IN THE

Supreme Court of the United States

TEVA PHARMACEUTICALS USA, INC.,

Petitioner,

v.

GLAXOSMITHKLINE LLC,
SMITHKLINE BEECHAM (CORK) LIMITED,

Respondents.

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

PETITION FOR A WRIT OF CERTIORARI

DARYL L. WIESEN
CHRISTOPHER T. HOLDING
ELAINE HERRMANN BLAIS
ROBERT FREDERICKSON, III
GERARD J. CEDRONE
WILLIAM E. EVANS
GOODWIN PROCTER LLP
100 Northern Avenue
Boston, MA 02210

WILLIAM M. JAY
Counsel of Record
GOODWIN PROCTER LLP
JAIME A. SANTOS
1900 N Street, NW
Washington, DC 20036
(202) 346-4000
wjay@goodwinlaw.com

Counsel for Petitioner

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QUESTION PRESENTED

Congress passed the Hatch-Waxman Act to "speed the introduction of low-cost generic drugs to the market." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012). The Act embodies a carefully crafted legislative compromise. On the one hand, Congress bolstered patent terms for brand-name drug companies. On the other, it ensured that once a brand drug is no longer patented, the fact that some of the drug's *uses* remain patented "will not foreclose marketing a generic drug for other unpatented [uses]." *Id.* at 415. Instead, a generic manufacturer can sell its product with a "skinny label" that "carves out" any patented uses found in the brand drug's labeling—and thereby avoid inducing infringement of the brand manufacturer's patent rights. *See* 21 U.S.C. § 355(j)(2)(A)(viii). To aid in this process, brand manufacturers must provide a sworn statement to FDA identifying "the specific section(s)" of their labeling "that describes the method of use" claimed by their patents. 21 C.F.R. § 314.53(c)(2)(i)(O)(2), (c)(2)(i)(P)(2). Those are the sections that generic manufacturers then carve out of their labeling in order to obtain FDA approval despite the brand manufacturer's remaining patents.

The question presented is:

If a generic drug's FDA-approved label carves out all of the language that the brand manufacturer has identified as covering its patented uses, can the generic manufacturer be held liable on a theory that its label still intentionally encourages infringement of those carved-out uses?

PARTIES TO THE PROCEEDING

All parties appear in the caption of the case on the cover page.

RULE 29.6 STATEMENT

Petitioner Teva Pharmaceuticals USA, Inc., is directly owned by Teva Holdco US, Inc., and is an indirect, wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. Teva Pharmaceutical Industries Ltd. is the only publicly traded company that owns 10% or more of Teva Pharmaceuticals USA, Inc.

RELATED PROCEEDINGS

U.S. District Court for the District of Delaware:

GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc., No. 14-cv-878 (Apr. 25, 2018)

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

GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc., Nos. 2018-1976 and 2018-2023 (Aug. 5, 2021), *reh'g denied* (Feb. 11, 2022)

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

Other Authorities

Teva Pharmaceuticals USA, Inc., respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

INTRODUCTION

A divided panel of the Federal Circuit has blown a hole in the carefully calibrated regime governing the modern prescription-drug marketplace. The result is to allow a narrow patent on one way of using a drug to completely block *any* generic competition, potentially for years—precisely the opposite of what Congress prescribed.

In the Hatch-Waxman Act, Congress created an innovative pathway to bring low-cost generic drugs to market. When a brand-name drug has both patented and unpatented uses, its manufacturer must tell FDA the specific sections of its labeling that describe the patented uses. That allows generic manufacturers to carve out those sections and adopt a "skinny label"—one labeled for only *unpatented* uses.

Using a skinny label lets generic manufacturers launch skinny-labeled products without fear of crippling liability. Under the Patent Act, active and intentional encouragement of an infringing method can lead to liability for "inducing" infringement. But skinny labels *intentionally omit* infringing methods. The upshot: the Hatch-Waxman Act ensures that a patent on one of a drug's uses will not block generics from entering the market for other uses.

This pathway worked as intended for almost 40 years—until the Federal Circuit rewrote the inducement standard in this case. Teva launched a generic version of an off-patent medication that had one

patented use and two unpatented uses. It used a skinny label that carved out all the language that respondent GSK, the brand-name manufacturer, had identified under penalty of perjury as covering its single patented use. Seven years later, right before the last remaining patent on that use expired, GSK sued Teva, and a jury awarded GSK $235 million. The district court appropriately set aside that verdict.

A divided panel of the Federal Circuit then resurrected the verdict in an unusual set of proceedings that produced two oral arguments, two petitions for rehearing en banc, one sua sponte grant of panel rehearing, two panel opinions (with different rationales and each accompanied by a vigorous dissent), and a denial of rehearing en banc that inspired three separate dissents. The panel majority held that even though Teva's skinny label carved out GSK's sole patented use, Teva could nonetheless be held liable for inducement based on stray sections of the label providing information about *un*patented uses.

The majority's decision eviscerates the element of inducement liability that has for 70 years distinguished between inducement and non-inducement—the requirement that a defendant *actively encourage* an infringing use, 35 U.S.C. § 271(b), rather than merely "mention" or "describe" claim elements. And it "nullifies Congress's statutory provision for skinny labels—creating liability for inducement where there should be none[,] [c]ontrary to Congress's intent." Pet.App.112a (Prost, C.J., dissenting). Where there was once "equilibrium to the skinny-label system," there is now complete unpredictability. *Id.* at 87a. That unpredictability discourages generics from coming to market—"throw[ing] a wrench into Congress's

design" for *speeding up* generic launch of low-cost drug products. *Id.* at 49a.

The consequences of the majority's decision are enormous. Generic versions of no-longer-patented drugs with patented uses launch with a skinny label *almost half the time*, saving patients and the federal government billions. Now all those launches are at risk. Generic manufacturers that make pennies per pill could collectively face billions of dollars in liability for doing "everything right—proceeding exactly as Congress contemplated." *Id.* at 118a. The U.S. healthcare system cannot sustain that type of competition-killing uncertainty. Given the importance of this issue to patients, payors (including the federal government), and prescription-drug competition, this Court should grant review.

OPINIONS BELOW

The Federal Circuit's opinion (Pet.App.1a-87a) is reported at 7 F.4th 1320. The panel's prior vacated opinion (Pet.App.88a-146a) is reported at 976 F.3d 1347. The order denying rehearing en banc and the opinions concurring in, and dissenting from, that order (Pet.App.182a-210a) are reported at 25 F.4th 949. The district court's opinion (Pet.App.149a-181a) is reported at 313 F. Supp. 3d 582.

JURISDICTION

The court of appeals entered judgment on August 5, 2021. A petition for rehearing en banc was denied on February 11, 2022 (Pet.App.182a). On May 3, 2022, the Chief Justice extended the time to file a petition for a writ of certiorari until July 11, 2022. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The relevant statutory and regulatory provisions are reproduced in the appendix, *infra*, at 211a-215a.

STATEMENT

A. Congress enacts § 271(b), making "actively induc[ing] infringement of a patent" itself an act of infringement.

One way to establish patent infringement is to establish that the defendant actively induced another to infringe. Section 271(b) of the Patent Act, enacted in 1952,[1] provides that "[w]hoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). To prove inducement (under both copyright and patent law), a plaintiff must demonstrate (i) direct infringement by another that was (ii) knowingly aided and abetted by "affirmative steps" taken by the defendant "to encourage direct infringement" (iii) with the "affirmative intent that the product be used to infringe." *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936 (2005) (citing *Water Techs. Corp. v. Calco, Ltd.*, 850 F.2d 660, 668 (Fed. Cir. 1988)); *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 760 (2011).

