No. 22–37

In the Supreme Court of the United States

TEVA PHARMACEUTICALS USA, INC., PETITIONER

v.

GLAXOSMITHKLINE LLC,
SMITHKLINE BEECHAM (CORK) LIMITED

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR MYLAN PHARMACEUTICALS INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

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?

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INTRODUCTION AND STATEMENT OF INTEREST OF *AMICUS CURIAE*[1]

The Federal Circuit's divided ruling in this case thwarts Congress's decision to create an expedited path to market for critical, low-cost generic medicines sold only for unpatented, FDA-approved uses. This Court's review is urgently needed.

The majority below declared that its "narrow, case-specific" decision does not "impose liability on ANDA filers that carve out patented uses under section viii" or "upset the careful balance struck by the Hatch-Waxman Act regarding section viii carve-outs." Pet. App. 11a-12a. Yet the decision invites juries to decide whether generic labels prescribed by the FDA are "true section viii carve-out[s]." Pet. App. 32a n.7. Further, "the jury [is] free to credit as evidence of induced infringement" snippets from various parts of the label that, even cobbled together, at most *describe* the infringing use's elements without *encouraging* infringement. *Ibid*.

While expressing "concern[s] that GSK's representations to the FDA are at odds with [GSK's] enforcement efforts," the judges concurring in the denial of en banc review suggested that Teva take refuge "on remand" in its "affirmative defense of equitable estoppel." Pet. App. 190a (Moore, J.). But that suggestion misses the point. Congress designed section viii to avoid not only inducement *liability*, but *litigation itself and all related delay and uncertainty*—so as to

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[1] No counsel for any party authored this brief in whole or in part, and no person other than *amicus* and its counsel made a financial contribution to the preparation or submission of the brief. All parties have consented to its filing.

"speed the introduction of low-cost generic drugs to market." *Caraco Pharm. Labs., Ltd.* v. *Novo Nordisk A/S*, 566 U.S. 399, 405 (2012). Having to litigate yet another defense to liability only multiplies the harm to generic drug makers and those who need their products.

The court of appeals' insistence that its revised decision is "narrow" is thus cold comfort. As Judge Prost noted, "most skinny-label cases" involve similar facts. Pet. App. 84a. The upshot? "[N]o generic can know" if its label is a "true" carve-out until the jury speaks and the generic is "hit with the bill"—years into litigation, itself filed years after the product launched. Pet. App. 86a.

The decision also flouts the text of the Patent Act—where Congress required proof that defendants "actively" induced infringement (35 U.S.C. § 271(b))—and conflicts with this Court's induced infringement precedent, which requires a showing of "affirmative steps to bring about" infringement (*Global-Tech Appliances, Inc.* v. *SEB S.A.*, 563 U.S. 754, 760 (2011)). Generic drug makers invest in section viii products, which typically have low profit margins, on the understanding that there is a speedier path to market than contested litigation. The costs of unwarranted litigation can make the difference as to whether a generic can launch a product. And by upending induced infringement law and placing it directly in conflict with section viii, the decision below promises to generate unnecessary litigation and ultimately to stifle the launch of critical low-cost drugs—and force the withdrawal of others from the market.

The Court need not take our word for it. HHS itself has predicted that the decision will "discourage

the use of carve-outs and thus delay the approval of some generic drugs." U.S. Dep't of Health & Human Servs., X. Becerra, *Comprehensive Plan for Addressing High Drug Prices* 21 (Sept. 9, 2021).[2] The decision has already sparked copycat suits, threatening carve-out labels generally. Absent this Court's review, the ultimate losers will be consumers who urgently need affordable medicines, but will now be forced to wait while brands assert follow-on method-of-use patents that should have no bearing on the sale of section viii products—a result directly contrary to Congress's goal in passing the Hatch-Waxman Act. This Court should intervene, or at least invite the views of the Solicitor General.

Amicus Mylan Pharmaceuticals Inc., a leading pharmaceutical company that often markets low-cost section viii products, files this brief to explain how the decision below "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 (Prost, J., dissenting).

