No. 18-1976, 18-2023

In the United States Court of Appeals for the Federal Circuit

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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

CORRECTED 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.

6. Any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees) is as follows: Not applicable.

Dated: OCTOBER 21, 2021

/s/ Steffen N. Johnson
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INTRODUCTION AND STATEMENT OF INTEREST OF *AMICUS CURIAE*[1]

Citing "concerns about the lack of clarity" in its first ruling, the panel granted rehearing and issued a new opinion stressing that its "narrow, case-specific" decision does not "impose liability on ANDA filers that carve out patented uses under section viii." Op. 10. Yet the majority invites *juries* to determine whether FDA-approved generic labels are "true section viii carve-out[s]." Op. 28 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, simply *describe* the infringing use's elements without *encouraging* infringement. *Id*. This "Where's Waldo?" approach to reading labels makes it irrelevant that the generic manufacturer deleted all references to patented uses from the label's "Indications and Usage," "Dosage and Administrations," "Adverse Reactions," "Pharmacodynamnics," "Specific Populations," and "Clinical Studies" sections. Appx6908-6951. The upshot? Generics cannot know if their labels are "true" carve-outs until the jury speaks—years into litigation, itself filed years after the product launched. And this, under a law designed to avoid not only infringement liability, but litigation itself.

[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.

The majority's insistence that its new ruling is "narrow" is thus cold comfort. As Judge Prost noted, "most skinny-label cases" involve similar facts, meaning "no generic can know" whether it acted lawfully "until hit with the bill." Dissent 35, 37. The decision also flouts the statutory text—Congress required proof that defendants "actively" induced infringement (35 U.S.C. § 271(b))—and conflicts with this Court's induced infringement precedents. Indeed, it tracks their *dissents*.

The divided decision has already sparked copycat suits, threatening carve-out labels generally. HHS predicts the decision will "discourage the use of carve-outs and thus delay the approval of some generic drugs." Xavier Becerra, *Comprehensive Plan for Addressing High Drug Prices*, U.S. Dep't of Health & Human Servs. 21 (September 9, 2021), https://aspe.hhs.gov/sites/default/files/2021-09/Drug_Pricing_Plan_9-9-2021.pdf. Absent en banc review, the ultimate losers will be consumers who urgently need affordable medicine, but will be forced to wait until every method-of-use patent has expired—a result directly contrary to Congress's goal in passing Hatch-Waxman. The full Court should intervene, or at least invite the views of the government. *E.g.*, *Guarantee Co. of N. Am., USA, Inc. v. Ikhana, LLC*, 959 F.3d 1354, 1354 (Fed. Cir. 2020) (noting that the Court "invited the United States" to address whether en banc review should be granted).

Amicus Mylan Pharmaceuticals Inc., a leading pharmaceutical company that markets low-cost section viii products, can explain practically how the panel ruling

"throw[s] a wrench into Congress's design for enabling quick public access to generic versions of unpatented drugs with unpatented uses." Dissent 3.

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). Congress thus created two paths to market: Paragraph IV litigation, in which FDA approval to sell generic drugs depends on success in court (21 U.S.C. § 355(j)(2)(A)(vii)(IV)), and "section viii" 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 Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 404–06 (2012)). The section viii path, available for drugs with some unpatented FDA-approved uses, enables generic manufacturers to market drugs with labels that indicate only those unpatented uses—"carve-out" or "skinny" labels.

Congress designed section viii to enable generics to avoid "actively induc[ing] infringement." 35 U.S.C. § 271(b). Indeed, until this case, it was well settled that using a carve-out label was 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 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). As

this Court previously held, 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 evidence an affirmative step to "encourage doctors to infringe." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003). *Takeda* reaffirmed that rule, over a dissent contending that evidence of doctors' prescription habits "require[d] trial." 785 F.3d at 636 (Newman, J., dissenting).