The law of inducement is clear that "mere knowledge about a product's characteristics or that it may be put to infringing uses is not enough." *HZNP Medicines LLC v. Actavis Labs. UT, Inc.*, 940 F.3d 680, 701 (Fed. Cir. 2019); *accord Grokster*, 545 U.S. at 937. And in the context of unpatented products with both patented and unpatented uses, the active-

[1] Pub. L. 593, 66 Stat. 792, 811.

encouragement requirement is critical—it "overcomes the law's reluctance to find liability when a defendant merely sells a commercial product suitable for some lawful use." *Grokster*, 545 U.S. at 936.

B. Congress enacts the skinny-label statute so that narrow method-of-use patents do not block the sale of generic drugs with unpatented uses.

The Drug Price Competition and Patent Term Restoration Act of 1984[2]—commonly known as the Hatch-Waxman Act (or simply "Hatch-Waxman")—reflects a "grand compromise between two competing sets of interests" held by brand-name and generic manufacturers. Henry Waxman C.A. Amicus Br. 2 (Dkt. No. 170) (quotation marks omitted). It bolstered patent protection for brand manufacturers while creating a faster pathway for generic manufacturers to secure marketing approval for their products. Under the Act, if a generic manufacturer files an abbreviated new drug application (ANDA) demonstrating that its drug is therapeutically bioequivalent to a brand-name "reference" drug, it need not duplicate the clinical trials already performed by the brand manufacturer to demonstrate the drug's safety and effectiveness. *See Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003); 21 U.S.C. § 355(j)(2)(A)(iv), (j)(4)(F); 21 C.F.R. § 314.94(a)(7)(i).

1. Hatch-Waxman gives generic manufacturers three options for addressing brand manufacturers' outstanding patents when filing an ANDA and planning generic launch.

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[2] Pub. L. No. 98-417, 98 Stat. 1585.

First, a generic manufacturer can certify that it will wait until every patent covering the brand-name reference drug has expired. 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(III).

Second, it can file a "paragraph IV" certification stating that any patents held by the brand manufacturer are invalid or will not be infringed by generic launch. *Id.* § 355(j)(2)(A)(vii)(IV). Brand manufacturers then have an immediate right to sue, because Hatch-Waxman treats the filing of an ANDA as an artificial act of infringement when the reference drug or one of its uses is claimed by a patent. 35 U.S.C. § 271(e)(2)(A); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670-671, 676 (1990). As a result, paragraph IV certifications usually "provok[e]" pre-launch litigation by brand manufacturers, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 407 (2012), fulfilling Hatch-Waxman's goal of resolving patent disputes "as early as possible." Pet.App.54a (Prost, J., dissenting). This pre-launch litigation triggers an automatic stay of FDA approval and generic launch for 30 months or until a finding of invalidity or noninfringement, which means the paragraph IV process "is likely to keep the generic drug off the market for a lengthy period." *Caraco*, 566 U.S. at 408.

The third avenue is one of Hatch-Waxman's most important innovations—its carve-out, or "skinny-label," provision. 21 U.S.C. § 355(j)(2)(A)(viii). If a brand-name reference drug is off-patent (*i.e.*, all patents on the drug molecule *itself* have expired) and only method-of-treatment patents remain, a generic manufacturer can submit a "section viii" statement that it will launch with a "skinny label"—one identical to the brand label, except that it "carves out" any

patented use. By omitting the instructions that actively encourage physicians who prescribe the drug to directly infringe patented uses, the generic manufacturer avoids inducement (and the risk of liability). The provision thus ensures "that one patented use will not foreclose marketing a generic drug for other unpatented ones." *Caraco*, 566 U.S. at 415. And it prevents brand manufacturers from maintaining "de facto indefinite exclusivity" by procuring myriad method patents on unpatented drug products. *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1380 (Fed. Cir. 2012). Unlike the paragraph IV pathway, the section viii pathway does not lead to prelaunch litigation or a 30-month stay of generic launch. That is the point of the carve-out statute: it allows generic manufacturers *to avoid infringement* (and prelaunch litigation) altogether, rather than simply channeling litigation to an earlier time period.

Congress knew that carve-outs "would result in some off-label infringing uses," because when physicians prescribe drugs for patented uses, pharmacies may (and in many states must) fill those prescriptions with generic versions of the drug—regardless of which drug the doctor wrote on the prescription pad. *Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 631, 633 (Fed. Cir. 2015); Pet.App.68a (Prost, J., dissenting). Congress nonetheless decided to "enable the sale of drugs for non-patented uses" *even if* some off-label sales would naturally occur. *Takeda*, 785 F.3d at 631.

2. For Hatch-Waxman's generic-entry pathways to function properly, FDA and generic manufacturers need "clarity" about which patents cover which brand-name reference drugs and—particularly for method-

of-use patents—the scope of those patents. Pet.App.54a (Prost, J., dissenting). So Congress and FDA require brand manufacturers seeking drug approval to provide information regarding "any patent which claims the drug … or … a method of using such drug." 21 U.S.C. § 355(b)(1)(A)(viii)(I)-(II). Brand manufacturers submit a declaration to FDA, signed under penalty of perjury, identifying each "method of use and related patent claim" and "the specific section(s) and subsection(s)" of their brand-name drug labeling "that describes the method of use claimed by" patents. 21 C.F.R. § 314.53(c)(2)(i)(O), (c)(2)(ii)(P).[3] They also provide a corresponding, shorter "use code" to describe the method claimed. *Id.* § 314.53(c)(2)(ii)(P)(3); *see also Caraco*, 566 U.S. at 405-406. FDA publishes use codes in the "Orange Book"[4] to alert generic manufacturers "to the existence of a patent that claims an approved use." 68 Fed. Reg. 36,676, 36,683 (June 18, 2003).

FDA does not independently evaluate the accuracy of brand manufacturers' patent declarations. It takes them "as a given," *Caraco*, 566 U.S. at 406; *see also*

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[3] Section 314.53(c)(2)(i)(O) applies to patent information submitted before approval of the brand manufacturer's new drug application (NDA), on Form 3542a. Section 314.53(c)(2)(ii)(P) applies to patent information submitted after NDA approval, on Form 3542. Both forms are in this record. C.A.App.6880-6903. For ease of reference, this brief cites the current regulation, amended in 2020; the pre-2020 regulation contained materially identical reporting requirements in the same subsections. *See* 21 C.F.R. § 314.53(c)(2)(i)(O), (c)(2)(ii)(P) (2008).

[4] FDA, Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) (2022), https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.

Pet.App.54a (Prost, J., dissenting), and relies on them in making approval decisions and "[i]n determining whether an ANDA applicant can 'carve out' the [patented] method of use." 68 Fed. Reg. at 36,682. Those declarations also provide public notice to generic manufacturers regarding the scope of any method-of-use patents. Because the declarations must "include[] the complete description of the method-of-use claim and the corresponding language in the labeling of the approved drug," FDA makes them "publicly available" following brand-name drug approval. *Id.*

This regime prevents "gotcha" litigation. It allows generic manufacturers to choose a pathway to market. And for skinny-label launches, it provides FDA and generic manufacturers with the information necessary to decide what language in the labeling must be carved out to launch securely without pre-launch litigation and a 30-month stay, giving generic manufacturers the certainty they need to bring low-cost generic drugs to the market, saving patients and the federal government billions.

