No. 18-1976, 18-2023

In the United States Court of Appeals for the Federal Circuit

GLAXOSMITHKLINE LLC AND SMITHKLINE BEECHAM (CORK) LIMITED,
PLAINTIFFS-APPELLANTS

v.

TEVA PHARMACEUTICALS USA, INC.,
DEFENDANT-CROSS-APPELLANT

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE, NO. 1:14-CV-00878, HON. LEONARD P. STARK, PRESIDING

BRIEF FOR MYLAN PHARMACEUTICALS INC. AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANT-CROSS-APPELLANT'S PETITION FOR REHEARING EN BANC

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CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae* certifies that:

1. The full name of every party or *amicus curiae* represented by the undersigned counsel in this case is: Mylan Pharmaceuticals Inc.

2. The names of the real party in interest (if the party named in the caption is not the real party in interest) represented by the undersigned counsel are: none.

3. Parent corporations and publicly held companies that own 10% or more of stock of a party represented by the undersigned counsel: Mylan Pharmaceuticals Inc. is wholly owned by Mylan Inc., which is wholly owned by Viatris Inc., a publicly held company. No publicly-held company owns 10% or more of Viatris Inc.'s stock.

4. The names of all law firms and the partners or associates that appeared for the parties now represented by the undersigned counsel in the trial court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are: None.

5. The title and number of any cases known to undersigned counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this Court's decision in the pending appeal: None.

Dated: December 16, 2020

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

If the divided panel decision here does not warrant en banc review, it is difficult to imagine any decision that would. Without acknowledging binding Supreme Court and Circuit precedent, the majority held that generic drug manufacturers may be subjected to damages for selling and accurately marketing drugs with a section viii "carve-out" statement—a mechanism that Congress designed to *preclude* infringement liability. The decision threatens to upend both Congress's path to marketing generic drugs for concededly non-infringing uses and the law of induced infringement, to the detriment of those who urgently need affordable medicine. Brand-name drug makers are already invoking the decision in hopes of deterring the use of section viii. The full Court should intervene now.

Amicus Mylan Pharmaceuticals Inc. is a leading pharmaceutical company. Mylan routinely files Abbreviated New Drug Applications (ANDAs) and markets low-cost drugs in reliance on section viii. Thus, Mylan is well-positioned to speak to the practical implications of the panel decision, and it has a vital interest in ensuring that section viii and limits on induced infringement liability are not rendered a "nulli[ty]." Dissent 3.

[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 its preparation or submission. All parties consented to the filing of this brief. Pursuant to Federal Circuit Rule 35(g), a motion for leave to file is being submitted with this brief.

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 two paths to market: Paragraph IV litigation, in which FDA approval to sell generic drugs depends on success in full-on patent litigation (21 U.S.C. § 355(j)(2)(A)(vii)(IV)), and "section viii" carve-outs, which are designed to *avoid* such litigation and speed market entry for uses of generic drugs that are *unpatented* (*id.* § 355(j)(2)(A)(viii)); *see Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 404–06 (2012). The section viii route to market, which is open when only some of a drug's FDA-approved uses are patented, allows generics to obtain FDA approval to market drugs with labels that indicate only the unpatented uses—"carve-out" or "skinny" labels.

Congress designed section viii to enable generics to avoid induced infringement liability, which requires "actively induc[ing] infringement." 35 U.S.C. § 271(b). Indeed, until now it has been settled that using a carve-out label is not an "affirmative step[] to bring about" infringement under § 271(b) (*Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 760 (2011)), a "particularly important" requirement here "because [Hatch-Waxman] was designed to enable the sale of drugs for non-patented uses even though this would result in some off-label infringing uses." *Takeda Pharm. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631

(Fed. Cir. 2015). To date, *omitting* patented uses from drug labels has not been an "affirmative step" to *induce* infringement.

In keeping with that reasoning, this Court previously held that the "common knowledge" that "physicians routinely prescribe approved drugs for purposes other than those listed on the drugs' labels," or that pharmacies often fill prescriptions for patented uses with generic substitutes, does not show that the manufacturer intended to induce infringement. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003). "[W]hether or not" such facts exist, they do not evidence affirmative steps to "promote or encourage doctors to infringe." *Id*. This Court reaffirmed that rule in *Takeda*, over a dissent contending that evidence of doctors' prescription habits "require[d] trial on the facts." 785 F.3d at 636 (Newman, J., dissenting). As the Court there held, "vague label language cannot be combined with speculation about how physicians may act to find inducement." *Id.* at 632.

Without mentioning this precedent, the panel majority followed the *Takeda* dissent, reinstating the jury's imposition of liability based on evidence that (1) marketing a generic drug's "AB rating" informs doctors that drugs are "therapeutically interchangeable" and (2) prescribing doctors are aware that pharmacies often substitute generic versions of branded drugs. Majority 6. As Chief Judge Prost explained, that reasoning conflicts with *Warner-Lambert*'s teaching that "mere knowledge of possible infringement by others does not amount to inducement; specific intent and

action to induce infringement must be proven." Dissent 20 (citation omitted). In short, the majority threatens to "nullif[y]" section viii, "undermin[ing] Congress's design for efficient generic drug approval" and "discourag[ing] generics from entering the market." Dissent 3, 33.