STATEMENT

When enacting Hatch-Waxman, "Congress sought to get generic drugs into the hands of patients at reasonable prices—fast." *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991). To that end, Congress created different ways for generic drug makers to address patent issues: Paragraph IV litigation, in which FDA approval to sell a generic drug requires the generic to defeat the brand's patent infringement claims in court (21 U.S.C. § 355(j)(2)(A)(vii)(IV)), and "section viii"

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[2] https://aspe.hhs.gov/sites/default/files/2021-09/Drug_Pricing_Plan_9-9-2021.pdf

carve-outs, which are designed to *avoid* litigation and speed market entry for *unpatented* uses of generic drugs (*id.* § 355(j)(2)(A)(viii); see *Caraco*, 566 U.S. at 404-406). The section viii path, which is available for drugs with some unpatented FDA-approved uses, enables generic manufacturers to market drugs with labels—known as "carve-out" or "skinny" labels—that indicate only those unpatented uses.

Congress designed section viii to enable generics to avoid "actively induc[ing] infringement." 35 U.S.C. § 271(b). Until this case, it was settled that using a carve-out label was not an "affirmative step[] to bring about" infringement under § 271(b) (*Global-Tech*, 563 U.S. at 760)—a "particularly important" requirement because Congress recognized that section viii "would result in some off-label infringing uses" (*Takeda Pharms. U.S.A., Inc.* v. *West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015)). In fact, it is "common knowledge" that "physicians routinely prescribe approved drugs for purposes other than those listed on the drugs' labels," and that pharmacies often fill prescriptions for patented uses with generic substitutes," but until this case such facts did not evidence affirmative steps to "encourage doctors to infringe." *Warner-Lambert Co.* v. *Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003). The idea that, despite the drug's section viii carved-out label, evidence of doctors' prescribing habits "require[d] trial" was a *dissenting* view. *Takeda Pharms*, 785 F.3d at 636 (Newman, J., dissenting).

The divided decision below adopts that dissenting view, reinstating liability because (1) Teva's carve-out label, if spliced and reassembled, "mentioned" each claim limitation, (2) marketing a drug's "AB rating"

informs doctors that drugs are "therapeutically equivalent," and thus constitutes "further affirmative evidence supporting [a] jury's inducement finding," and (3) doctors are likely to prescribe generics for their branded counterparts. Pet. App. 34a, 31a, 32a, 33a. But as Judge Prost explained, Teva's label fragments did not *encourage* infringement—they at most "*described* the infringing use (if pieced together just right)." Pet. App. 65a. Moreover, the facts cited by the majority may exist in other section viii cases. In short, a generic drug maker that "play[s] by the rules, exactly as Congress intended" (Pet. App. 47a (Prost, J., dissenting)) can no longer be certain that a label is a "true" carve-out at the key moment—when it launches its product.

SUMMARY OF ARGUMENT

This case is exceptionally important to patent law, to the pharmaceutical industry, and to those who need affordable medicine. The majority below purported to issue a "narrow, case-specific" ruling (Pet. App. 12a), but this Court should not be fooled—the decision has far-reaching implications, and the majority's revised opinion only "exacerbates[] concerns raised by the original" opinion (Pet. App. 87a) (Prost, J., dissenting)).

I. The court below offered no guidance as to "what another generic in [Teva's] shoes should do differently" (*id*. at 84a), and its reassurance that juries will surely know "a true section viii carve-out" label when they see it—one with "no infringing indications[]" (Pet. App. 32a n.7)—rings hollow. Teva followed the same path that other generics follow when releasing section viii products. That well-worn path is in fact mandated by the FDA, which—as Congress required—spells out

word-for-word precisely what each carve-out label must say. *Mutual Pharm. Co.* v. *Bartlett*, 570 U.S. 472, 477 (2013) (citing 21 U.S.C. § 355(j)(2)(A)(v); 21 C.F.R. §§ 314.94(a)(8)(iii), 314.150(b)(10)).