3. When enacting Hatch-Waxman, Congress understood the longstanding requirements of inducement under § 271(b). Indeed, the skinny-label statute neatly maps onto the elements of inducement: it permits a generic manufacturer to avoid inducement liability by intentionally omitting—the opposite of actively encouraging—instructions for infringing uses. For years, inducement doctrine and the skinny-label statute have worked in tandem, just as Congress intended—ensuring that narrow method-of-use patents do not keep generic versions of off-patent drugs entirely off the market. When a brand drug has both patented and unpatented uses, the first generic

launch relies on a skinny label nearly half the time.[5] The entire Hatch-Waxman system has been widely popular and predictable—each pathway to generic launch is frequently traveled, and generic and brand manufacturers alike have clearly understood whether and when each path could lead to infringement liability. Until now.

C. Eight manufacturers launch a generic equivalent of GSK's unpatented drug Coreg® with a skinny label omitting the only use GSK said was claimed by its remaining patents.

This case is about an off-patent drug, carvedilol (brand-name Coreg®), and GSK's patent covering a narrow method of using that drug to treat congestive heart failure (CHF). Pet.App.7a.

1. Carvedilol is FDA-approved for (1) managing hypertension, (2) treating mild-to-severe CHF, and (3) treating dysfunction of the heart's left ventricle following a heart attack ("post-MI LVD"). Pet.App.5. The patent on the carvedilol compound expired in 2007. *Id.*

GSK also obtained two method-of-treatment patents. Pet.App.5a, 8a; Pet App. 118a (Prost, C.J., dissenting). GSK certified to FDA—under penalty of perjury—that those patents claimed *only* the CHF indication. C.A.App.6894-6907.

2. Teva filed an ANDA in 2002 seeking FDA approval to market generic carvedilol upon expiration of

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[5] Bryan S. Walsh et al., *Frequency of First Generic Drug Approvals With 'Skinny Labels' in the United States*, 181 JAMA Intern. Med. 995-997 (2021), https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2777965.

the compound patent. Teva initially sought approval for all three approved indications and submitted a paragraph IV certification that GSK's CHF-method-of-treatment patents were invalid. Pet.App.6a; Pet.App.56a (Prost, J., dissenting). Teva was right. GSK did not sue on those patents; instead, it abandoned one patent and sought reissue of the other, admitting its invalidity and seeking to narrow it. *Id.*; *see* 35 U.S.C. § 251.

In 2004, while GSK's reissue proceedings were pending, FDA granted "tentative approval" of Teva's ANDA—meaning approval pending resolution of any patent issues. Pet.App.6a; Pet.App.56a, 71a-72a (Prost, J., dissenting); C.A.App.7790-7791. Three years later, with expiration of the compound patent approaching, Teva decided to join 13 other generic manufacturers who were planning to carve out the CHF indication. Pet.App.7a; Pet.App.55a-56a (Prost, J., dissenting).

FDA sent Teva a redlined label instructing what to carve out based on GSK's patent declaration. Pet.App.57a-58a (Prost, J., dissenting) (showing redline of "INDICATIONS AND USAGE" section). Teva launched in 2007 "with the same carve-out as" the seven other generics that ultimately launched with a skinny label—one that "included everything but CHF." *Id.* at 58a. GSK did not sue upon generic launch.

By 2008, generic carvedilol was selling at $.02 and Coreg® at $2.33 per pill. GSK's market share was below 8%. C.A.App.6769. Thereafter, GSK's CHF patent reissued as the "'000 patent," a narrower patent claiming only *some* uses of carvedilol to treat CHF—*i.e.*, administered daily, with one of three specific

other medications, for more than six months, for the specific purpose of decreasing mortality caused by CHF. Pet.App.6a-7a. This claimed use represented (according to GSK) just 17.1% of carvedilol prescriptions. Pet.App.42a. GSK again submitted a sworn declaration identifying the CHF indication as the only one claimed, and it did not sue for infringement of that patent. Pet.App.58a (Prost, J., dissenting); C.A.App.6880-6887.

In 2011, after GSK's original method-of-treatment patents were removed from the Orange Book (as one had been abandoned and the other had been reissued as the narrow '000 patent), FDA directed Teva to amend its carvedilol label to add the information that had previously been carved out. Pet.App.93a. Teva complied, and the amendment had no impact on physicians' prescribing practices—Teva and GSK maintained their respective market shares. *Id.* at 58-59a.

D. GSK sues Teva for $750 million for inducing infringement of the carved-out use.

In 2014, seven years after generic launch and shortly before the '000 patent expired, GSK sued Teva for inducing infringement. Pet.App.9a. GSK sought nearly $750 million in lost profits—ten times Teva's revenue ($74.5 million, for a net *loss* of $13 million) from *all* carvedilol sales. Pet.App.123a (Prost, C.J., dissenting); C.A.App.12281-12282.

1. At trial, GSK sought to prove liability through its expert, Dr. McCullough, whom GSK's counsel "walk[ed] through" Teva's skinny label to establish *direct* infringement by prescribing physicians. C.A.App.10617. During that testimony, Dr. McCullough was never asked and did not testify about

whether Teva's skinny label had *encouraged* or *instructed* the method of treatment that it omitted. C.A.App.10623-10631; Pet.App.65a (Prost, J., dissenting). "[M]ov[ing] on to inducement," Dr. McCullough testified that Teva had encouraged infringement by stating in product guides, press releases, and similar materials that carvedilol was the "AB-rated" generic equivalent of Coreg® without expressly *disclaiming* approval for the patented CHF indication. C.A.App.10631-10644. The lack of CHF disclaimers later became the focus of GSK's inducement argument to the jury. C.A.App.11859-11861.

That focus on disclaimers was little surprise given what had happened at trial just a few days earlier—Teva moved for judgment as a matter of law, arguing that GSK had not established the causation element of induced infringement because it provided no evidence that any physicians had actually read Teva's generic label before prescribing carvedilol. Pet.App.125a (Prost, C.J., dissenting).[6] GSK ultimately conceded that Dr. McCullough had not provided any testimony to that effect but represented that "he would absolutely" do so if recalled. *Id.* When GSK recalled him, however, he said the opposite—that he had *not* read Teva's label before administering generic carvedilol, and that generic substitution happened "automatic[ally]" at pharmacies. *Id.*; C.A.App.11662-11663. He even said that he *would not have used*

[6] Although this might sound counterintuitive, it isn't. Physicians do not prescribe *particular* generic products to patients—indeed, they do not even know *which* generic product will be dispensed by the pharmacy—and therefore cannot be assumed to look at (much less rely on) a particular generic label in making prescribing decisions. C.A.App.10675, 10678-10679, 11088-11089.

Teva's skinny-labeled product to treat CHF if he had read the label, because it was "missing too much information" about CHF. C.A.App.11660-11661. Following that testimony, GSK's closing argument regarding inducement focused primarily on the lack of CHF disclaimers in Teva's product materials.

The jury awarded GSK $235 million in damages.

2. The district court granted Teva post-trial judgment as a matter of law. Pet.App.149a-181a. The court concluded that there was no evidence Teva's skinny label caused physicians to infringe, both because it did not actively encourage the patented method of use, and because both sides' physician witnesses testified that they had not read Teva's label before prescribing carvedilol. Pet.App.164a-166a.

