No. 22-37

IN THE
# Supreme Court of the United States

TEVA PHARMACEUTICALS USA, INC.,

*Petitioner,*

*v.*

GLAXOSMITHKLINE LLC, ET AL.,

*Respondents.*

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

## REPLY BRIEF FOR PETITIONER


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## RULE 29.6 STATEMENT

The corporate disclosure statement included in the petition remains accurate.

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## INTRODUCTION

The decision below erodes foundational principles of patent law while upsetting a careful legislative compromise that ensures ready access to low-cost generic medicines. As Teva, amici, and countless commentators have explained, the resulting upheaval will harm patients, taxpayers, and the public at large.

Not to worry, GSK insists—generic manufacturers can still claim "the carve-out statute's protection" if they "fully and truly carve out" patented indications. Opp.33. But there's the rub: under the Federal Circuit's decision, the carve-out statute provides *no* protection, not even to a company that follows FDA's directions and carves out everything the brand manufacturer identifies.

The facts here are no aberration. Teva did what generic applicants routinely do—and Congress authorized—when a drug's active ingredient is no longer patented: it adopted an FDA-drafted "skinny label" that carved out the one indication GSK identified as patented in its sworn representations to FDA. Seven other generics used the same skinny label. Nevertheless, the Federal Circuit held that a jury could find Teva liable for "actively" inducing infringement through information scattered across different portions of its label—portions GSK never identified to FDA. That is more than just a misapplication of settled precedent: it is an about-face, because it adopts what was previously a dissenting view and allows a jury to find active inducement in virtually *any* carve-out case.

Contrary to GSK's attempt to grandfather this case, the regulatory obligations that FDA applies

today are materially identical to those it applied when Teva adopted its skinny label. And, regardless, the Federal Circuit's new rule makes any regulatory change irrelevant, because its decision gave no weight to the Hatch-Waxman statute *or* regulations. That is precisely why certiorari is needed.

The proceedings below spanned two oral arguments, sua sponte panel rehearing, a divided en banc vote, and eight total opinions. Those are not the hallmarks of a factbound dispute. The Federal Circuit has replaced a regime of predictability and certainty with one of doubt and risk. The result will be less competition and higher prices. This Court should intervene without delay.

## ARGUMENT

### I. The decision below upends settled legal principles and an important legislative compromise.

The Federal Circuit now permits inducement liability based on label language that does not recommend infringement and that the brand never identified as patented. That decision guts a key element of inducement law and distorts Hatch-Waxman's careful balance.

#### A. The Federal Circuit eviscerated an essential element of inducement law.

1. GSK contends (at 24-28) that the Federal Circuit correctly recited (and the jury was properly instructed) that § 271(b) requires proof that the defendant took "active steps" to induce infringement. Anything beyond that top-line point, GSK says, is too factbound to review. But the Federal Circuit's legal analysis does not stop at the highest level of generality.

The court fractured on a pivotal legal question: what qualifies as "active" inducement? Teva's FDA-drafted skinny label excised the patented use GSK had identified. So GSK pointed to scattered phrases elsewhere in the label that, according to its expert, just "mentioned" elements of the patented method (Pet.13-14, 18). Until now, those pieces of Teva's label would not have qualified as active inducement under this Court's precedents because they do not recommend the patented use (Pet.22-27), and they would have been protected by Hatch-Waxman (Pet.28-32). But the Federal Circuit held GSK's theory legally proper. That is a repudiation of precedent, not just a one-time misapplication (Opp.27-28). *See, e.g.*, Professors' Br. 5; Mylan Br. 11; Pet.18-19.

This Court has repeatedly reviewed such legal-sufficiency questions in patent cases, *e.g.*, *Life Technologies Corp. v. Promega Corp.*, 137 S. Ct. 734 (2017), and this case likewise warrants review. Virtually any skinny-label case can involve similar facts; after all, when a drug is approved for multiple uses, the unpatented use is often related enough to the patented one that even a skinny label could "mention" patented elements. *E.g.*, *Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 630 (Fed. Cir. 2015) (label discussing unpatented use, *preventing* gout flareups, mentioned but did not instruct patented use, *treating* gout flareups). As a result, every significant case will now go to trial.

2. GSK insists (at 29-30) that it can harmonize the decision below with the long line of cases holding that passive description is not active inducement. For example, GSK says that in cases like *Takeda*, *HZNP*, and *Bayer*, there was no evidence the defendant's

label actually encouraged the alleged infringement. But the supposed "encouragement" in those cases (description of infringing elements in scattered sections of a label) is materially indistinguishable from Teva's supposed "encouragement." Pet.25-27, 30-31. The dissenter's view in those cases has become the majority holding here. Pet.31.