Most importantly, the majority's reasoning ignores *when* generic drug makers need clarity about whether their section viii products infringe—namely, *before* the products launch. Leaving generics to roll the dice, in hopes that a jury will later see their carve-out label as "true," will deter them from using a path to market that Congress designed to avoid not only liability, but litigation itself. Worse, the prospect of down-the-road liability incentivizes brands to lie in wait for up to six years—while damages accrue—before finally filing suit. Even where a generic drug maker manages to avoid after-the-fact liability, it will be injured—by both the costs of litigation and years of uncertainty and delay. This Court should not permit that result.

For the same reason, it is no answer to let generics invoke "equitable estoppel." That requires yet another roll of the dice, prolonging the uncertainty as to whether the generic drug maker will face inducement liability. Given these risks and the modest profit margins of generic drugs, some may not even be launched. And even if Teva prevails, the decision below will remain. For all these reasons, the Court should intervene now, rather than await a future case.

II. Review is also warranted because the decision below, in upholding liability for induced infringement based on labels prescribed by the FDA, conflicts with a venerable body of this Court's precedent concerning how to read related federal statutes. Congress passed section viii so generics could avoid inducing infringement by using FDA-mandated labeling that omits "an

indication * * * protected by patent." 21 C.F.R. § 314.94(a)(8)(iv). For its part, § 271(b) prohibits only "actively induc[ing] infringement." Yet the ruling below treats acts intended to *avoid* infringement as acts intended to *induce* infringement, thus upsetting both bodies of law. It makes far more sense to read section viii and § 271(b) harmoniously, and standard rules of statutory construction in fact compel that result.

REASONS FOR GRANTING THE PETITION

I. By saddling Congress's path to streamlined FDA approval of generic drugs with the risk of litigation and damages, the decision below will deter the development of needed non-infringing drugs.

Congress created several paths for generic drug makers to get products to market—including one that by design "means provoking litigation" (*Caraco*, 566 U.S. at 407), and thus is contested and uncertain, and another that by design is streamlined and litigation-free, so a product "can quickly come to market" (*id*. at 415). Under the divided ruling below, however, both paths are now contested and uncertain. If allowed to stand, that ruling will deter generic drug companies from developing needed, low-cost drugs and marketing them for uses that all agree are *not* patented—to the detriment of consumers.

A. Congress designed section viii as a litigation-free path to market for generics that seek FDA approval to market their products only for unpatented uses.

Paragraph IV litigation begins when the generic certifies to the agency that its proposed ANDA product does not infringe a patent listed in the Orange Book, but the brand disagrees—and sues within 45

days. 21 U.S.C. § 355(j)(5)(B)(iii). The brand's suit triggers an automatic, 30-month stay of effective FDA approval while the parties litigate (*ibid.*), to resolve questions of validity and infringement *before* launch.

If the brand does not sue within the prescribed 45-day period, a generic can file a declaratory judgment suit—a "[c]ivil action to obtain patent certainty"—and get the benefit of a court decision on infringement and validity. 21 U.S.C. § 355(j)(5)(C); 28 U.S.C. §2201. Thus, whether the brand sues the generic or vice versa, the Paragraph IV route to market provides a mechanism to obtain certainty about validity and infringement before product launch.

The "section viii" path to market, by contrast, is designed to avoid litigation over certain patents that cover methods of using the product where there should be no serious claim of infringement. 21 U.S.C. § 355(j)(2)(A)(viii). That path begins when a generic certifies that it will sell its drug only "for one or more methods of use not covered by the brand's patents"—typically, "when the brand's patent on the drug compound has expired and the brand holds patents on only some approved methods of using the drug." *Caraco*, 566 U.S. at 406.