The court also examined the other materials GSK introduced: two press releases (predating the patent) announcing tentative approval in 2004 and final approval in 2007, and product catalogs describing generic carvedilol as the AB-rated generic equivalent of Coreg®. None included the elements of the claimed method. And as the district court recognized, accurately stating that generic carvedilol was AB-rated by FDA—meaning that *when administered as labeled*, the drug is therapeutically equivalent to Coreg®[7]—did not even arguably advocate infringement of the patented method. Pet.App.167a-169a.

The district court also concluded that GSK did not present substantial evidence to support causation after Teva had amended its label, because GSK conceded

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[7] *See* C.A.App.10542, 10583; FDA, Orange Book Preface § 1.2 (42d ed. 2021), https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface.

that physicians' practices and GSK's market share were unaffected by the amendment. Pet.App.177a.

E. The Federal Circuit resurrects the jury verdict.

The Federal Circuit reversed in unusual proceedings that involved two oral arguments, two petitions for rehearing en banc, one sua sponte grant of panel rehearing, two panel opinions (and two dissents), and a denial of rehearing en banc that inspired three separate dissents.

1. In October 2020, a panel majority (authored by Judge Newman and joined by Judge Moore) reversed over then-Chief Judge Prost's dissent. Pet.App.88a-146a.

For evidence of inducement, the majority pointed primarily to evidence that Teva had described its product—accurately—as the AB-rated generic equivalent of Coreg®. It also pointed to pre-patent press releases and testimony that Teva knew it would "get sales" for CHF prescriptions resulting from pharmacies' automatic-substitution practices. Pet.App.100a-104a. The majority also obliquely pointed to "the FDA labels" as relevant evidence, though the court did *not* suggest that the skinny label actually instructed the patented method of treatment. Pet.App.105a. Nor did the majority register any disagreement with the dissent's extensive discussion of how Teva's label *carved out*, rather than *encouraged*, the patented use, *See* Pet.App.118a-120a, 126a, 129a-131a, 133a-134a (Prost, C.J., dissenting).

As commentators noted afterwards, the majority "[s]urprisingly" failed to discuss Hatch-Waxman's carve-out regime, much less apply (or distinguish) the

line of precedents holding that a skinny label does not "actively encourage" infringement of the carved-out method.[8] Instead, the majority almost exclusively cited pre-launch, *non-carve-out* cases involving labels containing the same instructions as the brand. Pet.App.99a-100a, 105a.

Chief Judge Prost dissented. She said, "Teva did everything right—proceeding precisely as Congress contemplated" by "launch[ing] its low-cost generic carvedilol for unpatented uses using a skinny label" that "*never* stated that [Teva's product] was approved, or could be used, to treat CHF." Pet.App.118a, 120a. The majority's decision, she explained, was "directly contrary to Congress's intent" as discussed in this Court's precedents, and irreconcilable with longstanding Federal Circuit precedents governing skinny labels and inducement liability. Pet.App.129a-132a.

The dissent recognized the enormity of the panel's decision: it "nullifie[d] Congress's statutory provision for skinny labels" by "creating infringement liability for any generic entering the market with a skinny label," and "discourage[d] generics from entering the market in the first instance." Pet.App.112a, 145a; *see* Pet.App.128a-131a, 145a-146a.

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[8] Paul Dietze et al., *Fed Circ. Ruling Is Troubling for Generic Drug Manufacturers*, Law360 (Oct. 21, 2020), https://www.law360.com/articles/1320956; *accord* Zachary Silbersher, *Can Amarin Benefit from the* GSK v. Teva *Decision Regarding Induced Infringement for Off-Label Sales?*, Markman Advisors (Oct. 7, 2020), https://www.markmanadvisors.com/blog/2020/10/7/can-amarin-benefit-from-the-gsk-v-teva-decision-regarding-induced-infringement-for-off-label-sales ("majority opinion strangely fails to address" the carve-out precedents).

2. The 2020 decision sparked "widespread" criticism—from generic *and brand* manufacturers, law professors, and Congressman Waxman himself, all of whom filed amicus briefs in support of rehearing en banc. Pet.App.59a-60a (Prost, J., dissenting). Commentators and analysts described the decision as a "monumental,"[9] "major decision"[10] that "stretched" inducement liability,[11] "upset the expected scope of liability for most generic launches with skinny labels,"[12] and threatened the viability of carve-outs.[13]

The majority warded off rehearing en banc by sua sponte granting panel rehearing and reargument. It then reached the same result using a new rationale—this time in a per curiam opinion.

The court now said its skinny-label precedents were inapplicable because Teva's label was not a "true section viii carve-out." Pet.App.32a n.7. Even though Teva had omitted everything that *GSK told FDA* corresponded to its patented method of treatment, the

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[9] Silbersher, *supra.*

[10] Kyu Yun Kim et al., *A Major Decision Evaluating the Effect of a Skinny Label in a Post-Launch, Non-Hatch Waxman Litigation, Jury Trial World*, Mondaq (Oct. 15, 2020), https://www.mondaq.com/unitedstates/patent/994650/a-major-decision-evaluating-the-effect-of-a-skinny-label-in-a-post-launch-non-hatch-waxman-litigation-jury-trial-world.

[11] Kevin E. Noonan, GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc. (Fed. Cir. 2020), Patent Docs (Oct. 8, 2020), https://www.patentdocs.org/2020/10/glaxosmithkline-llc-v-teva-pharmaceuticals-usa-inc-fed-cir-2020.html.

[12] Silbersher, *supra.*

[13] Dani Kass, *Generics Worry Fed. Circ. Blew Up 'Routine' Labeling Practice*, Law360 (Oct. 7, 2020), https://www.law360.com/articles/1317312/generics-worry-fed-circ-blew-up-routine-labeling-practice.

majority held that Teva's skinny label induced infringement. The majority emphasized that, during his testimony on *direct infringement by doctors*, Dr. McCullough "compared" each claim element to disparate portions of Teva's skinny label and testified that the label "satisfied" or "met" (or, in Dr. McCullough's words, "mentioned," *e.g.*, C.A.App.10623, 10625) each claim limitation. Pet.App.15a-17a, 20a, 27a. But he never testified that it *encouraged* that method-of-treatment. C.A.App.10623-10631.

Judge Prost again dissented, saying that the "new opinion does little to assuage, and even exacerbates, concerns raised by the original." Pet.App.87a. She observed that Teva "played by the rules, exactly as Congress intended." Pet.App.47a. In nonetheless holding Teva liable, she explained, the majority's new opinion "effectively eliminat[es]" inducement's affirmative-encouragement requirement. Pet.App.48a. "Far from being a disagreement among reasonable minds about the individual facts," she said, "this case signals that our law on this issue has gone awry." *Id.*

3. Commentators and analysts immediately recognized the new opinion as an "important, controversial decision"[14] that "changed everything" and rendered the skinny-label statute effectively "dead"[15]—leaving

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[14] Khadijah M. Silver, *Teva's Generic Label Not Skinny Enough To Protect from $234M Damages to GSK*, MedCityNews (Aug. 6, 2021), https://medcitynews.com/2021/08/tevas-generic-label-not-skinny-enough-to-protect-from-234m-damages-to-gsk.

