No. _____

IN THE SUPREME COURT OF THE UNITED STATES

TEVA PHARMACEUTICALS USA, INC.,

Applicant,

v.

GLAXOSMITHKLINE LLC AND SMITHKLINE BEECHAM (CORK) LIMITED,

Respondents.

APPLICATION FOR AN EXTENSION OF TIME TO FILE
A PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT
OF APPEALS FOR THE FEDERAL CIRCUIT

RULE 29.6 STATEMENT

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

To the Honorable John G. Roberts, Jr., Chief Justice of the United States and Circuit Justice for the United States Court of Appeals for the Federal Circuit:

Pursuant to Supreme Court Rule 13.5, Teva Pharmaceuticals USA, Inc. ("Teva") respectfully requests a 60-day extension of time, until July 11, 2022, within which to file a petition for a writ of certiorari. The United States Court of Appeals for the Federal Circuit entered its judgment on August 5, 2021. The court of appeals denied Teva's petition for rehearing en banc on February 11, 2022.[1] Unless extended, the time for filing a petition for a writ of certiorari will expire on May 12, 2022. The jurisdiction of this Court would be invoked under 28 U.S.C. § 1254(1).

1. This case concerns a provision of the patent and food-and-drug statutes that allows generic drug manufacturers to bring low-cost generic drug products to market once the drug itself is no longer patented. Because the statute operates by allowing the generic manufacturer to omit the patented uses from its label, with regulatory approval, it is known as the "carve-out" or "skinny label" provision.

This Court described the relevant regulatory scheme (the Hatch-Waxman Amendments) in *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 404-408 (2012). Briefly, the manufacturer of a brand-name drug must tell the Food and Drug Administration ("FDA") what patents claim the drug or methods

[1] The Federal Circuit's February 11, 2021 order denying en banc rehearing and the concurring and dissenting opinions relating to that order ("Reh'g Order") are attached to this motion as Exhibit A. The Federal Circuit's August 5, 2021 decision ("2021 Op.") is attached as Exhibit B. This motion also discusses a prior vacated panel decision by the Federal Circuit in this case, dated October 2, 2020 ("2020 Op."), which is attached as Exhibit C.

of using it, when those patents expire, and—especially relevant here—what aspects of the brand drug's labeling correspond to the method patents. Once the drug itself is no longer patented, and FDA has approved the drug for some unpatented uses, Congress provided that "one patented use will not foreclose marketing a generic drug for other unpatented ones." *Caraco*, 566 U.S. at 415. The skinny-label statute allows a generic drug company seeking FDA approval to market a generic drug product to inform FDA that it will omit ("carve out") any reference to a patented indication from its product's labeling and launch with a "skinny label" that includes only unpatented indications. *See* 21 U.S.C. § 355(j)(2)(A)(viii). (This is known, after the statutory subdivision, as a "Section viii statement.") FDA, in turn, determines what may be carved out based on the brand manufacturer's prior certification—made under penalty of perjury—of the portions of the brand's label claimed by its patent. 21 C.F.R. §§ 314.53(b)(1), 314.53(c)(2)(i)(O); 18 U.S.C. § 1001.

By launching with a skinny label, generic manufacturers can bring off-patent, low-cost drug products to market more quickly while avoiding patent-infringement claims. Notably, when passing Hatch-Waxman, Congress knew that carve-outs "would result in some off-label infringing uses," because when physicians prescribe drugs for patented uses, pharmacies may fill those prescriptions with generic versions. *Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 631, 633 (Fed. Cir. 2015). (Indeed, state law often requires it.) But Hatch-Waxman "enable[s] the sale of drugs for non-patented uses" *even if* some off-label sales would naturally occur. *Id.* at 631.

2. Teva followed the skinny-label statute to launch a generic version of the cardiovascular generic drug carvedilol.

Carvedilol (brand-name Coreg®) is FDA-approved for three indications: (1) managing hypertension, (2) treatment of mild-to-severe congestive heart failure ("CHF"), and (3) treating dysfunction of the heart's left ventricle following a heart attack ("post-MI LVD"). 2021 Op. 4-5. Respondent GSK held patents on a method covering one specific way of treating CHF, and (as required by 21 C.F.R. § 314.53(c)(2)(i)(O)) certified under penalty of perjury that only the CHF indication was claimed by its method-of-treatment patents. 2021 Op. 19-20. Based on GSK's certification, FDA drafted a skinny label. Teva (along with 13 other generics) carved out the CHF indication using the skinny label proposed by FDA, and then launched its generic version of carvedilol after GSK's patent on the drug compound expired in 2007. 2020 Op. 5; 2020 Dissent 9-10; 2021 Dissent 17.