In those circumstances, section viii permits the generic to use an FDA-mandated drug label that "'carves out' from the brand's approved label the still-patented methods of use"—which is "an exception to the usual rule that a generic drug must bear the same label as" the brand's. *Ibid.* (citing 21 CFR §§ 314.94(a)(8)(iv), 314.127(a)(7), and 21 U.S.C. §§ 355(j)(2)(A)(v), (j)(4)(G)). The "carve-out label" intentionally omits all language instructing doctors to practice the drug's patented uses, and FDA approval allows the generic "to

place its drug on the market" for the "subset of approved uses" that are "not covered by the brand's patents." *Ibid.* Carve-out labels thus prevent brands from using follow-on method patents to extend their monopolies to cover uses that are no longer patented. In sum, Congress passed section viii so brands cannot "foreclose marketing a generic drug for [its] unpatented [uses]" and "a product with a label matching them can quickly come to market." *Id.* at 415.

B. The record here belies the majority's reassurance that the decision below was "narrow" and "case-specific."

Until this case, section viii had worked just as Congress intended—as a vital tool for bringing new, noninfringing generic drugs to market. Mylan and other generic drug companies have launched literally hundreds of section viii products, saving consumers—including the elderly, insurers, and the federal government—billions of dollars. Association for Accessible Medicines, *2020 Generic Drug & Biosimilars Access & Savings in the U.S. Report* 4 (2020). The FDA has explained that "78 percent of the drug products for which new patents were listed in the Orange Book from 2005-2015 were existing drug products, not new drugs entering the market." Janet Woodcock, *Letter to the Director of the USPTO*, U.S. Food & Drug Admin. 3 (Sept. 10, 2021).[3] In fact, nearly half of recent first generic launches rely on carve-out labels. Bryan

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[3] https://pink.pharmaintelligence.informa.com/-/media/supporting-documents/pink-sheet/2021/09/fda-letter-to-pto.pdf?rev=a9088a7df6b1467dadd237ea53b19631&hash=1854798EF674A7CDE10BE9F414E137D2.

S. Walsh et al., *Frequency of First Generic Drug Approvals With 'Skinny Labels' in the United States*, 181 JAMA Intern. Med. 995-997 (2021).[4] And with generics accounting for 90% of U.S. prescriptions dispensed—but just 20% of total prescription drug costs—the efficient functioning of the industry is critical to controlling drug prices. *2020 Generic Drug & Biosimilars Access & Savings in the U.S. Report* at 16.

Before this case, the Federal Circuit consistently recognized that "[m]erely describing [an] infringing use" in a label does "not suffice" to support liability. See *HZNP Meds. LLC* v. *Actavis Labs. UT, Inc.*, 940 F.3d 680, 702 (Fed. Cir. 2019). That is unsurprising. The FDA prescribes carve-out labels, often word for word, and omitting all language instructing doctors to use drugs in patented ways is the antithesis of "actively" inducing infringement. 35 U.S.C. § 271(b). As this Court has held, active inducement entails taking "affirmative steps to bring [it] about" (*Global-Tech*, 563 U.S. at 760, 763)—*i.e.*, "purposeful, culpable expression and conduct." *Metro-Goldwyn-Mayer Studios Inc.* v. *Grokster, Ltd.*, 545 U.S. 913, 937 (2005). In other words, an infringement plaintiff "needs to show that [the defendant] took affirmative steps to induce, not affirmative steps to make sure others avoid infringement." *Takeda*, 785 F.3d at 632 n.4.

Enter the decision below, which invites *juries* to decide whether generic carve-out labels mandated by the FDA are "true section viii carve-out[s]." Pet. App. 32a n.7. Teva "did everything right" (Pet. App. 118a (Prost, J., dissenting)), omitting reference to patented

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[4] https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2777965.

uses from its label's "Indications and Usage," "Dosage and Administrations," "Adverse Reactions," "Pharmacodynamnics," "Specific Populations," and "Clinical Studies" sections. CA App. 6908-6951. But that was not enough to prevail on induced infringement as a matter of law. According to the majority below, "the jury was free to credit as evidence of induced infringement" various portions of the label that, even read together, simply *described* the infringing use's elements without *actively encouraging* infringement. *Ibid*. The Federal Circuit's reasoning thus converts Congress's prohibition on "actively induc[ing] infringement" into a requirement that companies actively *prevent* others' infringement, in direct conflict with this Court's decisions in *Global-Tech* (563 U.S. at 760) and *Grokster* (545 U.S. at 937).

