900 mg (5.6)."); JTX-011.1 (DRUG INTERACTIONS – "CYP3A inhibitors: Caution should be used when mifepristone is used with strong CYP3A inhibitors."), JTX-011.4, § 2.5 & Tbl. 1 ("Mifepristone tablets should be used in combination with strong CYP3A inhibitors only when necessary."); JTX-011.5–6, § 5.6 ("The benefit of concomitant use of these agents should be carefully weighed against the potential risks."); JTX-011.9, § 7.2 ("Caution should be used when strong CYP3A inhibitors are prescribed in combination with mifepristone. The benefit of concomitant use of these agents should be carefully weighed against the potential risks.").] Dr. Snyder credibly testified that physicians would read Teva's label as a warning not to coadminister mifepristone and a strong CYP3A inhibitor, unless medically necessary (*i.e.*, unless the benefit to the

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Corcept's label was revised in degree: the 2019 label recommended "caution" instead of "extreme caution" and indicated that the allowable dose of mifepristone was 900 mg instead of 300 mg of mifepristone, among other relevant changes. [*Compare* JTX-016.6, *with* JTX-015.6.] Though there are meaningful differences between the 2012 label and 2019 label based on this breakthrough, the current label still represents a warning against coadministration. Therefore, the label's history reinforces the Court's conclusion that Teva's label, like Corcept's 2019 label, does not encourage the coadministration of mifepristone and strong CYP3A inhibitors. *See United Therapeutics Corp. v. Sandoz, Inc.*, 2014 WL 4259153, at *18 (D.N.J. Aug. 29, 2014) ("[T]here is a rather significant difference between a warning and an instruction. A warning provides information regarding a potential risk. It does not prescribe a course of action.").

patient outweighs the risks). [*See* Tr. at 393:11–18, 394:18–395:8, 396:14–18, 397:7–22, 399:4–12.]

Second, in the unlikely event that a physician decides to coadminister mifepristone with a strong CYP3A inhibitor, Teva's label does not provide exclusively infringing instructions. Said differently, Teva's label permits non-infringing options for coadministering the substances. Infringement thus cannot be assumed. *See Warner-Lambert Co.*, 316 F.3d at 1364–65 ("[T]he request to make and sell a drug labeled with a permissible (non-infringing) use cannot reasonably be interpreted as an act of infringement (induced or otherwise) with respect to a patent on an unapproved use, as the ANDA does not induce anyone to perform the unapproved acts required to infringe."). For instance, as Corcept's own expert acknowledged, a physician could prescribe up to 600 mg of mifepristone to a patient who is already taking a strong CYP3A inhibitor and not infringe any of the asserted claims. [*See* Tr. at 268:5–270:9 (Dr. Carroll) (describing the series of steps required over the course of months for a physician to infringe claim 6 of the '800 Patent); *see also* JTX-001.37 ('214 Patent, claim 10); JTX-003.41 ('800 Patent, claim 1); JTX-003.41 ('800 Patent, claim 6).] Similarly, prescribing a strong CYP3A inhibitor and 300 mg or 600 mg of mifepristone to a patient would not infringe the asserted claims either. [*See* Tr. at 271:18–272:17 (Dr. Carroll) (acknowledging that § 2.5 of Teva's label would not result in infringement if strong CYP3A inhibitor added where patient already taking 300 mg or 600 mg of mifepristone); *see also* JTX-001.37 ('214 Patent, claim 10); JTX-003.41 ('800 Patent, claim 1); JTX-003.41 ('800 Patent, claim 6).] *See also supra* Section III.A.2 (pp. 35–36).

Accordingly, because Teva's label cautions physicians against coadministering mifepristone with a strong CYP3A inhibitor unless medically necessary and because infringement of Corcept's patented method is not guaranteed if a physician decides to coadminister the substances, the Court will not infer Teva's specific intent to induce infringement of the asserted claims. *See HZNP*, 940 F.3d at 702; *Vita-Mix*, 581 F.3d at 1329 n.2; *Takeda*, 785 F.3d at 631, 634–35.

Finally, Corcept's remaining arguments fail to persuade the Court to adopt a contrary conclusion. For example, Corcept submits that Teva's intent to induce is evidenced by its failure to seek alternative labeling given its position that coadministration is dangerous. "[H]ad Teva actually believed this, it could have petitioned the FDA to allow Teva to revert back to the original, more restrictive, 2012 Korlym label." [Pl.'s Post-Trial Br. at 20.] It cites this Court's disposition of *AstraZeneca LP v. Apotex, Inc.*, 623 F. Supp. 2d 615, 618 (D.N.J. 2009) (Bumb, J.). Corcept's argument is unconvincing. In *AstraZeneca*, Apotex's attempt to develop an alternative, non-infringing label was at the heart of the Court's analysis of specific intent, in part because the evidence suggested Apotex was aware of an infringement problem and persisted in distributing its generic drug nevertheless. *See id.* at 616, 618; *see also AstraZeneca*, 633 F.3d at 1060–61.

Here, as the Court previously explained, no such infringement problem exists, and Corcept has not met its burden of demonstrating a likelihood of direct infringement if Teva's mifepristone were placed on the market. Furthermore, evidence that a label was materially altered can demonstrate a defendant's lack of intent to induce infringement. *See, e.g.*, *United Therapeutics*, 2014 WL 4259153, at *17–21 (rejecting

a patentee's argument that carve out should be discounted because information remaining in generic product's label amounted to an "implicit" instruction). But the reverse is not true. The Court is not aware of any precedent requiring an ANDA applicant to modify its product label to avoid direct infringement arguments. That would turn the legal test "on its head." *See Takeda*, 785 F.3d at 632 n.4 (explaining that patentee needs to show that ANDA applicant took affirmative steps to induce, "not affirmative steps to make sure others avoid infringement").

IV. CONCLUSION

In sum, the Court concludes that Corcept has not met its burden of proving induced infringement pursuant to 35 U.S.C. § 271(b). Corcept has not demonstrated that direct infringement of the asserted claims is more likely than not if Teva's generic mifepristone product were placed on the market, and Corcept has not persuaded the Court of Teva's affirmative intent to induce infringement based on the language contained in Teva's product label. Because the credible record evidence discloses that no one has ever practiced the patented method, that physicians seek to avoid coadministering mifepristone and strong CYP3A inhibitors, that non-infringing alternatives are available, and that Teva's product label discourages physicians from coadministering, among other reasons, the Court will enter judgment in Teva's favor. An accompanying Order shall issue separately. Fed. R. Civ. P. 58(a).

s/Renée Marie Bumb
RENÉE MARIE BUMB
Chief United States District Judge

DATED: December 29, 2023

APPENDIX E

35 U.S. Code § 271 - Infringement of patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

(c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement; (4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale

of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

(e)

(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit—

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent,

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151–158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is

claimed in a patentor the use of which is claimed in a patent, or

(C)

(i) with respect to a patent that is identified in the list of patents described in section 351(l)(3) of the Public Health Service Act (including as provided under section 351(l)(7) of such Act), an application seeking approval of a biological product, or

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)—

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date

which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product,

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product, and

(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(l)(6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act.