GSK insists that those cases must be factually different—but just what facts make them different, GSK never says. The closest it comes is claiming (at 8, 17) that Teva "manipulat[ed]" its label to "capture" the carvedilol market. But Teva simply followed the standard carve-out path, which Congress created precisely so manufacturers would not have to "wait until [a method patent] expire[s]" to market low-cost generics, as GSK would prefer (Opp.6). Indeed, Teva's carve-out was not even unique *compared to other generic carvedilol manufacturers:* seven others launched with the same skinny label that FDA supplied to Teva. Pet.11. This is a run-of-the-mill skinny-label case, making the Federal Circuit's conclusion that a jury can find inducement on these facts a dramatic legal shift.

### B. The Federal Circuit's rule is inconsistent with the Hatch-Waxman regime.

GSK argues (at 8, 11, 28, 31-32) that the decision below does not disturb the Hatch-Waxman framework because generic applicants must independently determine which parts of a brand's label implicate patented uses. That argument distorts the statutory and regulatory regime.

Hatch-Waxman relies on a simple information exchange. Brand manufacturers must provide sworn

representations about what methods, and what corresponding sections of labeling, their patents claim; FDA uses those representations to assess and approve skinny labels for generics, which are exceptions to the same-labeling requirement generics otherwise must follow. Pet.7-10; AAM Br. 6, 11-12. That is the rule now—and it was the rule when FDA prepared Teva's skinny label. FDA made clear in 2003 that it would require brand manufacturers "to identify *specifically* the approved uses claimed by [any] method-of-use patent, *with reference to the approved labeling*," so that a generic applicant can "assess whether [it] is seeking approval for a use the sponsor states is claimed in the listed patent." 68 Fed. Reg. 36,676, 36,682 (Jun. 18, 2003) (emphasis added).[1] Indeed, FDA contrasted its chosen approach against one requiring the generic "to make its own independent decision on whether a listed method-of-use patent claims the use for which the [generic] applicant seeks approval." *Id.*

GSK repeatedly cites (at 8, 11, 31-32) FDA's admonition that the 240-character "use codes" that brands submit to FDA "are not meant to substitute for the [generic] applicant's review of the patent and the approved labeling." 68 Fed. Reg. at 36,683. But as FDA explained *in the very next sentence*, while Tweet-length use codes "may not fully describe the use as claimed in the patent," that sort of detail *is* supplied by the brand manufacturer's sworn "declaration, which includes the complete description of the method-of-use-claim *and the corresponding language in the labeling of the approved drug*." *Id.* (emphasis added). FDA and generic applicants do use that

[1] FDA's 2016 clarifications echoed the same point. 81 Fed. Reg. 69,580, 69,597 (Oct. 6, 2016).

"publicly available" declaration—and the portions of the label it identifies—in drafting skinny labels. *Id.* The limitations on use codes that GSK emphasizes are precisely *why* FDA insists on the sworn declarations.

GSK also emphasizes (at 31-32) that FDA plays a "ministerial" role that does not involve a "substantive review" of any listed patents. But that is because FDA defers entirely to the brand manufacturer's representations about what its patents cover. *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S,* 566 U.S. 399, 406-407 (2012). That just highlights why a carve-out *consistent with those representations* cannot be active inducement—and why the Federal Circuit's decision, requiring the generic applicant to beware even a carve-out *drafted by FDA*, leaves the skinny-label system broken.

The government endorses carve-outs as "critical," Pet.35-36, and never contemplated that its own carve-out drafting would lead generics into massive liability. The Federal Circuit declined requests to invite the government's views before ruling. This Court should not credit GSK's arguments without first hearing from the government.

## II. This issue warrants the Court's prompt attention.

The decision below will seriously compromise manufacturers' ability to market low-cost generic versions of unpatented drugs—to the detriment of patients, taxpayers, and the U.S. healthcare system. *See* Pet.32-36; AAM Br. 14-18; Mylan Br. 13-19; Professors' Br. 8-11 (providing data showing the reach of the decision below). And it will have ripple effects beyond just generics. *See* Alvotech Br. 16-22 (explaining the

chilling effect on alternatives to high-priced "biologic" medicines). GSK fails to refute the urgent need for this Court's review.