SUMMARY OF ARGUMENT

This case is exceptionally important—to patent law, to the pharmaceutical industry, and to those whose lives depend on affordable generic medicine. By leaving generic drug makers vulnerable to damages merely for accurate marketing of AB rated drugs with carve-out labels, the panel's split decision hamstrings the ability of companies like Mylan to bring non-infringing generics to market.

Since 2010, Mylan alone has launched at least nine products with carve-out labels, giving consumers access to affordable versions of these drugs years before the relevant patents expired, and the generic drug industry as a whole has launched hundreds more. In effecting a judicial repeal of section viii and upending the law of induced infringement, the majority's decision threatens both to entangle such products in litigation and to stifle the launch of others, all to the detriment of consumers. Congress created section viii so generic manufacturers could avoid inducing infringement by using FDA-approved labels that "omit[] an indication … protected by patent." 21 C.F.R. § 314.94(a)(8)(iv); *see* 21 U.S.C. § 355(j)(2)(A)(viii). For its part, § 271(b) imposes liability only for "actively induc[ing] infringement." By

purporting to convert acts intended to *avoid* infringement into acts intended to *induce* infringement, the majority's decision conflicts with both bodies of law. Brands are already citing the ruling, which threatens to impose enormous consequences on the industry and consumers. Review is needed now.

ARGUMENT

I. The panel's decision is already being used to deter the development and launch of generic drugs that use section viii carve-out labels.

The panel's divided ruling gravely threatens the section viii carve-out scheme, which allows drug makers to get low-cost generic drugs to market fast. In particular, the decision threatens years of uncertainty for both new and existing products.

This concern is anything but theoretical. Before the panel ruled, section viii worked just as Congress intended—as a vital tool for bringing new generic drugs to market. For example, Mylan alone has launched at least nine section viii products since 2010. Likewise, generic manufacturers as a whole have launched hundreds of section viii products, saving consumers billions. Association for Accessible Medicines, *2020 Generic Drug & Biosimilars Access & Savings in the U.S. Report* 4 (2020). The efficient functioning of the industry is critical to controlling costs for consumers: generics account for 90% of U.S. prescriptions dispensed, but just 20% of total drug costs. *Id.* at 16.

If the panel's decision stands, however, drugs launched via section viii face a heightened risk of litigation, threatening generic manufacturers' ability to launch

those products at all. Recent events drive the point home. In late November, another generic's section viii product was accused of infringement. *See* Compl., *Amarin Pharma, Inc. v. Hikma Pharm. USA Inc.*, No. 20-cv-1630 (D. Del. Nov. 30, 2020). The brand's complaint there tracks the panel majority's reasoning, converting *Global-Tech*'s instruction that alleged infringers are liable only for "actively induc[ing] infringement" into a requirement that they take active steps to prevent others' infringement. 563 U.S. at 760.

For example, the new complaint relies on the generic's alleged "aware[ness]" that pharmacies filling prescriptions substitute generics for branded drugs. Compl., ¶ 95. It faults the generic for describing its product as "AB rated" to the branded drug. *Id*. ¶95, 110. It repeatedly criticizes the generic for issuing press releases that did "not state that [the] 'generic version'" of the branded drug "should not be used" for the patented indication. *Id.* ¶¶ 99, 106. It even blames the generic for failing to include in its carve-out label a specific limitation of use *against* the patented indication. *Id.* ¶ 111. The last criticism echoes GSK's argument here—even though, as GSK's expert admitted, no generic has *ever* included such a limitation, and FDA would almost certainly prohibit it (Trial Tr. 577–78, 1030). Absent review, similar suits will become the norm, creating unprecedented barriers to generic entry.

The ability of generic manufacturers to quickly launch low-cost drugs via section viii will be greatly inhibited if the risk of litigation plagues any drug marketed

with an AB rating and carve-out label. Predictably, brands are already invoking the panel's opinion, hoping to monopolize *every* use of their drugs "merely by regularly filing a new patent application claiming a narrow method of use." *Warner-Lambert*, 316 F.3d at 1359. Congress rejected that outcome, and this Court should not delay in intervening.

II. En banc review is needed to ensure that the majority's decision does not thwart Congress's goal of getting inexpensive generic drugs to consumers quickly without risking induced infringement liability.

The panel decision would be tolerable—though no less tragic—if the law supported it. But it is no exaggeration to say that the divided panel ruling both works a judicial repeal of section viii and upends induced infringement law.

A. The panel's decision eviscerates section viii by turning compliance with the statutory scheme into evidence of induced infringement.

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). But as Chief Judge Prost observed, imposing damages based on labeling that "d[oes] not encourage, promote, recommend, or even suggest the patented method" and marketing that simply refers to the generic drug as an AB rated equivalent of the branded drug "creat[es] liability for inducement where there should be none" and "nullifies" section viii. Dissent 3.