The remedies prescribed by subparagraphs (A), (B), (C), and (D) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section

505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

(6)

(A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent—

(i) that is identified, as applicable, in the list of patents described in section 351(l)(4) of the Public Health Service Act or the lists of patents described in section 351(l)(5)(B) of such Act with respect to a biological product; and

(ii) for which an action for infringement of the patent with respect to the biological product—

(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(l)(6) of such Act; or

(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

(C) The owner of a patent that should have been included in the list described in section 351(l)(3)(A) of the Public Health Service Act, including as provided under section 351(l)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.

(f)

(1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and

intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(g) Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after—

(1) it is materially changed by subsequent processes; or

(2) it becomes a trivial and nonessential component of another product.

(h) As used in this section, the term "whoever" includes any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this title in the same manner and to the same extent as any nongovernmental entity.

(i) As used in this section, an "offer for sale" or an "offer to sell" by a person other than the patentee, or any designee of the patentee, is that in which the sale will occur before the expiration of the term of the patent.

APPENDIX F

21 U.S. Code § 355 - New drugs

* * *

(b) Filing application; contents

(1)

(A) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as part of the application—

(i) full reports of investigations which have been made to show whether such drug is safe for use and whether such drug is effective in use;

(ii) a full list of the articles used as components of such drug;

(iii) a full statement of the composition of such drug;

(iv) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

(v) such samples of such drug and of the articles used as components thereof as the Secretary may require;

(vi) specimens of the labeling proposed to be used for such drug;

(vii) any assessments required under section 355c of this title; and

(viii) the patent number and expiration date of each patent for which a claim of patent

infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that—

(I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or

(II) claims a method of using such drug for which approval is sought or has been granted in the application.

* * *

(j) Abbreviated new drug applications

* * *

(2)

(A) An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

(ii)

(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to

show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 321(p) of this title, and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of

the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (ii) through (vi) of subsection (b)(1)(A);

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under

subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use. The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

* * *

APPENDIX G

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

No. 2024-1346

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 in
No. 1:18-cv-03632-RMB-LDW,
Honorable Renée Marie Bumb, Chief Judge

TEVA'S RESPONSIVE BRIEF

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April 22, 2024

* * *

3. The district court rules in Teva's favor for two independent reasons.

After hearing the evidence and receiving post-trial briefing, the district court issued a detailed opinion concluding that Corcept failed to prove induced infringement for two independent reasons. *First*, Corcept did not prove future direct infringement because it did "not establish[] that physicians are likely to co-administer mifepristone with a strong CYP3A inhibitor at an infringing sequence and/or dosage." Appx4. *Second*, "Corcept failed to demonstrate that Teva possesses the specific intent to encourage" infringement "because Teva's proposed product label does not clearly 'encourage, recommend, or promote' infringement." Appx4 (quoting *Takeda Pharm. USA, Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015)).

a. The district court finds that Corcept did not show that Teva's product would lead to direct infringement.

The district court began its direct-infringement analysis by noting "the lack of record evidence demonstrating that anyone has ever practiced the claimed methods." Appx25. Neither party's expert had "ever prescribed mifepristone with a strong CYP3A inhibitor to treat Cushing's syndrome," much less at the claimed doses and in the claimed order, Appx28—a notable fact given that the experts have nearly 70 years of practice experience between them. And Corcept presented no evidence that anyone else "had ever prescribed the drugs together at an infringing sequence and/or dosage." Appx28–29. Citing this Court's decision in *Genentech*, the district court

observed that, while Corcept was not *required* to adduce evidence of past infringement to meet its burden of proof, the lack of such evidence was "relevant" and "persuasive." Appx25–28 (quoting *Genentech*'s observation that "past conduct is relevant to what will happen in the future").

The district court did not end its analysis there, however. Rather, expressly "[c]rediting Dr. Snyder's testimony," the district court also found it "highly unlikely that physicians will practice the claimed methods" in the future, for several reasons. Appx31.

First, the evidence showed that "physicians generally avoid co-administering mifepristone and strong CYP3A inhibitors .... because of the challenges of dosing mifepristone and the dangers associated with co-administering the two substances." Appx31. The court found "persuasive[]" Dr. Snyder's testimony "that physicians should 'be very afraid' of co-administration" because "it could cause a 'problem.'" Appx32 (quoting Appx1438 (394:11); Appx1441 (397:22)). The court also noted that Corcept's own medical director, Dr. Moraitis, "reported that he strongly prefers monotherapy because of the possibility of adverse drug-drug interactions." Appx32 (citing Appx1098–1099). And the court found it "significant that Dr. Lynette Nieman, a leading authority on the treatment of Cushing's syndrome, did not mention combining mifepristone with other drugs in a topic review of hers published in UpToDate," a widely used medical periodical. Appx32–33.

Second, the district court cited the availability of an alternative treatment that avoids the risks associated with co-administering mifepristone and strong CYP3A inhibitors: osilodrostat. Appx33. Osilodrostat, the evidence showed, is a "'powerful' and 'effective' drug that 'acts rapidly'" to treat Cushing's and is easier to

dose than mifepristone. Appx33. Again crediting Dr. Snyder, the court found that "physicians are unlikely to co-administer mifepristone and strong CYP3A inhibitors in the future because osilodrostat is a better drug to treat Cushing's syndrome." Appx33–34. Osilodrostat presents less of a risk of adverse drug-drug interactions when co-administered with strong CYP3A inhibitors because, unlike with mifepristone, "one can measure cortisol and know if one's giving the right dose" of osilodrostat. Appx1533 (489:3–24) (Snyder).

Third, the court found that Teva's label "cautions against co-administration" and that a physician who nonetheless decided to co-administer "could follow the instructions on Teva's label and not infringe." Appx35. For example, as Corcept's expert Dr. Carroll admitted, "administering 300 mg mifepristone to a patient who is already taking a strong CYP3A inhibitor would not infringe claim 6 of the '800 patent." Appx35 (citing Appx1285–1286 (267:5–9, 268:5–12)) (emphasis omitted). "Nor would administering 600 mg of mifepristone." Appx35 (emphasis omitted). "Similarly"—as Dr. Carroll also admitted—"a physician who administers a strong CYP3A inhibitor to a patient who is already taking 300 mg or 600 mg of mifepristone would not infringe claim 10 of the '214 patent or claim 1 of the '800 patent." Appx36 (citing Appx1279–1282 (261:14–264:8)) (emphasis omitted). All these dosing regimens are described on Teva's label, but none of them infringes. Appx35–36.

Corcept had argued that infringement was likely "because most patients require 900 mg or 1200 mg of mifepristone to achieve an efficacious result." Appx36. The suggested implication was that, if such a patient were to take a strong CYP3A inhibitor with those

doses of mifepristone, infringement could result. Appx36–37. The district court rejected this argument on the facts, noting that Corcept had adduced no evidence supporting its speculation that most patients need 900 or 1200 mg mifepristone or that any such patients have taken or will take mifepristone with a strong CYP3A inhibitor. Appx36–37.

b. The district court finds that Corcept did not show that Teva possesses specific intent to induce.

The district court determined that this Court's decision in *HZNP* disposed of Corcept's specific-intent arguments. *HZNP* held that a product label for a topical solution instructing users to wait for the treated area to dry before applying a second substance did not induce infringement of a patent requiring (i) application of the solution, (ii) waiting for the area to dry, and (iii) applying a second substance. *HZNP*, 940 F.3d at 699–702. The accused label, *HZNP* reasoned, recommended "only the first step of this method, nothing else." *Id.* at 702.