### A. The issue has not been "mooted" by subsequent regulations.

GSK argues (at 30-32) that 2016 regulatory changes "mooted" the need for this Court's review by making "the regulatory scheme today" "dramatically different." Both the premise and the conclusion are wrong.

First, the Federal Circuit's (and GSK's) view of the law makes the regulations irrelevant to inducement liability. GSK persuaded the Federal Circuit that it *does not matter* what representations a brand manufacturer makes in its sworn declarations (or how specific they are), because the generic manufacturer can be liable even if it carves out everything the brand manufacturer identifies. *See* Pet.App.22a-25a; Opp.28. GSK cannot argue against certiorari by pointing to a supposed regulatory change that has no bearing under the legal rule it convinced the Federal Circuit to adopt.

Second, GSK's claim that the regulations are now materially different is demonstrably false. At all relevant times, brand manufacturers have had to submit detailed representations about their patents and labels. As early as 2003, for example, brand manufacturers had to "identify with specificity the section of the approved labeling that corresponds to the method of use claimed by the patent submitted." 21 C.F.R. § 314.53(b)(1) (2003); *supra* pp. 4-6. That was the rule in place in September 2006, when GSK submitted a

form[2] requiring it to identify the scope of its patent protections "with specificity" and "with reference to the proposed labeling." Pet.App.57a (Prost, J., dissenting); C.A.App.6895. FDA drafted Teva's skinny label, and Teva launched its generic product with that label, consistent with those representations. Pet.11.

GSK is simply wrong to suggest (at 15) that it had not yet identified the protected portions of its label when Teva launched in 2007. The only thing that happened in 2008 was the reissue of GSK's patent with *narrower* claims. GSK resubmitted its patent declaration after reissue, but identified *no change* in the portions of its labeling claimed. *Compare* C.A.App.6880-6887, *with* C.A.App.6890-6907.

Nothing about subsequent regulatory amendments materially changed brand manufacturers' obligations. FDA repeatedly described the 2016 amendments on which GSK relies as mere "clarifications." *See generally* 81 Fed. Reg. 69,580 (using forms of the words "clarify" more than 100 times). Most notably, the amendments clarified that if a method patent claims just a *subsection* of an indication, the brand manufacturer must identify that specific subsection. *See id.* at 69,581. That minor change is not even

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[2] As Teva explained, Pet.8 n.3, manufacturers submit two forms: Form 3542a (with applications) and Form 3542 (after approval). GSK suggests (at 10-12) that only the latter form matters. That is wrong: FDA uses post-approval forms "to determine whether a patent is eligible for listing" in the Orange Book, 68 Fed. Reg. at 36,697, but that is an entirely different determination. *Both* forms require sworn representations identifying the specific labeling sections claimed by any method patent, to make the carve-out process function. Pet.8 n.3.

relevant here—GSK has never contended that its patent claims *just a portion* of an indication.

### B. GSK ignores the unpredictability that the Federal Circuit's opinion engenders.

Like the Federal Circuit, GSK claims (at 33) that the decision below will not affect generic manufacturers that "truly" carve out patented uses. But as already discussed, this *is* a "true" carve-out case: nothing sets Teva apart from other skinny-label generics. *See supra* pp. 3-4. Going forward, *no* generic manufacturer can be confident it will avoid infringement liability by carving out everything the brand identifies to FDA. Even if some manufacturers can ultimately win a jury trial, they will *all* now face years of uncertainty and expense before any definitive resolution. *See* Pet.32-36. That risk will cause many generic manufacturers to forgo launching in the first place, as amici explain.

Hatch-Waxman was designed to avoid exactly that result. Generic manufacturers are supposed to be able to obtain certainty pre-launch—either by resolving patent disputes before launch, without a jury trial or damages (if seeking approval for *patented* indications), or by avoiding patent litigation altogether (if seeking approval only for *unpatented* indications through a section viii carve-out). But now, a carve-out is the worst of all worlds: it provides no pre-launch resolution *and* no protection from massive exposure. The result will be precisely what Congress did not want: one narrow method patent holding generics off the market entirely.

## III. This case presents an ideal opportunity to address these important issues.

GSK invents several unpersuasive reasons why this case is supposedly a poor vehicle.