[15] Sara W. Koblitz, *Ding Dong Is the Skinny Label (Effectively) Dead?*, FDA Law Blog (Sept. 7, 2021), https://www.thefdalawblog.com/2021/09/ding-dong-is-the-skinny-label-effectively-dead.

"generics makers steeped in uncertainty,"[16] and providing a "road map" for challenges to carve out generic drugs that have been on the market for years.[17]

The court denied rehearing en banc over three dissents, with two recusals. In a concurrence, Chief Judge Moore offered two defenses of the panel's decision. First, although GSK's attempt to circumvent FDA's skinny-label framework and precedent had dominated merits briefing, oral argument, both of Judge Prost's dissenting opinions, two rounds of en banc briefing, and almost a dozen amicus briefs, Chief Judge Moore newly suggested that the parties had not adequately ventilated these issues before the panel. Pet.App.186a-189a.

Second, Chief Judge Moore suggested that the majority's holding should cause no alarm, because GSK's inducement theory might trigger equitable estoppel—a discretionary defense for which defendants bear the burden of proof at a bench trial following an adverse jury verdict. Pet.App.190a-193a.

Judges Prost, Dyk, and Reyna each filed dissenting opinions. Pet.App.194a-210a. Although Chief Judge Moore had again tried to downplay the case as "narrow and fact dependent," Pet.App.188a, Judge Prost "note[d] that such questions at this court typically do not produce two panel opinions, two dissents, two rehearing processes, and over a dozen amicus

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[16] Dani Kass, *GSK Redo Doesn't Cure Generics' 'Skinny Label' Uncertainty*, Law360 (Aug. 9, 2021), https://www.law360.com/articles/1410679/gsk-redo-doesn-t-cure-generics-skinny-label-uncertainty.

[17] Daniel Knauss et al., *Fed. Circ. Teva Ruling May Shake Up Skinny Label Strategies*, Law360 (Sept. 1, 2021), https://www.law360.com/articles/1417824/fed-circ-teva-ruling-may-shake-up-skinny-label-strategies.

briefs throughout." Pet.App.202a n.4. She found the concurrence's "hodgepodge of forfeiture-like rationales" not "credible," given that the panel had squarely addressed the parties' substantive arguments on the merits. Pet.App.199a-203a. As to equitable estoppel, she saw no "indication that Congress … intended to stake the efficacy of [the skinny-label] system on a generic's case-by-case equity showing," rather than the application of § 271(b)'s bedrock active-inducement requirement. Pet.App.204a.

Judges Dyk and Reyna separately echoed Judge Prost's concerns. Pet.App.205a-210a. Judge Dyk further noted that if the majority's novel interpretation of inducement is correct, then "there is a direct conflict between the FDA-required labelling and the supposed requirements of federal patent infringement law." Pet.App.207a. Thus, under the specific-general canon, "the more specific and later-enacted provisions of the Hatch-Waxman Act" must govern over "the general infringement provisions of the Patent Act." *Id.*

REASONS FOR GRANTING THE WRIT

The divided panel's controversial opinion upends the legal rules facing the modern prescription-drug marketplace, wreaking doctrinal havoc in two equally troubling ways. Such a radical transformation warrants this Court's intervention now.

First, the decision below eviscerates the key element of inducement liability: the requirement that a plaintiff prove "active steps taken to encourage direct infringement." *Grokster*, 545 U.S. at 915. Actively encouraging or instructing an infringing use has always been required to support inducement, and merely "mentioning" or "describing" an infringing use has

always been legally insufficient. Now, however, that difference has disappeared, leaving would-be defendants who sell off-patent products labeled for unpatented uses in the dark about whether and when they will face massive infringement verdicts.

Second, the decision below effectively nullifies a Congressional enactment created specifically to encourage precisely what Teva did here: bring a low-cost generic drug to market labeled for unpatented uses. For decades, the skinny-label statute has worked as intended by providing generic manufacturers with the predictability they need to bring low-cost generic drugs to market labeled for unpatented uses. If they carved out the portions of the labeling that brand-name manufacturers *themselves* identified as covered by method-of-treatment patents, they could launch without risk of infringement liability. But now, *every* skinny-label launch is an at-risk launch—and patients, FDA, and the healthcare system will suffer the consequences.

The Court should not delay review of the question presented. This case allows the Court to address it on a full factual record knowing the answer is case-dispositive. The flaws in the majority's opinion are on prominent display in this case: the district judge (since promoted to the Federal Circuit) carefully analyzed the trial evidence and the law, and this Court has eight separate Federal Circuit opinions to aid its review. But if there is any question, this Court should at least seek the government's views (as it did in *Caraco*) given the critical interests—of FDA and the patent system—at stake.

I. The Federal Circuit's distortion of inducement doctrine and nullification of Hatch-Waxman's carve-out provision warrant this Court's review.

A. The skinny-label statute and § 271(b)'s active-inducement element speed generic launch by providing predictability and security to generic manufacturers.

1. Hatch-Waxman represents a "grand compromise between two competing sets of interests." Henry Waxman C.A. Amicus Br. 2 (quotation marks omitted). Before the Act's passage, brand manufacturers "had seen their effective patent terms shortened by the testing and regulatory processes." *Warner-Lambert*, 316 F.3d at 1358. Generic manufacturers, meanwhile, had seen their "entry into the market upon expiration of the innovator's patents … delayed by … regulatory requirements." *Id.*

Hatch-Waxman balanced these interests. For brand manufacturers, the statute extended certain patent terms and permitted pathways to initiate infringement litigation before generic entry. *See Eli Lilly*, 496 U.S. at 670-671. For generic manufacturers, the statute created clear avenues for faster generic entry and required that brand manufacturers disclose information regarding their patents. *See supra*, pp. 5-10.

As part of that balance, Congress sought to prevent the risk that brand manufacturers would obtain method-of-treatment patents covering off-patent drugs and use those patents to "foreclose marketing a generic drug for other unpatented uses." *Caraco*, 566 U.S. at 415. That result would directly undermine one of Hatch-Waxman's principal goals: "to speed the

introduction of low-cost generic drugs to market," *id.* at 405, because generic manufacturers could not realistically launch for pennies a pill when outstanding method-of-use patents created a risk of exponential damages liability.

So Congress and FDA devised a solution: "If a brand drug company … has a patent on one of a drug's uses, it tells the FDA which use is patented"—indeed, "it tells the FDA exactly what language from its label is covered by its patents." Pet.App.47a (Prost, J., dissenting); *see* 21 C.F.R. § 314.53(c)(2)(i)(O). "The FDA will then permit a generic version of that drug to come to market if the manufacturer 'carves out' such use from its drug label by omitting the language that the brand drug company identified." Pet.App.47a (Prost, J., dissenting). That "facilitate[s] the approval of generic drugs as soon as patents allow," and so "speed[s] the introduction of low-cost generic drugs to market." *Caraco*, 566 U.S. at 405.

This structure allows generic manufacturers to launch without risk that doing so could lead to multi-million-dollar liability. Generic manufacturers typically do not advertise or promote their products as brands do—the economics of generic-drug pricing do not allow it, nor would doing so make sense when physicians cannot prescribe *a specific* generic manufacturer's drug product. *See* Judith A. Johnson, Cong. Rsch. Serv., R44703, *Generic Drugs and GDUFA Reauthorization: In Brief* 1-2 (2017); C.A.App.10675, 10678-10679, 11088-11089. So if generic labeling *omits* the patented method-of-treatment language that brands say is patent-protected, generics can launch with confidence that they will not experience crippling liability.