The district court concluded that, "[j]ust as the product label in *HZNP* did not encourage, promote, or recommend the specified steps of the patented method because nothing required post-product application of ... another substance, Teva's label does not encourage co-administration of mifepristone and a strong CYP3A inhibitor." Appx40–41. "The label only provides instructions how to co-administer the substances to achieve an efficacious result *if* a physician determines that it is medically necessary," Appx41—which was "unlikely" to happen, Appx42. "In this context," the court explained, "the label only provides 'guidance' for physicians; it does not teach an infringing use 'such that we are willing to infer from those instructions an

affirmative intent to infringe the patent.'" Appx41 (quoting *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1329 n.2 (Fed. Cir. 2009)).

The district court also "emphasiz[ed]" two additional points. Appx42. *First*, Teva's label "does not outline any benefits of co-administration or indicate the circumstances in which the agents should be co-administered." Appx42. Again crediting Dr. Snyder's testimony, the court found that "physicians would read Teva's label as a warning not to co-administer mifepristone and a strong CYP3A inhibitor." Appx43. Indeed, Corcept itself told the Patent Office during prosecution that *nearly identical* language in the 2012 Korlym label "represented a 'forceful' warning against coadministration." Appx42 n.8. *Second*, the court noted that, "in the unlikely event that a physician decides to co-administer mifepristone with a strong CYP3A inhibitor, Teva's label does not provide exclusively infringing instructions." Appx44. "Said differently, Teva's label permits non-infringing options for co-administering the substances"—meaning infringement "cannot be assumed." Appx44 (citing *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364–65 (Fed. Cir. 2003)).

The district court therefore entered judgment in Teva's favor. Appx48–49.

SUMMARY OF THE ARGUMENT

The district court ruled in Teva's favor for two independent reasons: Corcept failed to prove direct infringement and failed to prove specific intent. To prevail on appeal, Corcept must show that both determinations were clearly erroneous. Corcept cannot make that showing for either issue, let alone both.

1. The district court did not clearly err in concluding that Corcept failed to prove that Teva's product, if marketed, would lead to direct infringement.

a. A patentee asserting induced infringement must prove an underlying act of direct infringement. In the Hatch–Waxman context, the patentee may satisfy that predicate by proving that the generic ANDA product, if marketed, would infringe. *See Genentech*, 55 F.4th at 1379. Corcept's repeated contentions (e.g., at 46) that it did not need to prove future infringement and instead could satisfy its burden merely by showing that "the ANDA label instructs an infringing use" are thus incorrect. Indeed, the patentee in *Genentech* made the same argument, and this Court rejected it. *See id.* Corcept therefore had to show that physicians will co-administer mifepristone and strong CYP3A inhibitors in the particular order and at the particular doses called for by the asserted claims.

b. The district court did not clearly err in finding that Corcept failed to meet this burden. There is—undisputedly—no record evidence that anyone has ever practiced the asserted claims. As *Genentech* observed, "past conduct is relevant to what will happen in the future." *Id.*

The district court concluded that Corcept failed to meet its burden on direct infringement for several additional reasons, each well supported in the record. *First*, physicians try to avoid co-administering mifepristone and strong CYP3A inhibitors because of a risk of drug-drug interactions. *Second*, physicians are unlikely to find co-administration necessary in the future because of the availability of osilodrostat, a recently approved drug that is easier to dose in

combination with strong CYP3A inhibitors. *Third*, Teva's product label warns against co-administration of mifepristone and strong CYP3A inhibitors and in any event describes non-infringing dosing regimens that a physician could follow in the unlikely event she were to co-administer. In making these findings, the district

* * *

Sandoz's 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." *Id.* In the district court's view, "Genentech had not shown that any patient would be prescribed both pirfenidone and fluvoxamine such that the methods of the DDI patents would even be relevant," and, in any event, "if any IPF patient were prescribed fluvoxamine, a physician would likely choose a non-infringing treatment adjustment over any of the claimed methods." *Id.*

This Court affirmed. In doing so, it rejected Genentech's argument (nearly identical to Corcept's argument here) that the district court "erred in concluding that Sandoz's proposed label, which encourages, recommends, and promotes infringement, is not dispositive." *Id.* at 1378. The dispositive issue, the Court explained, is whether infringement is likely "if a particular drug were put on the market"—an issue that "requires 'consideration of all the relevant evidence,' including the proposed label's instructions and physician practice." *Id.* at 1379.

And, while a patentee need not prove past infringement to prevail in a Hatch–Waxman case, "past conduct is relevant to what will happen in the future." *Id.* The district court therefore "did not clearly

err by considering all the relevant evidence .... including testimony from physicians that, in their decades of treating IPF patients, they had never prescribed pirfenidone to an IPF patient taking fluvoxamine; and were they to find themselves in that position, they would choose a non-infringing response—*i.e.*, prescribing nintedanib [another drug used to treat IPF] instead." *Id.* And "[t]he 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.*

Genentech eviscerates Corcept's argument that Teva's label is dispositive. In that case, both the district court and the Federal Circuit assumed certain language in Sandoz's label recommended infringement. *See id.* at 1375, 1378–79. Yet both courts *still* found no direct infringement, because Genentech failed to show that any future infringement was likely. *Id.* at 1380. This Court also declined to reach the issue of specific intent, underscoring that whether the label recommended infringement was irrelevant in view of the district court's supportable finding that direct infringement was unlikely. *Id.* at 1381.

It is thus decidedly not the law that "[w]hen the ANDA label instructs an infringing use, the elements of induced infringement do 'collapse' into 'one inquiry focused exclusively on the language of the product label,'" Corcept Br. 46. The district court correctly rejected this argument. *See* Appx26; *see also Takeda*, 785 F.3d at 634–35 (affirming district court's conclusion that patentee failed to carry its burden to "show likelihood of direct infringement," and therefore not "reach[ing] the question of whether there was evidence of inducement").

APPENDIX H

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

Civil Action No. ____

CORCEPT THERAPEUTICS, INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICALS INDUSTRIES LTD.,

Defendants.

COMPLAINT FOR PATENT INFRINGEMENT

(Filed Electronically)

* * *

commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product before expiration of the patents listed in the Orange Book with respect to KORLYM®.

34. Teva's 3rd Notice Letter alleges that the claims of the '242 patent and the '243 patent are invalid and/or will not be infringed by the activities described in Teva's ANDA.

35. On information and belief, in connection with ANDA No. 211436, Teva provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the claims of the '242 patent and the '243 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Teva's ANDA.

36. On information and belief, in connection with the filing of ANDA No. 211436, Teva provided written certifications to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), indicating that it seeks to obtain approval of its ANDA to engage in the commercial manufacture, use, or sale of Teva's Proposed Product before the expiration of the Orange Book patents with respect to KORLYM®.

37. On information and belief, following FDA approval of Teva's ANDA, Teva USA and Teva Ltd will work in concert with one another to make, use, offer to sell, or sell Teva's Proposed Product throughout the United States, or import such generic products into the United States.

Count I: Infringement of the '242 Patent

38. Corcept repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

39. Teva's submission of its ANDA and accompanying Paragraph IV Certifications to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product, prior to the expiration of the '242 patent,

constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

40. A justiciable controversy exists between the parties hereto as to the infringement of the '242 patent.

41. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '242 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States.

42. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '242 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '242 patent and knowledge that its acts are encouraging infringement.

43. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '242 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, Teva knew and knows that Teva's Proposed Product is designed for a use that infringes one or more claims of the '242 patent, and Teva's Proposed Product lacks a substantial non-infringing use.

44. Failure to enjoin Teva's infringement of the '242 patent will substantially and irreparably damage Corcept.

45. Corcept does not have an adequate remedy at law.

Count II: Infringement of the '243 Patent

46. Corcept repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

47. Teva's submission of its ANDA and accompanying Paragraph IV Certifications to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product, prior to the expiration of the '243 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

48. A justiciable controversy exists between the parties hereto as to the infringement of the '243 patent.

49. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '243 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States.

50. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '243 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '243 patent and knowledge that its acts are encouraging infringement.

51. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '243 patent under 35 U.S.C. § 271(c) by making, using, offering to sell,

selling, and/or importing Teva's Proposed Product in the United States. On information and belief, Teva knew and knows that Teva's Proposed Product is designed for a use that infringes one or more claims of the '243 patent, and Teva's Proposed Product lacks a substantial non-infringing use.

52. Failure to enjoin Teva's infringement of the '243 patent will substantially and irreparably damage Corcept.

53. Corcept does not have an adequate remedy at law.

Count III: Infringement of the '214 Patent

54. Corcept repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

55. Teva's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product, prior to the expiration of the '214 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

56. A justiciable controversy exists between the parties hereto as to the infringement of the '214 patent.

57. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '214 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States.

58. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '214 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the

United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '214 patent and knowledge that its acts are encouraging infringement.

59. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '214 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, Teva knew and knows that Teva's Proposed Product is designed for a use that infringes one or more claims of the '214 patent, and Teva's Proposed Product lacks a substantial non-infringing use.

60. Failure to enjoin Teva's infringement of the '214 patent will substantially and irreparably damage Corcept.

61. Corcept does not have an adequate remedy at law.

PRAYER FOR RELIEF

62. WHEREFORE, Plaintiff Corcept respectfully requests the following relief:

(A) A Judgment that Teva infringed the patents-in-suit by submitting ANDA No. 211436;

(B) A Judgment that Teva has infringed, and that Teva's making, using, offering to sell, selling, or importing Teva's Proposed Product will infringe one or more claims of the patents-in-suit;

(C) An Order that the effective date of FDA approval of ANDA No. 211436 be a date no earlier than the later of the expiration of each patent-in-suit, or any later

expiration of exclusivity to which Corcept is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Teva and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing Teva's Proposed Product until after the expiration of the each patent-in-suit, or any later expiration of exclusivity to which Corcept is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Teva, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any method claimed in the patents-in-suit, or from actively

* * *

APPENDIX I

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

Civil Action No. ____

CORCEPT THERAPEUTICS, INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICALS INDUSTRIES LTD.,

Defendants.

COMPLAINT FOR PATENT INFRINGEMENT

(Filed Electronically)

* * *

Count I: Infringement of the '800 Patent

38. Corcept repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

39. Teva's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product, prior to the expiration of the '800 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

40. A justiciable controversy exists between the parties hereto as to the infringement of the '800 patent.

41. Unless enjoined by this Court, Teva will infringe one or more claims of the '800 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States.

42. Unless enjoined by this Court, Teva will induce infringement of one or more claims of the '800 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, Teva will intentionally encourage acts of direct infringement with knowledge of the '800 patent and knowledge that its acts are encouraging infringement.

43. Unless enjoined by this Court, Teva will contributorily infringe one or more claims of the '800 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, Teva knew and knows that Teva's Proposed Product is designed for a use that infringes one or more claims of the '800 patent, and Teva's Proposed Product lacks a substantial non-infringing use.

44. Failure to enjoin Teva's infringement of the '800 patent will substantially and irreparably damage Corcept.

45. Corcept does not have an adequate remedy at law.

Count II: Infringement of the '801 Patent

46. Corcept repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

47. Teva's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product, prior to the expiration of the '801 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

48. A justiciable controversy exists between the parties hereto as to the infringement of the '801 patent.

49. Unless enjoined by this Court, Teva will infringe one or more claims of the '801 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States.

50. Unless enjoined by this Court, Teva will induce infringement of one or more claims of the '801 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, Teva will intentionally encourage acts of direct infringement with knowledge of the '801 patent and knowledge that its acts are encouraging infringement.

51. Unless enjoined by this Court, Teva will contributorily infringe one or more claims of the '801 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, Teva knew and knows that Teva's

Proposed Product is designed for a use that infringes one or more claims of the '801 patent, and Teva's Proposed Product lacks a substantial non-infringing use.

52. Failure to enjoin Teva's infringement of the '801 patent will substantially and irreparably damage Corcept.

53. Corcept does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Corcept respectfully requests the following relief:

(A) A Judgment that Teva infringed the patents-in-suit by submitting ANDA No. 211436;

(B) A Judgment that Teva has infringed, and that Teva's making, using, offering to sell, selling, or importing Teva's Proposed Product will infringe one or more claims of the patents-in-suit;

(C) An Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of FDA approval of ANDA No. 211436 be a date no earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Corcept is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Teva and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing Teva's Proposed Product until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Corcept is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Teva, its

officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any method claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Corcept is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of Teva's Proposed Product will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

(G) To the extent that Teva has committed any acts with respect to the methods claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Corcept damages for such acts;

(H) If Teva engages in the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of Teva's Proposed Product prior to the expiration of the patents-in-suit, a Judgment awarding damages to Corcept resulting from such infringement, together with interest;

(I) A Judgment declaring that the patents-in-suit remain valid and enforceable;

(J) A Judgment awarding Corcept its costs and expenses incurred in this action; and

(K) Such further and other relief as this Court may deem just and proper.

Dated: March 17, 2023

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APPENDIX J

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

Civil Action No. 18-3632 (SDW)(CLW)
Civil Action No. 19-5066 (SDW)(CLW)
(consolidated)

CORCEPT THERAPEUTICS, INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS (USA) INC.,

Defendant.

CONSOLIDATION AND SCHEDULING ORDER
(Filed Electronically)

THIS MATTER, having come before the Court by way of an Initial Scheduling Conference on February 1, 2019, and all Counsel having consented to the dates set forth herein, and for good cause shown,

IT IS on this 21st day of February, 2019,

ORDERED that Civil Action Nos. 18-3632 (SDW)(CLW) and 19-5066 (SDW)(CLW) (the "Consolidated Actions") are consolidated for all purposes;

IT IS FURTHER ORDERED that all filings going forward shall be filed in Civil Action No. 18-3632 and that Civil Action No. 19-5066 shall be administratively terminated by the Clerk's office;

IT IS FURTHER ORDERED that the Consolidated Actions shall proceed on the following schedule:

Date	Event
March 1, 2019	Teva Answer to Complaint Filed in C.A. No. 19-5066
March 22, 2019	Corcept's Response to Teva Answer to Complaint Filed in C.A. No. 19-5066
March 22, 2019	Amended initial disclosures
March 22, 2019	Disclosure of Asserted Claims
May 13, 2019	Defendants serve Invalidity/Noninfringement Contentions
July 2, 2019	Plaintiff serves response to Invalidity Contentions and Infringement Contentions
July 16, 2019	Parties exchange proposed terms for construction
August 6, 2019	Parties exchange preliminary claim constructions and supporting evidence
August 20, 2019	Parties exchange intrinsic/extrinsic evidence used to oppose other sides' construction
August 30, 2019	Parties file Joint Claim Construction and Prehearing Statement

September 30, 2019	Close of claim construction fact discovery
October 15, 2019	Parties file Opening *Markman* Briefs
November 14, 2019	Close of claim construction expert discovery
December 16, 2019	Parties file Responsive *Markman* Briefs
December 30, 2019	Deadline to propose schedule for *Markman* hearing
TBD	Date for *Markman* hearing

/s/ Cathy L. Waldor
Honorable Cathy L. Waldor, U.S.M.J.