The panel's opinion tracks that dissent, reinstating liability because (1) the 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 (3) doctors are likely to prescribe generics for their branded counterparts. Op. 27-30. But as Judge Prost explained, Teva's label fragments did not *encourage* infringement—they simply "described the infringing use." Dissent 19. Moreover, the other facts cited by the majority will likely exist in other section viii cases. In short, a generic that "play[s] by the rules, exactly as Congress intended" (Dissent 2) can no longer know whether its label is a "true" carve-out at the key moment—when it launches its product.

SUMMARY OF ARGUMENT

This case remains exceptionally important—to patent law, to the pharmaceutical industry, and to those needing affordable medicine. Although the panel's ruling purports to be "case-specific" (Op. 10), it only "exacerbates[] concerns raised by the original." Dissent 38. The new decision offers no clarity as to "what another generic in [Teva's] shoes should do differently." Dissent 35. Its reassurance that juries will recognize "true" carve-outs rings hollow, as Teva followed the well-worn path that all generics follow when releasing section viii products. And with no clear roadmap to avoiding inducement liability, generic manufacturers may well delay bringing non-infringing drugs to market.

By effectively nullifying section viii and upending induced infringement law, the decision promises both to generate unnecessary litigation and to stifle the launch of affordable drugs, all to consumers' detriment. Congress created section viii so generics could avoid inducing infringement—and litigation itself—by using FDA-approved labels that "omit[] 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." But the new decision converts acts intended to *avoid* infringement into acts intended to *induce* infringement, thereby upsetting both bodies of law. Brands are already suing, citing the majority's theory. Review is needed now.

ARGUMENT

I. The panel's decision on rehearing will deter the development and launch of non-infringing generic drugs that use section viii carve-out labels.

Like the original, the panel's new decision threatens years of uncertainty for section viii products. Previously, section viii worked just as Congress intended—as a vital tool for bringing new generic drugs to market. Bryan S. Walsh et al., *Frequency of First Generic Drug Approvals With 'Skinny Labels' in the United States*, 181 JAMA Intern. Med. 995-97 (2021) (nearly half of first generic launches rely on carve-outs), https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2777965. Mylan and other generics 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 industry's efficient functioning is critical to controlling drug prices: 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, section viii products will face unwarranted litigation, and many will never launch. Indeed, brands are already invoking the majority's reasoning, 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. For example, the complaint in *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, No. 20-cv-1630 (D. Del. Jan. 25, 2021) (Dkt. 17):

- relies on the generic's alleged "aware[ness]" that pharmacies substitute generics for branded drugs (*id.* ¶ 111);
- faults the generic for describing its product as "AB rated" (*id.*);
- repeatedly blames the generic for issuing press releases that do "not state that [the] 'generic version'" of the branded drug "should not be used" for the patented indication (*id.* ¶¶ 114, 121); and even
- criticizes the label for not specifically *discouraging* the patented indication (*id.* ¶ 126)—even though, as GSK's expert admitted here, no generic label has *ever* included such language, and FDA would almost certainly prohibit it (Trial Tr. 577–78, 1030).

Tracking the original decision here, the magistrate recommended denying Hikma's motion to dismiss, citing (1) the idea that various "portions of the label," if cobbled together, could instruct infringement, (2) press releases "describ[ing] [the] product as a generic version" of the branded drug, and (3) the product's AB rating. *Amarin*, 2021 WL 3396199, *7 (D. Del. Aug. 3, 2021). Notably, the brand has seamlessly transitioned to citing the new decision. *Amarin* (Dkt. 78).

The majority's reasoning thus converts Congress's prohibition on "actively induc[ing] infringement" into a requirement that companies take active steps to *prevent* others' infringement, in direct conflict with the Supreme Court's decision in *Global-Tech*. 563 U.S. at 760. Absent review, similar suits will become the norm, creating unprecedented barriers to generic entry.

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.