Indeed, the carve-out statute is deemed such a clear way to avoid inducement that, unlike the paragraph IV process, generic manufacturers carving out patented uses are required to certify their intention *only to FDA,* not to brand manufacturers. 21 U.S.C. § 355(j)(2)(A)(viii). Doing so is not an artificial act of infringement and does not permit the manufacturer to initiate pre-launch litigation and obtain a 30-month stay of generic launch. Those litigation mechanisms are not needed, because a carved-out label *is not an infringing label*.

2. Inducement's "active encouragement" requirement plays a critical role in the Hatch-Waxman regime. Since the 1950s, federal patent law has provided that "[w]hoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). For many years, a consistent body of decisions—from both the Federal Circuit and this Court—has shown that the term "actively" is more than just window dressing: one must affirmatively encourage a third party to infringe to face liability for inducement. In the context of unpatented products with unpatented uses, this element is critical: it "overcomes the law's reluctance to find liability when a defendant merely sells a commercial product suitable for some lawful use." *Grokster*, 545 U.S. at 936.

a. This Court's caselaw has made clear that inadvertently mentioning or describing an infringing use is not enough to incur liability. In *Global-Tech*, the Court explained that "[t]he term 'induce'" in § 271(b) "means 'to lead on; to influence; to prevail on; to move by persuasion or influence'"—all words that clearly connote encouragement. 563 U.S. at 760 (brackets omitted) (quoting Webster's New International

Dictionary 1269 (2d ed. 1945)). And, the Court emphasized, the term "induce" does not stand alone: "The addition of the adverb 'actively' suggests that the inducement must involve the taking of *affirmative steps* to bring about the desired result." *Id.* (emphasis added) (citing Webster's, *supra*, at 27); *see also Tegal Corp. v. Tokyo Electron Co.*, 248 F.3d 1376, 1378 (Fed. Cir. 2001) (distinguishing "*active steps knowingly taken*," as required to support inducement, from "accidental or inadvertent" steps).

Grokster likewise shows that mere description or inadvertent mention are not enough. In resolving the copyright question before it, the Court canvassed the law of inducement (under copyright *and* patent law). It explained that the common-law rule and the present-day patent rule—codified in § 271(b)—are the same: inducement requires "[e]vidence of active steps taken to encourage direct infringement, such as advertising an infringing use or instructing how to engage in an infringing use," in order to "show an affirmative intent that the product be used to infringe." *Id.* at 936 & n. 11 (citation and punctuation omitted).

b. Until the panel's decision here, the Federal Circuit followed the same understanding of § 271(b), including—indeed, *particularly*—for drug labeling.

Most notably, in *Takeda*—likewise involving a carve-out[18]—the Federal Circuit emphasized that "[m]erely 'describing' an infringing mode is not the same as 'recommending,' 'encouraging,' or 'promoting,' an infringing use, or suggesting that an infringing use

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[18] *Takeda* involved a "paper NDA" rather than an ANDA; both drug-approval mechanisms contain similar carve-out provisions. *Takeda*, 785 F.3d at 629-630.

'should' be performed." 785 F.3d at 631 (brackets and citations omitted). Takeda had argued that West-Ward's label for an off-patent drug, colchicine, infringed Takeda's method patent on the *use* of colchicine to treat gout flareups. *See id.* at 627-628. West-Ward's label did not actually instruct patients to take colchicine for gout flareups, but Takeda argued that *other* language in the label *mentioning* gout flare-ups might lead physicians to prescribe the drug for the patented use. *See id.* at 630. The court rejected the argument, explaining that "vague label language"—even in conjunction with "[s]peculation or even proof that some, or even many, doctors would prescribe" the drug for an infringing use—could not constitute *active* inducement. *Id.* at 631, 633.

Subsequent decisions made the point even more explicit. In *HZNP*, the patented method had three steps: applying diclofenac; waiting for it to dry; and applying sunscreen, insect repellant, or a second medication. 940 F.3d at 702. The defendant's generic label directed patients to perform the first and, *if* they chose to perform the third, to perform the second too. Because the label *permitted*, but did not *require*, each claim step, it "d[id] not encourage infringement"—even though it expressly "describ[ed]" every claim element. *Id.* As the court there explained, "[t]he focus is not on whether the instructions describe the mode of infringement, but rather on whether the instructions teach an infringing use." *Id.* at 701 (quotation marks omitted).

In *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316 (2012), meanwhile, the "Indications and Usage" section of the generic label contained instructions for just one unpatented use. *See id.* at 1322. Bayer

argued that other sections of the label described patented uses, but the court explained that "while the label *mention[ed]* [those patented uses], it [did] not do so in any way that *recommend[ed] or suggest[ed]* to physicians that the drug [was] safe and effective for administration to patients for [those] purposes." *Id.* (emphasis added).

This consistently enforced line between "encouraging" and merely "describing" has given generic manufacturers predictability and lower courts clarity—they have understood that if a brand manufacturer's infringement claim requires a "'scholarly scavenger hunt' through the label to identify statements that may inferentially but not inevitably tie to a physician's thoughts or acts, the inducement theory necessarily fails." *E.g.*, *Otsuka Pharm. Co. v. Torrent Pharms. Ltd., Inc.*, 99 F. Supp. 3d 461, 493 (D.N.J. 2015) (citation omitted).

In the skinny-label context, this rule is "particularly important," because Congress designed Hatch-Waxman expressly to encourage the launch of off-patent generics labeled for unpatented indications—"even though this would result in some off-label infringing uses." *Takeda*, 785 F.3d at 631. Blurring the line between encouraging and describing lets brand manufacturers use the threat of inducement liability as "a sword against any competitor's ANDA seeking approval to market an off-patent drug for an approved use not covered by the patent"—precisely the tactic Congress sought to prevent. *Warner-Lambert*, 316 F.3d at 1359.

B. The decision below fundamentally undermines Congress's objectives and defies settled principles of inducement law.

The decision below jumbles the rules that police the intersection of patent law and pharmaceutical regulation. It makes a hash of Congress's carefully crafted regime for bringing unpatented generic drugs to market, even when there are outstanding patents on certain uses of those drugs. And in the process, it "effectively eliminat[es] the demarcation between describing an infringing use and encouraging that use"—a demarcation that is not just essential to the inducement framework, but also necessary for Hatch-Waxman to function. Pet.App.48a (Prost, J., dissenting).

In holding that the combination of snippets of language in disparate portions of Teva's carved-out label could support a $235 million infringement verdict, the decision below overturns Hatch-Waxman's carefully crafted balance. Teva "played by the rules, exactly as Congress intended." *Id.* at 47a. Teva asked FDA to approve its generic drug product for two uses not covered by any patents: post-MI LVD and hypertension. As required by statute, 21 U.S.C. § 355(j)(2)(A)(v), Teva adopted a label that was identical to Coreg®—except that it carved out the sole patented use. Pet.App.7a. How did it know which language to excise? FDA told Teva what to cut—based on sworn representations from GSK about the scope of its patents and the label language claimed by those patents. *See* Pet.App.56a-58a (Prost, J., dissenting); 21 C.F.R. § 314.53(c)(2)(i)(O); C.A.App.6880-6887.