On this record, it is hard to take seriously the notion that the decision below is "narrow and fact dependent." Pet. App. 188a (Moore, J., concurring in the denial of rehearing en banc). Even if generics defeat some claims of induced infringement, brands are now emboldened to bring suit, and generics no longer can know whether their labels will be seen as "true" carveouts until the jury decides—years into litigation, itself filed years after the drugs went to market.

Brands are already invoking the majority's reasoning, in hopes of monopolizing *every* use of their drugs, for as long as possible, "merely by regularly filing a new patent application claiming a narrow method of use." *Warner-Lambert*, 316 F.3d at 1359; see *Amarin Pharma, Inc.* v. *Hikma Pharms. USA Inc.*, No. 20-cv-1630 (D. Del. Jan. 25, 2021) (Dkt. 17, ¶¶ 111, 114, 121, 126); see also Woodcock, *supra*, at 3 (citing "[c]oncerns" about brands "inappropriately imped[ing] competition from generic" drugs via "patent 'evergreening,' or the

practice of patenting * * * various additional methods of use"). But whether brands win or lose, the risk of unwarranted litigation itself will keep section viii products off the market. Generic drugs typically sell for a fraction of the price of their brand-name counterparts—sometimes for pennies. Even setting aside the risk of damages, therefore, having to spend millions of dollars and undergo years of litigation uncertainty with a narrow profit margin will cause generic drug companies to halt or forgo the development of many critical low-cost medicines. In short, unless this Court intervenes, suits like this may become commonplace, and even the risk of those suits creates barriers to generic entry—contrary to Congress's design.

C. Generics should not have to litigate equitable estoppel to invoke section viii.

The judges concurring in the denial of rehearing believed they had a solution to this problem. They too were "concerned that GSK's representations to the FDA [were] at odds with its enforcement efforts" here. Pet. App. 190a. But they brushed off this concern on the basis that GSK's conduct appeared to "fit[] squarely within the affirmative defense of equitable estoppel," which "the district court must still decide on remand." *Ibid.* That should not deter the Court from granting review.

Congress designed section viii to protect generics not only from *liability*, but from the *uncertainty of litigating* whether drugs that carve out every patented use from their FDA-mandated labels infringe. Prevailing on equitable estoppel might spare some generics from liability. But equitable estoppel is not "subject to resolution by simple or hard and fast rules." *A.C. Aukerman Co.* v. *R.L. Chaides Constr. Co.*, 960

F.2d 1020, 1043 (Fed. Cir. 1992) (en banc), abrogated on other grounds by *SCA Hygiene Prods. Aktiebolag* v. *First Quality Baby Prods., LLC*, 137 S. Ct. 954 (2017). And even when the generic manufacturer wins, having to undertake a second round of post-verdict equitable proceedings only *exacerbates* the injury of being forced to spend years in court—which Congress sought to prevent in enacting section viii.

Absent this Court's review, moreover, the decision below will remain on the books, creating uncertainty and deterring *other* generics from launching essential low-cost medicines. Regardless of what occurs on remand, the key legal issues involving section viii presented by the ruling below *are* certain, and the decision will have a tangible effect on the ongoing development and release of critical medicines to the public. Thus, the Court should grant review now, before it does further harm to both the industry and consumers.

II. This Court's review is needed to reconcile Congress's goal of getting low-cost generic drugs to consumers quickly with Congress's standards for induced infringement liability.

Review is also warranted because the ruling below, which conflicts with several venerable maxims of statutory construction, upsets the relationship between section viii and the Patent Act's provisions governing induced infringement.

A. The decision below eviscerates section viii by turning compliance with the statute into evidence of induced infringement.

Congress enacted section viii so that generic drug companies could market drugs with carve-out labels by affirming "that the [brand's] method of use patent"

"does not claim a use for which the applicant is seeking approval." 21 U.S.C. § 355(j)(2)(A)(viii). And under "one of the most basic interpretive canons," a law "should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." *Corley* v. *United States*, 556 U.S. 303, 314 (2009). The ruling below, however, effectively nullifies section viii by enabling litigation *and* liability for marketing drugs for noninfringing uses. Because juries will now decide whether the generic's label is a "true" carve-out—based on AB ratings, standard marketing material, and a "Where's Waldo?" approach to the label's contents—the risk of liability will "seemingly persist in most skinny-label cases." Pet. App. 198a, 84a (Prost, J.).