APPENDIX K

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

Civil Action Nos. 18-3632 (RMB) LDW)
(consolidated); 23-01505 (RMB)(LDW)

CORCEPT THERAPEUTICS, INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

Filed Electronically

STIPULATION REGARDING VALIDITY AND CONSOLIDATION

WHEREAS, on March 15, 2018, Plaintiff Corcept Therapeutics, Inc. ("Corcept") filed a complaint in *Corcept Therapeutics, Inc. v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 18-3632 (D.N.J.) alleging that Defendant Teva Pharmaceuticals USA, Inc. ("Teva") infringed U.S. Patent No. 8,921,348 ("the '348 patent") and U.S. Patent No. 9,829,495 ("the '495 patent") by filing Abbreviated New Drug Application ("ANDA") No. 211436 seeking approval to engage in the commercial manufacture, use, sale, importation, or offer for sale of generic 300 mg mifepristone tablets;

WHEREAS, on July 6, 2018, Corcept amended its complaint to include allegations of infringement of U.S. Patent No. 9,943,526 ("the '526 patent");

WHEREAS, on February 8, 2019, Corcept filed a complaint in *Corcept Therapeutics, Inc. v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 19-5066 (D.N.J.) alleging that Teva's filing of ANDA No. 211436 infringed U.S. Patent No. 10,166,242 ("the '242 patent"), U.S. Patent No. 10,166,243 ("the '243 patent"), and U.S. Patent No. 10,195,214 ("the '214 patent");

WHEREAS, on February 21, 2019, C.A. Nos. 18-3632 and 19-5066 were consolidated for all purposes, and C.A. No. 19-5066 was administratively terminated;

WHEREAS, on December 13, 2019, Corcept filed a complaint in *Corcept Therapeutics, Inc. v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 19-21384 (D.N.J.) alleging that Teva's filing of ANDA No. 211436 infringed U.S. Patent No. 10,500,216 ("the '216 patent");

WHEREAS, on March 27, 2020, C.A. Nos. 18-3632 and 19-21384 were consolidated for all purposes, and C.A. No. 19-21384 was administratively terminated;

WHEREAS, Corcept is no longer asserting infringement of the '348, '495, '526, '242, and '243 patents in C.A. No. 18-3632, and therefore the only remaining patents in that consolidated action are the '214 and '216 patents;

WHEREAS, on March 17, 2023, Corcept filed a complaint in C.A. No. 23-1505 alleging that Teva's filing of ANDA No. 211436 infringed U.S. Patent No. 10,842,800 ("the '800 patent") and U.S. Patent No. 10,842,801 ("the '801 patent");

WHEREAS, there is a need to conserve judicial economy and reduce the costs and burdens of litigation

on the Court and the parties, including the need to avoid delaying resolution of 18-3632 or avoid conducting two trials;

NOW THEREFORE, Corcept and Teva, by and through their undersigned counsel in this matter, and subject to the Court's approval, stipulate and agree as follows:

1. C.A. Nos. 18-3632 and 23-1505 (the "Consolidated Actions") are consolidated for all purposes;

2. All filings going forward shall be filed in C.A. No. 18-3632, and C.A. No. 23-1505 shall be administratively terminated by the Clerk's office;

3. Any judgment, order, or decision in the Consolidated Actions regarding the validity of the '216 patent shall apply with equal and binding force to the '801 patent;

4. Any judgment, order, or decision in an appeal of the final judgment of the validity of the '216 patent in the Consolidated Actions shall apply with equal and binding force to the '801 patent; and

5. The Consolidated Actions shall proceed on the following schedule:

Date	Event
May 12, 2023	Corcept to submit amended/ supplemental Opening expert reports on infringement of the '800 and '801 patents
June 12, 2023	Teva to submit amended/ supplemental Rebuttal expert reports on

	noninfringement of the '800 and '801 patents
July 14, 2023	Expert discovery deadline
~~August 25, 2023~~	Final Pretrial Order to be submitted to Court on August 24, 2023 at noon**
~~After August 25, 2023~~ ~~[*subject to Court and counsel availability*]~~	Final Pretrial Conference with Magistrate Judge Wettre in person on August 29, 2023 at 11:00 a.m. in Newark-Courtroom 3C
September 6, 2023	Each party shall submit its pre-trial brief (limited to 30 pages (12-point font, double-spaced) per side) The parties agree not to file proposed findings of fact and conclusions of law unless otherwise specifically ordered by the Court. Parties file opening Daubert Briefs (limited to 1 motion; 10 pages) and opening motions *in limine* (limited to 3 motions; 5 pages (12-point font, double-spaced) per motion)
September 13, 2023	Parties file rebuttals to any Daubert Briefs (limited to 10 pages) and motions *in limine* (limited to 5 pages

	(12-point font, double-spaced) per motion) The parties agree not to file responses to pre- trial briefs or proposed findings of fact and conclusions of law unless otherwise specifically ordered by the Court.
September 20, 2023	Each party shall submit a list of pre-marked exhibits and a witness list, including the name and address (city and state only) of each potential witness All trial exhibits must be pre-marked in accordance with each party's exhibit list. The parties shall not send courtesy copies of trial exhibits unless the Court requests them. Counsel shall retain custody of their trial exhibits until closings.
September 27	4-5 day trial before the Honorable Renée Marie Bumb [*subject to Court availability*]

Dated: May 10, 2023

s/ William C. Baton

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SO ORDERED: May 15, 2023

/s/ Leda D. Wettre

Hon. Leda D. Wettre, U.S.M.J.

APPENDIX L

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

Civil Action No. 18-3632 (SDW)(LDW)
(consolidated)
[redacted]

CORCEPT THERAPEUTICS, INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

Hon. Susan D. Wigenton, U.S.D.J.
Hon. Leda D. Wettre, U.S.M.J.
(Filed Electronically)

MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,195,214

* * *

1117, 1133 (Fed. Cir. 2018). Here, it is undisputed that Teva's label includes instructions that plainly direct healthcare providers how to practice each step of each asserted claim. And because these instructions are *the only* dosing instructions for healthcare providers to follow in order to co-administer mifepristone with strong CYP3A inhibitors, the law is clear that the Court may infer intent from Teva's label. The Court can therefore decide on summary judgment, without the need for trial, that Teva will induce infringement of Claims 1-13 of the '214 Patent.