According to the panel majority, Teva should have ignored FDA's instruction and GSK's sworn

declaration and adopted a different label. But "[f]or decades, everyone has assumed they could rely on what brands said about what their patents covered. The FDA's skinny-label approval pathway and regulations are expressly predicated on that." Pet.App.85a (Prost, J., dissenting). Now, a generic-drug manufacturer can be accused of inducing infringement for doing *precisely* what Hatch-Waxman contemplates. That decision "threatens to decimate the compromise at the heart of the Hatch-Waxman Act," "allow[ing] proof of induced patent infringement every time a generic uses a skinny label." Henry Waxman C.A. Amicus Br. 9, 11.

Moreover, given inducement doctrine's encouragement requirement, "it's unclear what Teva even did wrong—or, put another way, what another generic in its shoes should do differently." Pet.App.84a (Prost, J., dissenting). The decision below breaks from the well-settled body of precedent distinguishing between non-infringing "mentions" of patented uses and infringing "instruction" or "encouragement."

To effectuate the carve-out, Teva omitted more than 50 paragraphs of information at FDA's instruction, including the "Heart Failure" portions of the "Indications and Usage," "Dosage and Administration," "Adverse Reactions," "Pharmacodynamics," "Specific Populations," and "Clinical Studies" sections pertaining specifically to the use of carvedilol to treat CHF.

Even though Teva purposefully excised any express CHF instructions, the panel majority let GSK stake its inducement claim on stray sections of the label providing information about *un*patented uses, *see* C.A.App.6908-6952 (redlined label)—in particular, on GSK's expert's "march[] through Teva's label" to

establish *direct infringement by doctors*, Pet.App.18a, plucking out individual sentences and opining that each "met" or "satisfied" a discrete element of GSK's patent claim, Pet.App.15a-17a, 20a, 27a. The record is clear that Dr. McCullough "never testified that the skinny label *encouraged, recommended, or promoted* practicing the claimed method," Pet.App.65a (Prost, J., dissenting) (emphasis added)—indeed, he was never asked this question during that testimony, Pet.App.18a; C.A.App.10623-10631. The panel majority nonetheless held that crucial omission did not matter—that the scavenger-hunt-for-claim-language testimony was legally sufficient to support a finding of inducement. Pet.App.15a.

For example, the majority pointed to Dr. McCullough's direct-infringement testimony addressing the first claim element (decreasing mortality caused by CHF). Pet.App.16a. In that testimony, Dr. McCullough noted sections of the carve-out label where "there's a mention" of the phrase "heart failure," including one that was expressly agnostic about whether patients even *had* heart failure. C.A.App.10623; *see* C.A.App.5508 (directing use of carvedilol to treat post-MI LVD patients "with or without symptomatic heart failure"). This is the exact type of evidence that was rejected in *HZNP* and *Bayer* as mere *description* (not *encouragement*) and therefore legally insufficient to support liability. *See HZNP*, 940 F.3d at 702; *Bayer*, 676 F.3d at 1322.

The majority's holding cannot coexist with this Court's precedents or the consistent line of Federal Circuit decisions carefully policing the description-encouragement boundary. The majority did not even attempt to explain how its new inducement-by-hidden-

message approach is consistent with this Court's decisions in *Global-Tech* or *Grokster* or the Federal Circuit's decision in *Takeda*—because those decisions foreclose the approach it adopted. And while the panel majority did purport to reconcile its holding with that of *HZNP* and *Bayer*, its proposed distinction was nothing more than the assertion that the labels in those cases did not recommend the patented uses. Pet.App.18a-20a. That question-begging statement misses the point: the *reason* why there was no "encouragement" in those cases applies with equal or greater force here. *See* Pet.App.77a-79a (Prost, J., dissenting). Indeed, the majority opinion curiously echoes the *dissents* in *HZNP*, *Takeda*, and *Bayer*—all dissents authored by Judge Newman, who authored the 2020 panel opinion that effectively ignored the skinny-label statute and joined the 2021 per curiam opinion that eviscerated it. *See Takeda*, 785 F.3d at 635-636 (Newman, J., dissenting); *Bayer*, 676 F.3d at 1329 (Newman, J., dissenting); *HZNP*, 940 F.3d at 709 (Newman, J., dissenting).

If inadvertent description is now sufficient to satisfy § 271(b), then the statute is broken—the skinny-label statute cannot function if carving out a patented use is effectively the same (for liability purposes) as leaving in that use. As Judge Dyk's dissent recognized, because Congress enacted the skinny-label provision decades *after* enacting § 271(b) and the skinny-label statute expressly *permits* patented uses to be carved out while *requiring* all other language to remain in the label, that more recent and more specific provision must control. Pet.App.207a. Yet the majority did not even grapple with the tension—if not outright conflict—that its interpretation of these statutory provisions created.

In the end, the majority holds that inducement can lurk in disjointed factual statements scattered across a label. An oblique reference to one claim element here, a hint of another claim element over there: string them together, the majority says, and that can be inducement. That is not how § 271(b) has worked—until now.

C. The decision below has far-reaching consequences warranting this Court's attention.

The panel majority's dramatic redefinition of inducement would alone be worthy of this Court's review. But in the Hatch-Waxman context, the confusion it creates and the havoc it will wreak on Congress's design makes certiorari not just warranted, but necessary. Where there was previously clarity and "equilibrium to the skinny-label system," there is now confusion and uncertainty. Pet.App.87a (Prost, J., dissenting). That uncertainty discourages generics from using carve-outs, which "throw[s] a wrench into Congress's design for enabling quick public access to generic versions of unpatented drugs with unpatented uses." Pet.App.49a. The ramifications of such an outcome are enormous—skinny-label launches are extraordinarily common, and they save patients and the federal government billions.[19] If they are at-risk launches, then generic manufacturers will not be able to use them. The U.S. healthcare system cannot

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[19] *See, e.g.*, Walsh, *supra*, at 995-997; Ed Silverman, *'Skinny Label' for Generic Version of a Pricey Cancer Drug Cut Costs for Consumers*, Stat (Jan. 11, 2022), https://www.statnews.com/pharmalot/2022/01/11/skinny-label-generic-gleevec-cancer.

sustain that outcome given the cost of prescription-drug pricing.

As the dissent observes, this case is "far from … a disagreement among reasonable minds about the individual facts." Pet.App.48a. It is a "signal[] that [the Federal Circuit's] law on [inducement] has gone awry." *Id.* The reason is simple: "the background facts here will seemingly persist in most skinny-label cases." Pet.App.84a. Needing only to find claim elements "mentioned" in portions of their label that speak to *unpatented* uses, brands will regularly find *something* in the skinny label that can serve as the basis for an inducement complaint years (and hundreds of millions of dollars) after generic launch.

The carve-out statute cannot function if every carve-out leads to a jury trial. When inducement liability required clear evidence of affirmative encouragement, generics could launch with confidence that their skinny labels do not induce infringement, just as Congress intended. But now, the risk of generic launch with a carve-out label is far too great given that the lost-profits damages a jury can award dwarfs the profits a generic earns (pennies per pill—or worse, a net *loss*). Pet.App.123a & n.3 (Prost, C.J., dissenting).

Nor is this regime workable for FDA. Generics cannot write their own labels to avoid infringement. Rather, the brand identifies what parts of its own labeling its method-of-use patents claim, *see* 21 C.F.R. § 314.53(c)(2)(i)(O), and FDA relies on the brand's description when it makes approval decisions and proposes carved-out labeling. But the decision below makes clear that following FDA's instructions, based on the brand's explicit identifications, is no safe

harbor. And brands will now have every incentive to write their labels to facilitate claims of inducement after a carve-out.