The idea that generic drug makers risk inducing infringement by using labels mandated by FDA and stating that their products are "AB rated" eviscerates section viii. Generic drugs must be bioequivalent to their branded counterparts (§ 355(j)(2)(A)(iv)), and as GSK's expert admits, "AB rating[s]" *necessarily* compare generic drugs to those counterparts. CA App. 10534. Critically, the rating means the FDA deems the generic drug therapeutically equivalent to the branded drug *only* for indications listed on the label. *Ibid.* Teva's skinny label never recommended GSK's patented method, and it is "uncontroverted" that "it was other sources, and not Teva's label or other documents, that induced doctors to prescribe carvedilol according to the claimed method." Pet. App. 141a. "In particular, the record confirmed that doctors prescribed carvedilol according to the claimed method based on the prescribing guidelines established by the American Heart Association and the American Col-

lege of Cardiology, medical research studying carvedilol, and even GSK's own Coreg® label and GSK's promotional materials advertising it." *Ibid.*

The majority side-stepped section viii by declaring that Teva's label is not "a true section viii carve-out." Pet. App. 32a n.7. But what kept Teva's label from satisfying the statute? Only the words of GSK's expert witness, who cobbled together disparate parts of the label to contend that it "mentioned" each claim limitation. Pet. App. 78a (Prost, J.). Thus, generics must now scour their labels' language—which FDA dictates and they may not "unilateral[ly] change[]" (*Bartlett*, 570 U.S. at 477)—and hypothesize whether a brand could concoct an induced infringement theory by arguing that disconnected parts of a label, "pieced together just right" and reinterpreted (Pet. App. 65a), contain each step of the infringing method. The decision incentivizes brands to make their labels as broad and interwoven as possible, so generics acting in good faith will be compelled to mention each step of the patented method, and converts passive, congressionally authorized and FDA-mandated acts into evidence of active inducement. Cf. *Caraco*, 566 U.S. at 408 (citing FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* iii–vi (July 2002), which discussed how "some brands were exploiting this statutory scheme to prevent or delay the marketing of generic drugs" with "anticompetitive practices" including "submission of inaccurate patent information to the FDA"). But as Judge Dyk explained, "[i]t is hard to see how Congress could have intended that a mandated label could be used as evidence of infringement." Pet. App. 207a.

B. The court below read section viii to conflict directly with § 271(b), in violation of settled rules of statutory construction.

The divided decision below also conflicts with five other maxims of statutory interpretation—the "cardinal rule" that "a statute is to be read as a whole" (*King* v. *St. Vincent's Hosp.*, 502 U.S. 215, 221 (1991)), the rule that "statutes addressing the same subject matter generally should be read 'as if they were one law'" (*Wachovia Bank, N.A.* v. *Schmidt*, 546 U.S. 303, 316 (2006) (citation omitted)), the rule that separate statutes should be read harmoniously and with "coherence" (*Lindh* v. *Murphy*, 521 U.S. 320, 336 (1997)), the rule that "later" and "more specific" statutes generally govern earlier and more general ones (*United States* v. *Estate of Romani*, 523 U.S. 517, 532 (1998)), and the rule that absent a "clear intention otherwise, a specific statute will not be controlled or nullified by a general one, regardless of the priority of enactment" (*Morton* v. *Mancari*, 417 U.S. 535, 550-551 (1974)).

1. As discussed, Congress designed section viii to enable generic drug makers to market generic drugs solely for unpatented uses without risk of incurring inducement liability. *Caraco*, 566 U.S. at 406. Similarly, 35 U.S.C. § 271(b) creates liability only for those who "actively" induce infringement. Rather than harmonize these statutes, however, the decision below puts them on a collision course: Generics that certify and market their drugs as bioequivalent with labels that indicate only unpatented uses—practical necessities for invoking section viii—are treated as actively inducing infringement. As Judge Dyk observed, the majority's decision creates "a direct conflict between the FDA-required labelling and the supposed requirements of federal patent infringement law." Pet. App.