3. In 2014, some seven years after Teva had launched its generic with a skinny label carving out the CHF indication, GSK sued Teva for inducing infringement of its patented method of treating CHF. *See generally* 35 U.S.C. § 271(b). GSK sought nearly $750 million in profits—ten times Teva's revenue from all carvedilol sales ($74.5 million, for a net loss of $13 million). 2020 Dissent 12-13 & n.3.

After a jury awarded GSK $235 million in damages, the district court granted Teva's motion for judgment as a matter of law. 2021 Op. 9. The court concluded there was no evidence that Teva caused physicians to infringe, because Teva's skinny label

had carved out the CHF indication, physician experts from both sides testified they did not even read Teva's label before prescribing carvedilol, and the record demonstrated that prescription decisions were driven by other factors. *Id.*; 2021 Dissent 20-21.

4. a. Over a 33-page dissent, a panel of the Federal Circuit reversed on October 2, 2020. The panel majority held that, despite its skinny label, Teva had induced infringement—based mainly on Teva's statements that its product was a generic equivalent of Coreg®, which was entirely true. 2020 Op. 15-16. In her dissent, then-Chief Judge Prost countered that "Teva did everything right—proceeding precisely as Congress contemplated" by "launch[ing] its low-cost generic carvedilol for unpatented uses using a skinny label" that "*never* stated that [Teva's generic] was approved, or could be used, to treat CHF," the sole patented indication. 2020 Dissent 8, 10.

b. The panel's first decision sparked widespread criticism—from generic *and brand* manufacturers, law professors, and Congressman Waxman himself, all of whom filed amicus briefs in support of rehearing en banc. In response, the panel issued a new opinion in August 2021, which reached the same result with a new rationale.

This time, the panel majority said that Teva's skinny label had never actually been a "true section viii carve-out." 2021 Op. 28 n. 7. The panel majority emphasized testimony from GSK's expert that excerpts of language from disparate portions of Teva's skinny label could be patched together to match up with all the limitations of

GSK's CHF method patent, and concluded that a jury could take this as evidence the skinny label itself *encouraged* infringement of the patented method of treating CHF. 2021 Op. 13-15. The panel majority further explained that the jury could then "infer" the skinny label caused doctors to write infringing prescriptions, despite the fact that physician experts from both sides testified they did not read the label before prescribing carvedilol to CHF patients. 2021 Op. 36 & n.9; 2021 Dissent 3. Judge Prost again dissented. 2021 Dissent 38. She explained that the circuit's "law on this issue has gone awry": Teva was being held liable for intentionally inducing infringement "even though Teva, by carving out everything that GSK said would infringe, was trying to avoid having its label encourage infringement." *Id.* at 3.

Despite another wave of criticism from across the industry and from Congressman Waxman, the Federal Circuit denied Teva's petition for en banc rehearing by a vote of either 6-4 or 7-3, over three dissenting opinions.[2] Judge Prost's dissent, joined by Judges Dyk and Reyna, emphasized the need for further review based on "the obvious question" the panel majority's opinion raises: "how could this label, which faithfully followed what the brand said about its own patents and which the FDA required Teva to use, *itself* be evidence that Teva *intentionally encouraged* something it *knew* would infringe?" Reh'g Order, Prost Dissent 3. Judge Prost warned that in the wake of the panel's decision, "no skinny-label generic is safe" from an inducement claim, no matter how scrupulously the generic adheres to the

[2] Two judges did not participate, and Judge Hughes did not make public his vote.

statutory carve-out procedure. *Id.* Judges Dyk and Reyna also issued separate dissents echoing these concerns.

4. The Federal Circuit's decision warrants this Court's review. It contradicts this Court's precedent on inducement and eviscerates the carve-out statute. If undisturbed, it will cause enormous damage to the careful balance Congress struck in Hatch-Waxman, to FDA's drug-approval regime, and to the many millions of Americans who rely on the skinny-label statute to ensure that low-cost generics reach pharmacies quickly.

a. The decision threatens to throw this Court's precedent on inducement into disarray.