II. FACTUAL BACKGROUND

A. State of the Art Prior to the Claimed Inventions

1. Cushing's Syndrome is a Debilitating and Difficult-to-Treat Disorder

Cushing's syndrome is a "debilitating endocrine disorder" caused by elevated levels of the hormone cortisol, which are usually the result of tumors that afflict the pituitary or adrenal glands. Morgan at Abstract; Pivonello at 385-86. "The excess cortisol seen in Cushing's syndrome results in hypertension, hyperglycemia [high blood sugar], obesity, and a myriad of other problems." Morgan at 320. These myriad other problems include "a risk of life-threatening cardiovascular, infectious and metabolic complications." Guelho at 464. Excess cortisol (hypercortisolemia) can also have "major effects on the brain that can result in psychopathology and neurocognitive dysfunction." *Id*. As such, Cushing's syndrome is "associated with significant morbidity and mortality." Fleseriu 2013(a) at 1.

The first line treatment for patients with Cushing's syndrome is surgery to remove the tumors responsible for generating the excess cortisol. Morgan at 319. Many patients are not candidates for surgery, however, often because they are too sick to survive the procedure or have tumors that cannot be located or completely removed. These patients require pharmacological treatment. *See id*.

* * *

mifepristone product reflects how Teva intends for physicians to use its product. *Id.* at ¶¶ 16-18. [redacted] *Id.* at ¶ 19 [redacted]. Teva's package insert is identical in all material respects to the current Korlym® package insert. *Id.* at ¶ 20.

The content of Teva's package insert is undisputed. The Indications and Usage section of Teva's package insert states that Teva's mifepristone product is "indicated to control hyperglycemia secondary to hypercortisolism in [certain] adult patients with endogenous Cushing's syndrome." *Id.* at ¶ 21. The Dosage and Administration section of Teva's package insert states that the "recommended starting dose is 300 mg orally once daily," and that the daily dose "may be increased in 300 mg increments ... to a maximum of 1,200 mg once daily." *Id*. at ¶ 22.

The Dosage and Administration section also includes a subsection titled "Concomitant Administration with CYP3A Inhibitors." *Id.* at ¶ 23. This subsection of the package insert provides "dose adjustment" steps for physicians to follow for adding a strong CYP3A inhibitor to the treatment regimen of "patients already being treated with mifepristone

tablets." *Id.* at ¶ 24. The instructions in Teva's package insert for adding a strong CYP3A inhibitor to the treatment regimen of a patient receiving an original mifepristone dose of 900 mg require that the physician "reduce dose to 600 mg" before adding the strong CYP3A inhibitor. *Id.* at ¶¶ 25-27. This specific dose adjustment instruction is the only dosing option presented in the label "when [a] strong CYP3A inhibitor is added" to the treatment regimen of a patient receiving an original mifepristone dose of 900 mg. *Id.*

The Clinical Pharmacology section of Teva's package insert contains a table showing data derived from the "in vivo assessment of drug interactions." *Id.* at ¶ 30. The data are derived from two clinical studies (in human volunteers) in which mifepristone was co-administered with strong CYP3A inhibitors. In the first study, 600 mg of mifepristone was co-administered with ketoconazole. *Id.* at ¶ 31. In the second, 900 mg of mifepristone was co-administered with itraconazole. *Id*. Teva's package insert includes data regarding the increase in mifepristone blood serum concentrations as a result of co-administration with the strong CYP3A inhibitors, and states that a "dose adjustment [is] required" in order to co-administer mifepristone with either of ketoconazole or itraconazole. *Id.* at ¶ 32.

As explained more fully below, the language and data in the Dosage and Administration and Clinical Pharmacology sections of Teva's package insert plainly instruct a physician to perform each and every step of the methods claimed in the '214 Patent. And because Teva: (1) intends for physicians to use its ANDA Product in accordance with its package insert, and (2) intends to market its ANDA Product with a

package insert that plainly instructs doctors to engage in an infringing use, well-settled precedent makes clear that, as a matter of law, Teva has the requisite intent to induce infringement. The Court should therefore grant summary judgment.

III. LEGAL STANDARD

A. Summary Judgment

Summary judgment shall be granted when "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A fact is not "material" unless proof of its existence or non-existence would affect disposition of the case under applicable law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). An issue of material fact is not "genuine" unless the evidence offered is such that a reasonable fact finder might return a verdict for the non-movant. *Id*. To succeed, the party

* * *

Claim Element	Teva's Labeling
reducing the original once-daily dose to an adjusted once-daily dose of 600 mg mifepristone,	Table 1 instructs to "reduce dose to 600 mg" mifepristone "when [a] strong CYP3A inhibitor is added." SMF at ¶27. Table 3 states that a "[d]ose adjustment" is "required" in such circumstances. SMF at ¶ 32.

administering the adjusted once-daily dose of 600 mg mifepristone and a strong CYP3A inhibitor to the patient,	Section 2.5 states that "when necessary," the reduced mifepristone dose should be "used in combination with strong CYP3A inhibitors." SMF at ¶¶ 28-29.
wherein said strong CYP3A inhibitor is selected from the group consisting of ketoconazole, itraconazole, nefazodone, ritonavir, nelfmavir, indinavir, boceprevir, clarithromycin, conivaptan, lopinavir, posaconazole, saquinavir, telaprevir, cobicistat, troleandomycin, tipranivir, paritaprevir and voriconazole.	Section 2.5 of Teva's package insert instructs that the "strong inhibitors of CYP3A" that may be "used in combination" with mifepristone "when necessary" include "ketoconazole, ... itraconazole, nefazodone, ritonavir, nelfinavir, indinavir, ... clarithromycin, conivaptan, lopinavir/ritonavir, ... posaconazole, saquinavir, ... or voriconazole." SMF at ¶ 28.

B. The Court May Therefore Conclude as a Matter of Law that Teva Has the Requisite Intent to Induce Infringement

Teva does not dispute that it intends for physicians to follow the instructions set forth in its package insert. [redacted]

[redacted]

As set forth above, there can be no dispute that Teva's label presents a series of instructions for healthcare providers to follow when co-administering mifepristone with strong CYP3A inhibitors. Specifically, when adding a strong CYP3A inhibitor to the treatment regimen of a patient already receiving a 900 mg mifepristone dose, Teva's label unambiguously instructs healthcare providers to reduce the mifepristone dose to 600 mg for co-administration. That dosing regimen reads directly on the asserted claims of the '214 Patent. Teva's label does not provide any conflicting or alternate dosing regimens for healthcare providers to choose from. The Court therefore can infer, as a matter of law and consistent with well-established precedent, that the clear instructions provided in Teva's label will induce infringement of the claimed methods. *See Vanda Pharm.*, 887 F.3d at 1133 (defendant had requisite intent to induce where its "proposed label itself recommends infringing acts"); *see also, e.g.*, *Braintree Labs.*, 688 F. App'x at 910 ("Because Breckenridge's ANDA label 'instruct[s] how to engage in an infringing use, [it] show[s] an affirmative intent that the product be used to infringe.'" (alteration in original)); *Sanofi*, 875 F.3d at 646 ("The content of the label in this case permits the inference of specific intent to encourage the infringing use."); *BTG Int'l Ltd.*, 352 F. Supp. 3d at 397 ("In the context of patent infringement litigation involving pharmaceuticals, 'the sale of a product specifically labeled for use in a patented method constitutes inducement to infringe that patent.'" (citation omitted)). Accordingly, as a matter of law, Teva intends to induce infringement of the claims of the '214 Patent. Summary judgment should be granted.