Indeed, the impact of the decision below will reach beyond the immediate skinny-label context. If disparate sections of drug labeling addressing *un*patented uses are now fair game for an inducement claim, then the opportunities for brands to abuse the patent system and manipulate the pharmaceutical market are nearly infinite. Brand manufacturers often obtain patents on uses for which they *do not* seek FDA approval, and attempt to use those patents to discourage the launch of generic drugs labeled for *unpatented* uses. *See, e.g.*, *Bayer*, 676 F.3d at 1320 (infringement claims involving unapproved indication). Inducement's active-encouragement element has previously held those claims at bay. *See id.* at 1319-1324. But the decision below breathes new life into these liability theories, and the uncertainty created will only embolden brand manufacturers to bring these types of claims in the future—*years after* a generic drug has been on the market.

Because of the massive damages exposure, section viii will now be *riskier* than pre-launch paragraph IV litigation. Brand manufacturers can lie in wait for years after generic launch, then sue to recover six years of their lost market share. That daunting prospect will be too risky for generic manufacturers. The majority's "opaque" decision will leave generics "in the dark about what might expose them to liability," discouraging them from entering the market. Pet.App.48a-49a (Prost, J., dissenting).

In all events, a brand manufacturer will have every incentive to "maintain its exclusivity merely by

regularly filing a new patent application claiming a narrow method of use not covered by its NDA"— the outcome Congress sought to *avoid* through enactment of the skinny-label statute. *Warner-Lambert*, 316 F.3d at 1359. This well-recognized patent abuse—called "evergreening"—will be turbocharged by the decision below. *See* Cong. Rsch. Serv., R46221, *Drug Pricing and Pharmaceutical Patenting Practices* 9, 16 (2020), https://sgp.fas.org/crs/misc/R46221.pdf.

As the Department of Health and Human Services (HHS) has emphasized when expressing concern about this very litigation, carve-outs are "critical practices," and judicial interpretations that "may discourage the use of carve-outs and thus delay the approval of some generic drugs" can cause enormous harm to the healthcare market as a whole. U.S. Dep't of Health & Human Servs., *Comprehensive Plan for Addressing High Drug Prices* 21 (Sept. 2021), https://aspe.hhs.gov/sites/default/files/2021-09/Drug_Pricing_Plan_9-9-2021.pdf (*HHS Plan*). FDA, too, has recently emphasized the harm that patent abuses and generic-launch delays create for the healthcare system—harms that will inevitably follow from the decision below.[20] When a brand drug has both patented and unpatented uses, the first generic launch relies on a skinny label nearly half the time.[21] Without carve-outs, generic approval will take years longer. The re-

[20] Letter from Janet Woodcock, Acting Commissioner of Food and Drugs, to Andrew Hirshfeld, U.S. Patent and Trademark Office 2-5 (Sept. 10, 2021), https://pink.pharmaintelligence.informa.com/-/media/supporting-documents/pink-sheet/2021/09/fda-letter-to-pto.pdf.

[21] Walsh, *supra*, at 995-997.

sult will be "billions and billions" in lost savings for patients and the federal government.[22]

II. The Court should review this case without delay.

This Court's immediate review is vitally important. As HHS has explained, carve-outs are a "critical" mechanism for ensuring that low-cost generic versions of unpatented drugs are not kept off the market. *HHS Plan* 21. This case presents an excellent opportunity for this Court to prevent that outcome by addressing the appropriate interpretation of the skinny-label statute and § 271(b)—on a post-trial record in a context where the answer is case-dispositive, with a thoughtful district-court decision and eight Federal Circuit opinions to aid review. Neither reason offered by the concurrence in the denial of rehearing en banc to justify denying further appellate review provides any basis for delay.

A. Chief Judge Moore's concurrence suggested that the availability of an equitable-estoppel defense on remand makes further review unnecessary now. That suggestion is misguided.

First, a petition is not fatally "interlocutory" where the very question is whether the remand was erroneous. This Court regularly reviews appellate decisions that mistakenly remand for further proceedings, including in *Caraco* (another skinny-label case), and in *Eli Lilly*, when this Court granted review to decide whether 35 U.S.C. § 271(e)(1) provided a defense to infringement, even though the Federal Circuit had "remanded for the District Court to determine whether

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[22] Kass, *GSK Redo*, *supra*.

in fact [the] condition[s] [for applying the defense] had been met." 496 U.S. at 664.

Second, the suggestion that the availability of a discretionary, equitable defense could blunt the impact of the majority's erroneous decision misses the "point" of Hatch-Waxman: clarity and predictability. Pet.App.54a & n.9 (Prost, J., dissenting). Hatch-Waxman is designed around "resolv[ing] patent disputes as early as possible." *Id.* That is because at-risk launch is rarely feasible for generics. *See supra* pp. 22-23. But equitable defenses are not resolved before generic launch, or even *before trial*—they are resolved *after a jury trial* to avoid Seventh Amendment issues. *See* Peter S. Menell, *Patent Case Management Judicial Guide* § 8-5 (3d ed. 2015).

Moreover, equitable estoppel is a *defense* for which an infringement defendant bears the burden of proof—one dependent on equitable considerations, and reviewable only for abuse of discretion. *A.C. Aukerman Co. v. R.I. Chaides Constr. Co.*, 960 F.2d 1020, 1041 (Fed. Cir. 1992) (en banc). Given the centrality of clarity and predictability to the Hatch-Waxman regime, it is unfathomable that "Congress, when enacting this specific statutory skinny-label system (implemented by copious detailed regulations), intended to stake the efficacy of that system on a generic's case-by-case equity showing." Pet.App.204a (Prost, J., dissenting).

B. Chief Judge Moore's concurrence also vaguely suggested that these issues were not adequately ventilated by the parties at the panel stage. Pet.App.186a-190a. But as the dissenting judges observed, that odd suggestion is demonstrably "not the case." Pet.App.200a-203a (Prost, J., dissenting); *see*

also Pet.App.208a (Dyk, J., dissenting). The proper interpretation of § 271(b) and the skinny-label statute *dominated* merits briefing, two en banc petitions, and both of Judge Prost's dissents. *See, e.g.*, C.A.Red.Br.9, 14-15, 47-54. "Put simply: this argument was made to the panel, the panel addressed it on its merits, and the majority resolved it against Teva." Pet.App.202a (Prost, J., dissenting).

* * *

The profound implications of this case on the patent system, the pharmaceutical market, patients, and the federal government warrant this Court's intervention now. In light of the importance of the carve-out system, this Court has previously sought the government's views on certiorari in a related case regarding Hatch-Waxman's skinny-label provision. *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 563 U.S. 902 (2011) (Mem.). At a minimum, this Court should not deny certiorari without first seeking the government's views given the interests of numerous federal agencies—and the public fisc—at stake.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

DARYL L. WIESEN
CHRISTOPHER T. HOLDING
ELAINE HERRMANN BLAIS
ROBERT FREDERICKSON, III
GERARD J. CEDRONE
WILLIAM E. EVANS
GOODWIN PROCTER LLP
100 Northern Avenue
Boston, MA 02210

WILLIAM M. JAY
Counsel of Record
GOODWIN PROCTER LLP
JAIME A. SANTOS
1900 N Street, NW
Washington, DC 20036
(202) 346-4000
wjay@goodwinlaw.com

Counsel for Petitioner

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