First, GSK suggests (at 8-13) that, as a factual matter, it *did* identify the post-MI LVD indication in its declaration—FDA and Teva just failed to recognize it. That brand-new argument is a brazen distortion of the record. GSK's label identified three uses for carvedilol, including the CHF indication:

> **Congestive Heart Failure:** COREG is indicated for the treatment of mild to severe heart failure of ischemic or cardiomyopathic origin, usually in addition to diuretics, ACE inhibitor, and digitalis, to increase survival and, also, to reduce the risk of hospitalization (see CLINICAL TRIALS).
>
> **Left Ventricular Dysfunction Following Myocardial Infarction:** COREG is indicated to reduce cardiovascular mortality in clinically stable patients who have survived the acute phase of a myocardial infarction and have a left ventricular ejection fraction of ≤ 40% (with or without symptomatic heart failure) (see CLINICAL TRIALS).
>
> **Hypertension:** COREG is also indicated for the management of essential hypertension. It can be used alone or in combination with other antihypertensive agents, especially thiazide-type diuretics (see PRECAUTIONS, Drug Interactions).

C.A.App.7992 (highlighting added). When asked which of those uses its patents claimed, GSK recited the CHF indication nearly verbatim:

| | | |
|---|---|---|
| 4.2a | If the answer to 4.2 is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product. | Use: *(Submit indication or method of use information as identified specifically in the approved labeling.)*<br><br>Treatment Of Mild-To-Severe Heart Failure Of Ischemic Or Cardiomyopathic Origin, Usually In Addition To Diuretics, ACE Inhibitor, And Digitalis, To Increase Survival |

C.A.App.6895 (highlighting added). It said nothing about the post-MI LVD indication. Now, GSK seeks to rewrite its sworn declaration using ellipses, Opp.12, rather than acknowledge that it tracks the CHF indication so specifically.

To make matters worse, GSK misstates the scope of both its patent claims and the post-MI LVD indication. GSK claims (at 7) that its patent applies "no matter the patient's specific heart failure symptoms." But GSK's patent covers only treatments specifically intended to reduce mortality *caused by symptomatic heart failure*; GSK conceded that the patient *must* have been diagnosed with congestive heart failure. C.A.App.130, *available at* 2016 WL 3186657, at *19 & n.22 (D. Del. June 3, 2016). The post MI-LVD indication, by contrast, involves reducing mortality in certain patients after a heart attack, "*with or without symptomatic heart failure*"—*i.e.*, the patient *need not* be diagnosed with congestive heart failure. GSK also never mentions that the patent requires co-administration with an ACE inhibitor, diuretic, or digoxin, Pet.App.5a, but the post-MI LVD indication does not. The latter indication is "outside the scope of the claims." Pet.App.167a n.9. That is why FDA approved *eight* skinny-labeled generics without requiring them to carve out the post-MI LVD indication—and why GSK didn't utter a peep of protest then.

Second, GSK claims (at 32-33) that the Federal Circuit's remand for Teva to pursue an equitable-estoppel defense somehow makes the record "not yet complete." Nonsense. The jury-trial record is closed and fully developed, and the question presented is whether that record required JMOL, making any remand erroneous. This Court routinely grants certiorari in that posture. Pet.36-37.

Finally, GSK wrongly suggests (at 2, 24, 32-33) that the question presented is "not case dispositive," primarily because a GSK witness claimed that "over 70% of the damages" accrued after Teva amended its

label at FDA's direction, Pet.12.[3] But GSK cannot prove damages during the amended-label period if Teva's skinny label did not encourage doctors to infringe. "The reason is simple: nothing about doctors' prescribing practices changed when Teva amended its label to the full version," as the majority did not dispute and GSK conceded. Pet.App.76a-77a (Prost, J., dissenting). GSK's 70/30 argument could not sustain the verdict in any event: the verdict sheet did not apportion damages between the two periods, and the jury declined to adopt GSK's proffered damages amount. And even if GSK were right that skinny-label damages were "only" $70 million, that is no reason to leave the Federal Circuit's erroneous rule unreviewed—and let GSK keep that windfall.

[3] GSK also refers (at 27) to marketing materials calling Teva's product "AB-rated" or the "generic equivalent" of Coreg. But the panel majority acknowledged that those materials just "point physicians to [the supposedly inducing] partial label." Pet.App.32a n.7; *see id.* at 74a-76a (Prost, J., dissenting). If that label does not induce, these materials add nothing. *Id.* The majority's *first* opinion placed greater reliance on these materials, Pet.App.100a, but GSK declined to defend that rationale and focused instead on the post-MI LVD indication. GSK Reh'g Resp. 14-17 (Jan. 29, 2021). It cannot backtrack now that the panel, too, has retreated from relying on those materials.

## CONCLUSION

The petition should be granted.

Respectfully submitted.

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