Whatever the panel's goals in issuing its new opinion, it suffers from the same defects as the original. First, the decision guts section viii by imposing liability for following the standard process for releasing drugs with carve-out labels. Second, it upends induced infringement law by permitting liability where carve-out labels *at most* describe patented uses without encouraging them.

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 the panel's decision effectively nullifies section viii by facilitating unwarranted litigation *and* liability for marketing noninfringing uses of drugs. Because juries will now decide whether the generic's label is a "true" carve-out—based on AB ratings, standard marketing materials, and a "Where's Waldo?" approach to the label's contents—the risk of liability will "seemingly persist in most skinny-label cases." Dissent 35.

Congress enacted section viii so 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

notion that generics risk inducing infringement by stating that their products are "AB rated" eviscerates section viii. Congress required bioequivalence (*id.* § 355(j)(2)(A)(iv)), and as GSK's expert admitted, "AB rating[s]" *necessarily* compare generic drugs to branded counterparts. Appx10534. Critically, the rating means FDA deems the generic drug therapeutically equivalent to the branded drug *only* for indications listed on the label. *Id*. Teva's skinny label never recommended GSK's patented method, and it is "uncontroverted" that "alternative factors … caused physicians to prescribe carvedilol in an infringing manner." Appx20.

The majority downplays the seismic implications of its decision, stating that an AB rating will be "evidence of induced infringement" only when the jury finds—years after launch—that the generic's label is not "a true section viii carve-out." Op. 28 n.7. But what kept Teva's label from qualifying as a "true" carve-out? Nothing except the work of GSK's expert witness, who cobbled together disparate parts of the label to contend that it "mentioned" each claim limitation. Dissent 19. Thus, generics must now scour their labels' language—which is largely dictated by FDA—to determine whether a brand could concoct an induced infringement theory by arguing that disconnected parts of a label, "pieced together just right" and reinterpreted (*id*.), contain each step of the infringing method. Indeed, the decision incentivizes brands to make their labels as interwoven as possible, so generics acting in good faith will be compelled to mention each step of the patented method. It is no

exaggeration to say that the new decision converts passive, congressionally authorized and FDA-mandated acts into evidence of active inducement.

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

The new decision also conflicts with three 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 v. Schmidt*, 546 U.S. 303, 316 (2006) (citation omitted)), and the rule that separate statutes should be read harmoniously and with "coherence." *Lindh v. Murphy*, 521 U.S. 320, 336 (1997). Further, the ruling upends settled law holding that "[m]erely describing an infringing use" in a label "will not suffice" to support liability. *HZNP Meds. LLC v. Actavis Labs. UT, Inc.*, 940 F.3d 680, 702 (Fed. Cir. 2019).

As discussed, Congress designed section viii to enable generics to market generic drugs solely for unpatented uses without incurring infringement liability. *Carraco*, 566 U.S. at 406. Similarly, 35 U.S.C. § 271(b) imposes liability only on those who "actively" induce infringement. Rather than harmonize these provisions, the new decision puts them on a collision course. Generic manufacturers who certify and market their drugs as bioequivalent with labels that indicate only unpatented uses—practical necessities for generics invoking section viii—are treated as having actively induced infringement. That is, doing the very thing that section viii

authorizes—with an FDA-blessed label—is unlawful under § 271(b). Appx11025. That result cannot be squared with Supreme Court's admonition that "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.

In holding that juries may find induced infringement based on a "skinny label [that] describe[s] the infringing use (if pieced together just right)" (Dissent 19), the new decision is just as problematic as the old. Under the majority's theory, Congress used one hand to give generic manufacturers a path to carving out non-infringing uses, while using the other to impose damages for following that path. The majority thus adopted a reading 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 statutes harmoniously.

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 precedents, 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.* (citations omitted). The panel's ruling squarely conflicts with these precedents, but 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. Review is urgently needed.

CONCLUSION

Congress authorized carve-outs 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.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that, on October 26, 2021, 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.

Dated: OCTOBER 26, 2021

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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 2,592 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: OCTOBER 21, 2021

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