Congress enacted section viii so that generics 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). The majority's holding that generics invite claims of liability for actively inducing infringement simply by accurately stating in marketing that their section viii products are "AB rated" versions of branded drugs, when Congress itself required bioequivalence, eviscerates section viii. *Id.* § 355(j)(2)(A)(iv). As GSK's expert admitted, an "AB rating" is a relative designation that necessarily compares the generic drug to some branded drug. Appx10534. Crucially, the rating means FDA deems the generic drug therapeutically equivalent to the branded drug *only* for indications listed on the label. *Id*. Teva's carve-out label never mentions GSK's patented method, and it is "uncontroverted" that "alternative factors … caused physicians to prescribe carvedilol in an infringing manner." Appx20. If the majority ruling stands, therefore, brands will assert "inducement for almost any generic that legally enters the market with a skinny label" (Dissent 15–16), insisting that passive, congressionally authorized acts actively infringe. This Court should intervene.

B. The panel improperly failed to interpret section viii and 35 U.S.C. § 271(b) in a harmonious fashion.

The majority's decision also conflicts with three other settled rules 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 v. Schmidt*, 546 U.S. 303, 316 (2006) (citation omitted)), and the rule that, where possible, separate statutory provisions should be read harmoniously and with "coherence." *Lindh v. Murphy*, 521 U.S. 320, 336 (1997).

As discussed, the point of section viii is to enable generics to market generic AB rated drugs solely for FDA-approved uses that are not patented without incurring infringement liability. *Caraco*, 566 U.S. at 406 (citing 21 CFR § 314.94(a)(8)(iv)). Similarly, 35 U.S.C. § 271(b) imposes liability only on those who "*actively* induce infringement." (Emphasis added.)

Enter the panel decision. Rather than harmonize section viii with § 271(b), the majority puts them on a collision course. Generics who certify and market their drugs as bioequivalent under labels that indicate their use for only unpatented uses—practical necessities for generics invoking section viii—are treated as having actively induced infringement. In other words, doing the very thing that section viii authorizes—with an FDA-blessed label—is unlawful under § 271(b). Appx11025. But "the adverb 'actively' suggests that the inducement must involve the taking of affirmative steps to bring about the desired result." *Global-Tech*, 563 U.S. at 760.

The majority cites purported "ample evidence" of inducement that was either created *before* the patent-in-suit was issued, created by FDA, or related to a use

intentionally omitted from Teva's label. Such "evidence" does not show "affirmative steps [by Teva] to bring about" practice of the claimed method. *Id*.

If the panel's interpretation is correct, Congress used one hand to give generic drug companies a path to carving-out non-infringing uses, while using the other to expose those companies to damages for following that path. By reinstating liability based on common and truthful section viii marketing practices, the panel improperly adopted an interpretation of § 271(b) that was "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 these statutory provisions as a harmonious whole.

Previously, this Court has 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 (quoting *Warner–Lambert*, 316 F.3d at 1360). Under still-binding precedent, the rule is 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.'" *Id.* (emphasis added) (quoting *Caraco*, 566 U.S. at 406) (internal citation omitted). The panel's decision squarely conflicts with these precedents, but

it did not (and could not) overrule them—meaning each side in Hatch-Waxman cases will keep invoking the precedent supporting its position, and district courts will be left to reconcile these irreconcilable decisions. Review is urgently needed. Fed. R. App. P. 35(a)(2).

Nor does the majority's precedent support its holding. *Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1129 (Fed. Cir. 2018), and *Sanofi v. Watson Labs. Inc.*, 875 F.3d 636, 645 (Fed. Cir. 2017), recognize that a label's contents can be "evidence of inducement to infringe." Majority 7. But "[t]he label must encourage, recommend, or promote infringement." *Takeda*, 785 F.3d at 631. The label in *Sanofi*, for example, pointed "medical providers to information identifying the desired benefit for only patients with the patent-claimed risk factors." 875 F.3d at 645. Teva's carve-out label, by contrast, listed only non-infringing indications.

To say that a label and statements that mention only *unpatented* uses "actively induce" *patented* uses deprives words of meaning. Further, Congress authorized carve-outs precisely to ensure "that one patented use will not foreclose marketing a generic drug for other unpatented ones." *Caraco*, 566 U.S. at 415. Review is warranted now, to prevent that catastrophic result.

CONCLUSION

For the foregoing reasons, rehearing en banc should be granted.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that, on December 16, 2020, I caused the foregoing Brief for *Amicus Curiae* to be electronically filed with the Clerk of Court using the CM/ECF system, and thereby served via CM/ECF on counsel for all parties.

Date: DECEMBER 16, 2020

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE STYLE REQUIREMENTS

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(b)(4) and Federal Circuit Rule 40(f)(3) because it contains 2600 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in 14-point Times New Roman, a proportionally spaced typeface, using Microsoft Word 2010.

Dated: December 16, 2020

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