207a (dissent from denial of rehearing en banc). In other words, doing the very thing that section viii authorizes is unlawful under § 271(b). CA App. 11025. That result cannot be squared with the rules that laws addressing the same topic should be read as "one law" (*Wachovia Bank*, 546 U.S. at 316), or at least with "coherence" (*Lindh*, 521 U.S. at 336), particularly when inducement liability requires "purposeful, culpable expression and conduct" (*Global-Tech*, 563 U.S. at 763 (quoting *Grokster*, 545 U.S. at 937)).

In the majority's view, Congress used one hand to give generic drug manufacturers a path to carving out non-infringing uses, while using the other to impose damages for following that path. But the idea that juries may find induced infringement based on a "skinny label [that] *describe[s]* the infringing use (if pieced together just right)" (Pet. App. 65a (Prost, J.)) is highly problematic as a matter of basic statutory construction. That reading of § 271(b) is "closed to considerations evidenced in affiliated statutes." Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 252 (2012) (citation omitted). It makes far more sense to read the two statutes harmoniously.

In prior cases, the Federal Circuit had done just that, recognizing that "[the] requirement of inducing acts is particularly important in the Hatch–Waxman Act context" because "Congress intended 'that a single drug could have more than one indication and yet that [an] ANDA applicant could seek approval for less than all of those indications.'" *Takeda*, 785 F.3d at 630-631 (quoting *Warner–Lambert*, 316 F.3d at 1360). Under (still-binding) Federal Circuit precedent, the rule is (or should be) clear: "a generic manufacturer may avoid infringement by proposing a label that does not

claim a patented method of use, ensuring that 'one patented use will not foreclose marketing a generic drug for other unpatented ones.'" *Ibid.* (citations omitted). The decision below squarely conflicts with these precedents, but the panel could not overrule them—meaning each side in Hatch-Waxman cases will invoke the precedent supporting its position, and district courts will be left to reconcile these irreconcilable decisions.

2. As Judge Dyk recognized (Pet. App. 207a), the majority's reading also runs afoul of the rule that, insofar as there is tension between section viii and §271(b), section viii—the "later" and "more specific" statute—should govern. *Romani*, 523 U.S. at 532. This Court has repeatedly recognized that generic labels are not free-form artistic expression; but for carve-outs, they must be identical to the brand's label. *E.g.*, *Caraco*, 566 U.S. at 406. For instance, the Court has twice held that Hatch-Waxman preempts state-law design-defect claims alleging that generic drug labels inadequately warned consumers about the risks of their products, calling it "impossible" to "comply with both the[] state-law duty to change the label and the[] federal-law duty to keep the label the same." *PLIVA, Inc.* v. *Mensing*, 564 U.S. 604, 618 (2011); see *Bartlett*, 570 U.S. at 475 (federal law bars generics "from independently changing their drugs' labels").

If Hatch-Waxman's mandates override conflicting state law—which enjoys the benefit of a presumption against preemption (*Hillsborough County* v. *Automated Med. Labs., Inc.*, 471 U.S. 707, 715-716, 718 (1985))—it makes even less sense to treat them as supporting liability under the federal Patent Act. Hatch-Waxman "is the later statute, the more specific statute, and its provisions are comprehensive, reflecting an obvious attempt to accommodate the strong

policy objections to" imposing inducement liability on generics whose product labels omit instructions to perform infringing uses of the drug. *Romani*, 523 U.S. at 532. Thus, the "specific policy embodied in [Hatch-Waxman] should control [the] construction of the priority statute." *Id.* at 530. Indeed, given the "specific" nature of Hatch-Waxman and the "general" nature of the induced infringement provision, that result should obtain "regardless of the priority of enactment." *Mancari*, 417 U.S. at 550-551.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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