The panel sustained massive liability through a scavenger-hunt theory of inducement. According to the panel, if all the elements of a patented method can be found hidden in a skinny label by rearranging disparate pieces, that is enough evidence of inducement to infringe. This Court's cases (from both the patent and copyright inducement contexts) say otherwise. There must be "active steps taken to encourage infringement," such as "instructing how to engage in an infringing use," not just an awareness that the product could be used to infringe. *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936 (2005) (citation and ellipsis omitted). This requirement is especially important in the prescription-drug context, because Congress designed Hatch-Waxman expressly to encourage the launch of off-patent generics labeled for unpatented indications, even if the result is that some infringing prescriptions are filled with a generic at the pharmacy. *Caraco*, 566 U.S.

at 415; *Takeda*, 785 F.3d at 631, 633. The proper question is whether the skinny label *affirmatively instructs* infringement, not whether a reader could theoretically glean an infringing method by cobbling together disparate portions from the label.

The decision also nullifies the causation requirement for inducement. To induce infringement means "to influence" the infringer—"to prevail on" someone to commit the act of infringement. *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 760 (2011) (citation omitted). Talk is not enough; the infringer must both listen and be moved. There was no evidence of that here. To the contrary, both sides' physician experts testified they did not read Teva's label before prescribing. 2021 Dissent 20. Yet the panel held that if a label is capable of causing infringement, the jury can simply assume causation. An element of a claim that can be assumed away when another purportedly is met is not an independent element at all.

b. This Court's review is crucially important because the Federal Circuit panel's decision threatens to render the carve-out statute a dead letter.

As this case shows, under Hatch-Waxman, FDA relies on the brand's representation of what its method patent covers to determine the contents of a skinny label. Generics cannot write their own labels to avoid infringement; they are required to follow the brand's label *except* to the extent that FDA allows them to carve out patented indications. And in that carve-out procedure, the brand identifies what parts of its own labeling its method-of-use patents claim, 21 C.F.R. § 314.53(c)(2)(i)(O), and FDA relies on the brand's description for carved-out labeling. Now, following the brand's representations and FDA's instructions is no longer

sufficient, and every skinny label is a target for an inducement suit. As Judge Prost warned, "the background facts here will seemingly persist in most skinny-label cases." 2021 Dissent 35. Generics will face the prospect of lost-profits damages that, as here, could dwarf actual profits by hundreds of millions of dollars. 2020 Dissent 13 & n.3.

The result will be exactly what the skinny-label statute was written to preclude: a narrow patent on one use will keep a generic off the market even for other, unpatented uses. When a brand drug has both patented and unpatented uses, the first generic launch relies on a skinny label nearly half the time.[3] Without a carve-out, generic approval will take years longer. The result will be billions in lost drug savings for patients and the government.

5. Teva respectfully requests an extension of time to file its petition for certiorari from the Federal Circuit's decision. Teva's undersigned appellate counsel have been heavily engaged with other matters and have other commitments that make a shorter extension impracticable, including a Seventh Circuit brief filed March 25, 2022; a Fifth Circuit brief filed March 30, 2022; a Third Circuit brief filed April 4, 2022; a Fourth Circuit brief on remand from a GVR by this Court due May 4, 2022; an oral argument in the Fourth Circuit on May 4, 2022; an oral argument in the Third Circuit on May 4, 2022; an oral argument in the Second Circuit on May 10, 2022; an oral argument in the Ninth Circuit on June 6, 2022; and an oral argument in the

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

Federal Circuit on June 10, 2022. The requested extension would allow counsel to continue to research the relevant legal issues, and to prepare a petition that fully addresses the important issues raised by the extensive proceedings below.

Accordingly, Teva respectfully requests an extension to file a petition for a writ of certiorari to and including July 11, 2022.

April 29, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, William M. Jay, a member of the Bar of this Court, hereby certify pursuant to Rules 22.2, 29.3, and 29.5 on this 29 day of April, 2022, that a copy of this Application for Extension of Time to Petition for a Writ of Certiorari in the above-entitled case was mailed, first class postage prepaid, to counsel for respondents at the following address:

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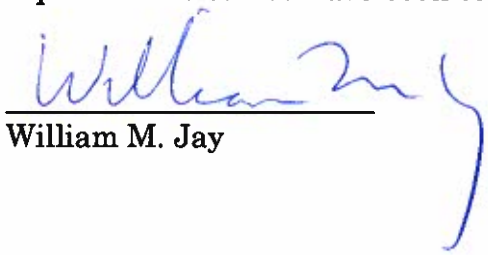
As required by Rules 29.3 and 29.7, an electronic version is being filed with the Court and transmitted to counsel at the email address listed above.

I further certify that all parties required to be served have been served.



William M. Jay