Expert testimony is not required to determine that Teva infringes the '214 Patent. As set forth above, there is a readily apparent correlation between the undisputed content of Teva's package insert and the claims of the '214 Patent. An expert need not testify whether the instructions in the package insert read upon the claims when it is clear to a layperson that the instructions in the package insert and the steps of the claim are the same. For instance, another court in this District granted summary judgment of induced infringement in similar circumstances. In *Hoffmann-La Roche Inc. v. Apotex Inc.*, there was "no genuine dispute that the proposed product labels direct patients to take actions which constitute infringement of [the asserted claims]." No. 07-4417, 2010 WL 3522786, at *3 (D.N.J. Sept. 2, 2010) (Chesler, J.). The defendants in *Hoffman* attempted to argue that they nonetheless did not intend to induce infringement because patients could choose instead to use the products for "substantial non-infringing uses." *Id.* The court rejected that argument as a matter of law, explaining that the defendants "are expressly instructing others to perform a method which infringes a method patent. The fact that they may, in addition, be instructing others to do things which do not infringe has no bearing on the inference of specific intent to induce infringement." *Id.* at *4. The court therefore found summary judgment appropriate, because where "the evidence unequivocally demonstrates that Defendants intend that their purchasers follow the [infringing] package insert instructions, [they] therefore have the requisite specific intent to induce infringement." *Id.* at *5.

The same conclusion is warranted here. It is undisputed that Teva's package insert provides step-by-step instructions that direct healthcare providers

to practice each element of the methods claimed in the '214 Patent when they co-administer mifepristone with strong CYP3A inhibitors. It is therefore immaterial that Teva's ANDA product can also be put to other uses; the fact that the package insert plainly instructs healthcare providers to engage in the infringing use demonstrates as a matter of law that Teva has the requisite intent to induce infringement. The Federal Circuit has made clear that where the proposed ANDA product label contains "instructions [that] are unambiguous on their face" and teach healthcare providers to practice an infringing use, those instructions "encourage or recommend infringement." *Eli Lilly & Co.*, 845 F.3d at 1368-69. Accordingly, Corcept's motion for summary judgment should be granted.

C. Teva's Non-Infringement Defense Is Without Merit

In opposing Corcept's request for leave to file the instant motion, Teva took the position that the Federal Circuit's split-panel decision in *HZNP Medicines LLC v. Actavis Laboratories UT, Inc.*, 940 F.3d 680 (Fed. Cir. 2019), "demonstrates that Teva cannot be held liable for induced infringement based on [its proposed] label language." *See* February Letter. Teva went

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APPENDIX M

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

24-1346

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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* * *

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

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[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.

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

* * *

APPENDIX N

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2024-1346

CORCEPT THERAPEUTICS, INC.,

Plaintiff-Appellant,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Appellee.

On Appeal form the United States District Court for the District of New Jersey in No. 1:18-cv-03632-RMB-LDW, Honorable Renée Marie Bumb, Chief Judge

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REPLY BRIEF FOR PLAINTIFF-APPELLANT

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May 28, 2024

* * *

2. Outside Evidence Cannot Override the ANDA

Teva contends (Br. 22-23 (citing *Genentech*)) this Court's precedent "requires" the district court to consider "all relevant evidence," including "physician practice." Teva then misstates Corcept's position in asserting (Br. 29) that "Corcept is contending that courts may not look at real-world practice to determine whether future infringement of a patented method involving the ANDA product is likely." Not so. Corcept's position is that where the ANDA Label itself clearly answers the direct infringement inquiry, evidence outside the ANDA cannot override the ANDA. *Cf. Sunovion*, 731 F.3d at 1280. *Genentech* does not hold otherwise. In that case, the ANDA label instructed doctors to *avoid* coadministering the drugs set forth in the patented methods. This Court endorsed the district court's crediting of physician practice where the ANDA label did not clearly show infringement—and that outside evidence showed physicians avoided coadministering those drugs, and had never coadministered them in the past.

Here, by contrast, Teva's ANDA Label instructs physicians to coadminister when "necessary," and to perform the patented dosage adjustments when doing so. Appx35. The record also includes numerous instances of past medical necessity requiring coadministration (Appx1060-61, Appx1262-63), such that the district court stopped admitting further such evidence as cumulative (Appx1507-08). Yet the district court credited Dr. Snyder's contrary testimony that he personally would nonetheless avoid coadministration as dispositive of the direct infringement inquiry. Appx32-34. Teva cites no case where this Court has

ever held that such extrinsic evidence can be used to *override* the content of the ANDA in this manner. Indeed, *Sunovion* held the contrary—that the ANDA filer was bound by the ANDA even if it submitted evidence that its manufacturing process deviated from the specifications of the ANDA. 731 F.3d at 1279-80. Thus, Teva's argument fails as a legal matter.

Teva's argument also fails because it improperly requires of Corcept evidence that has never been required under this Court's precedent. Here, the patient population is small (1,500 persons in the U.S.) and the methods newly developed (part of the branded label for only 11 months prior to the close of fact discovery). It makes no sense to conclude that because no doctor testified at trial that they provided infringing doses in the 11 months immediately after the updated Korlym® Label was approved, that Teva can now market a product with an infringing ANDA Label describing a medically-beneficial therapeutic method over the remaining *13 years* of the patents-in-suit. Instead, and contrary to Teva's argument, this Court's precedent demands that the focus remain on the ANDA Label itself.

3. Method Patents Should Not Be Treated Differently

Teva incorrectly suggests (Br. 27-28) that application of these well-settled legal principles is "misplaced" in a "case involving method patents." Not so. "[T]raditional patent law principles" apply in every case; the ANDA applicant is bound by the "ANDA specification." *Ferring*, 764 F.3d at 1408. This Court has never used a different direct infringement inquiry for method of treatment patents, and there is no reason to adopt such a standard now. Instead, adherence to this Court's precedent, including most significantly *Vanda*,

requires that where an accused generic drug label recommends or encourages an infringing use, the ANDA answers the direct infringement inquiry. 887 F.3d at 1130 (finding direct infringement based on the content of the accused label because "the ANDA itself dominates the analysis.").

Teva is also wrong to argue (Br. 23) that *Genentech* "squarely rejected" the possibility of the ANDA label resolving the direct infringement inquiry with respect to method claims. Teva overlooks a key difference between *Genentech* and this case: there, unlike here, the accused ANDA label instructed *against* the infringing use. The accused label stated that "[t]he concomitant administration of pirfenidone and fluvoxamine or other strong CYP1A2 inhibitors (e.g., enoxacin) *is not recommended*." *Genentech*, 55 F.4th at 1375. And so, because the ANDA did not answer the direct infringement inquiry in *Genentech*, this Court considered other evidence, such as prior physician practice. *Id.* at 1379-80. Consideration of that other evidence revealed that, unlike here, no physician had *ever* coadministered the two drugs at issue, despite many years of availability. *Id.* As a result of *that* evidence, future direct infringement was deemed unlikely. *Id. Genentech* does not hold that evidence outside the ANDA can override the ANDA itself.

4. *Vanda* Does Not Require Evidence of Physician Practice

Teva also misreads *Vanda* in arguing (Br. 27) that it "did not hold that the label necessarily resolves the direct-infringement inquiry" and instead "emphasized the relevance of real-world practice." There, in accordance with well-settled law, the patentee had argued that "it did not need to prove instances of direct infringement by physicians because this is a Hatch-

Waxman case." 887 F.3d at 1129. This Court *agreed* with the patentee, holding that "a patentee *does not* need to prove an actual past instance of direct infringement by a physician to establish infringement." *Id.* And it held that "patentees in Hatch-Waxman litigations asserting method patents do not have to prove that prior use of the NDA-approved drug satisfies the limitations of the asserted claims." *Id.* at 1130. Accordingly, this Court further held, a patentee "can satisfy its burden to prove the predicate direct infringement by showing that if the proposed ANDA product were marketed, it would infringe the [asserted] patent," and "the ANDA itself dominates [that] analysis." *Id.* Thus, *Vanda* did not hold or "emphasize" that it is proper to credit testimony regarding past physician practice (and then allow that testimony to override the ANDA) when the ANDA itself answers the direct infringement question.

Teva also misreads (Br. 27) the *Vanda* holding as having "reaffirmed the proposition that 'the infringement determination is based on consideration of all the relevant evidence,'" including past physician practice. Teva—like the district court—takes *Vanda's* discussion of "all relevant evidence" out of context. Instead, in support of its holding that it was proper for the *Vanda* district court to find direct infringement based on the label alone, this Court cited to *Ferring*. The full quote from *Ferring* confirms that the "all the relevant evidence" is the ANDA itself when the ANDA directly resolves the infringement question:

> The infringement determination is thus based on consideration of *all the relevant evidence*, and "[b]ecause drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the

> ANDA's description of the drug," *the ANDA itself dominates the analysis*. . . . In some cases, the ANDA specification directly resolves the infringement question because 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. . . . In cases in which the ANDA specification does not resolve the infringement question in the first instance, we have endorsed the district court's reference to relevant evidence.

Ferring, 764 F.3d at 1408. What that means is that, as in *Sunovion* and *Brimonidine*, "other relevant information" cannot change the outcome of a direct infringement inquiry that an ANDA has already clearly answered.

C. Even If Teva's ANDA Label Alone Were Not Sufficient To Prove Direct Infringement, the Extrinsic Evidence Together With The ANDA Label Is More Than Sufficient

Even assuming Teva's ANDA Label itself does not resolve the inquiry, the "real world" evidence coupled with the ANDA Label demonstrates that direct infringement will likely occur. Here, Teva's ANDA Label instructs physicians to practice the patented dosage adjustments when dual therapy is "necessary" for the patient. At trial, the evidence showed that numerous different doctors—including Teva's own expert, Dr. Dobs—have in fact found dual therapy to be "necessary" for their patients. *See* Opening Brief § I.B.1. This is why FDA asked Corcept to run the studies in the first place. Appx13. Thus, this is far from a case where clinical practice bears little resemblance to the patented methods of use. This case is not like

Genentech, where the label instructed doctors to avoid dual therapy, and the real-world evidence showed that doctors followed that instruction.

Moreover, as noted in the PTAB decision that was affirmed by this Court, when the FDA first approved Korlym® in 2012, it recognized that because doctors already prescribed ketoconazole (a strong CYP3A inhibitor) to patients with Cushing's syndrome, there was a "high potential for concomitant use" with mifepristone and thus a drug-drug interaction trial was necessary to "help provide more therapeutic options available to Cushing's patients and appropriate labeling of mifepristone when co-administered with CYP3A inhibitors." *Teva v. Corcept*, PGR2019-00048, 2020 WL 6809812, at *5 (P.T.A.B. Nov. 18, 2020). Corcept did the work and invented a safe course of treatment for those patients. Teva cannot defend the district court's three legal errors in discounting the real-world evidence.

First, Teva cannot defend the district court's adoption of an erroneous legal standard in ruling that future infringement would be unlikely because "Corcept has not persuaded this Court that today *most* patients who receive a strong CYP3A inhibitor are already taking at least 900 mg of Korlym® or that patients who are already receiving a strong CY3PA inhibitor will be prescribed at least 900 mg of Korlym®." Appx37. There is no "most" requirement; infringement requires a reasonable likelihood that there will be *some* infringement of the method. *Vanda*, 887 F.3d at 1130 ("we have not required evidence regarding the general prevalence of the induced activity"). Teva does not dispute that requiring prevalence would be error. Instead, Teva argues (Br. 42) that the district court "neither stated nor implied

that a finding of infringement would require most patients to infringe." But that is exactly what the district court erroneously required of Corcept. Appx37.

Second, Teva fails to persuasively defend (Br. 37-39) the district court's reliance on the availability of the drug Isturisa® as an alleged off-label non-infringing alternative to mifepristone. This Court has repeatedly held that allegedly non-infringing alternatives are irrelevant to inducement. *See, e.g.*, *Vanda*, 887 F.3d at 1133; *see also AstraZeneca LP v. Apotex Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010)

* * *

to induced infringement; instead, as discussed above, the *HZNP* instructions failed to induce infringement because two of the three claimed method steps were optional. 940 F.3d at 700. Here, in contrast, Teva's ANDA Label's instructions that a doctor should coadminister "only when necessary" does not make optional any of the instructed steps when coadministration is required. An instruction that "if" the claimed conditions apply "then" the claimed method should be practiced is nothing less than an instruction to practice the claimed method. That is the essence of induced infringement. *AstraZeneca*, 633 F.3d at 1060 ("The pertinent question is whether the proposed label instructs users to perform the patented method.").

There is nothing unusual about patenting novel methods of treatment that enhance safety for a small cohort of patients for an already existing drug. As this Court recently explained, it is common for innovators to discover "new method[s] of use to ensure patient safety." *Lundbeck*, 87 F.4th at 1371. If the "FDA requires" that the new method "be included in the label, the ANDA label may induce infringement" of the

new patents. *Id*. That is what happened here. The FDA required Corcept to conduct drug-drug interaction studies because of the "high potential" of dual therapy in some patients. *Teva*, 18 F.4th at 1379 ("[The FDA] noted that coadministration 'may present a safety risk' and that, without a drug-drug interaction study, a 'lack of accurate knowledge' may 'deprive the patients on strong inhibitors of the use of mifepristone.'"). Corcept made a medically-valuable, patentable discovery that helps those patients. And the FDA required this use be included on the amended 2019 label, precisely because it would provide instructions for safe coadministration for patients who would otherwise be deprived of Korlym®.[5]

2. Warnings Do Not Defeat Inducement

Teva argues (Br. at 51) that the phrase "only when necessary" in its ANDA Label discourages coadministration, and thus cannot induce infringement. But the district court never found that the label discourages coadministration in all instances. Instead, the district court relied on testimony from Dr. Snyder, who opined that "physicians would read Teva's label as a warning not to coadminister mifepristone and a strong CYP3A inhibitor, *unless medically necessary*." Appx43 (emphasis added). And Teva ignores the district court's factual finding regarding the meaning of "medically necessary": "*i.e.* unless the benefit to the

[5] Unlike in *Genentech* where this Court dismissed Genentech's arguments regarding why the FDA included the instructions in the label because there was "no evidence to support its speculation," here the evidence shows that the FDA included the instructions in the label to "provide more therapeutic options available to Cushing's patients and appropriate labeling of mifepristone when co-administered with CYP3A inhibitors." Appx4451.

patient outweighs the risks." Appx43-44. As Teva's expert Dr. Dobs explained, "all medications ... have a risk-benefit ratio." Appx1058. Dr. Dobs further testified that she had previously prescribed mifepristone with the strong CYP3A inhibitor ketoconazole because:

> Q. [T]here's instances where it may be necessary to take advantage of mifepristone and ketoconazole's dual
>
> * * *