No. 22-37

In the Supreme Court of the United States

TEVA PHARMACEUTICALS USA, INC.,

Petitioner,

v.

GLAXOSMITHKLINE LLC,

SMITHKLINE BEECHAM (CORK) LIMITED,

Respondents.

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

BRIEF IN OPPOSITION

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QUESTION PRESENTED

When a generic drug is doubly indicated for a patented use, and there is strong record evidence of intent and inducing conduct, can the generic manufacturer evade liability for induced patent infringement merely because it did not include on its label (i.e. "carved out") one of the two indications corresponding to the patented use?

RULES 24(B) AND 29.6 STATEMENT

All parties are identified in the caption of this brief. Respondent GlaxoSmithKline LLC, is a for-profit Pennsylvania corporation. Respondent SmithKlineBeecham (Cork) Limited is a for-profit organization. GlaxoSmithKline plc owns 10% or more of the stock in respondents.

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INTRODUCTION

This Court has considered the issue of induced infringement at least four times over the last approximately fifteen years. *Commil USA, LLC v. Cisco Systems, Inc.*, 575 U.S. 632 (2015); *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915 (2014); *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754 (2011); *Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 545 U.S. 913 (2005). It also has considered the inner workings of FDA use codes and "Orange Book" listings under the Hatch-Waxman Act. *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399 (2012). This fact-bound case presents no new issues in those areas of law, and was properly decided by the appellate court under those authorities. Certiorari should be denied.

Coreg® (carvedilol) is a life-sustaining treatment for congestive heart failure developed against the great weight of scientific consensus. Only through the counter-intuitive vision of the inventors and hundreds of millions of dollars of investment did GSK develop the patented method and obtain FDA approvals for Coreg® to treat patients with congestive heart failure. Coreg® pioneered an entirely new category of treatment for heart failure unknown to medicine—the use of beta blockers to prolong the life of heart failure sufferers.

Teva, for its part, chose to sell a generic version of Coreg® and capture this market for itself. It did so years before GSK's patent on the use of carvedilol to treat heart failure expired, and without taking appropriate steps to ensure its generic drug was approved only for non-patented uses. Instead, Teva left one of Coreg®'s two approved heart failure uses on its generic label and launched its product. Within weeks,

Teva captured over 40% of the market for Coreg®, including the market for the use of Coreg® to treat heart failure, exactly as its trial witnesses admitted it intended.

Based on this record, and as detailed below, a properly-instructed jury and the Federal Circuit found liability under this Court's inducement authorities. Simply put, Teva sold a generic drug with a patented use on its label and marketed the drug, with the intent to capture the sales for that patented use. Liability here under the law of induced patent infringement is clear.

Nothing about the potential legal consequences of this case warrants re-visiting the fact-specific decision of the Federal Circuit, or reversing the jury's verdict. Indeed, for all of Teva's complaints, it is telling that it resorts to a blatantly misleading "question presented" that relies on a premise—that Teva's label "carved out" the patented use—rejected by the jury and the Federal Circuit.

Teva also fails to mention that the "skinny-label" issue impacts less than 30% of the damages. After launching with a "carve-out" label, four years later, Teva went to a full label and never notified GSK, as required by law.

In short, this case presents no novel issues under the law and concerns the liability of a party whose problems are of its own making. It presents no threat to generic companies who operate properly under the law of induced infringement as applied to generic drug labels—"skinny" or not. And, it concerns circumstances highly unlikely to be repeated, as well as regulations and policies FDA has changed multiple times

since the events relevant to this case occurred. Certiorari should be denied.

STATEMENT

I. COREG®—A PIONEERING, LIFE-PROLONGING TREATMENT FOR CONGESTIVE HEART FAILURE

A. The Coreg® Breakthrough

Congestive heart failure ("CHF" or, simply, "heart failure") is a devastating condition affecting millions of Americans annually. Broadly characterized by a reduced pumping ability of the heart, untreated, heart failure has a high mortality rate and radically reduces patients' quality of life. Symptoms include shortness of breath, fluid retention and inadequate blood flow to the limbs and vital organs. C.A.App.11519.

When launched by GSK in 1997, Coreg® was the first heart failure treatment that significantly prolonged most patients' lives. Its history—and that of the '000 patent claiming that use—is extraordinary.

The story of Coreg® as a heart failure treatment begins with the discovery of carvedilol four decades ago. Carvedilol is a beta blocker, and like other beta blockers, can be used to treat hypertension, as has been known since the 1960s. Beta blockers work by reducing heart rate and the heart's pumping action. C.A.App.10357; C.A.App.11276. Cardiologists (and FDA) thus believed beta blockers could ***kill*** heart failure patients, and the drugs were therefore contraindicated for these patients. C.A.App.2996; Pet.App.5a; C.A.App.10357–10358; C.A.App.11274–11275. Because heart failure patients already have reduced cardiac pumping capacity, it was accepted that beta blockers would further impair blood circulation,

thereby putting heart failure patients even more at risk. C.A.App.10357–10358. Or so everyone thought.

Enter the inventors of the '000 patent. Based on observations they made in working with carvedilol, the inventors conceived carvedilol could treat, rather than worsen, heart failure, contrary to the medical consensus. C.A.App.11275–11280. And while it took some convincing, GSK eventually pursued the inventors' conception in a full-blown clinical trial beginning in 1993. C.A.App.2997; C.A.App.11279–11280; C.A.App.10436–10438.

This clinical trial was a spectacular success. Rather than killing heart failure patients, carvedilol was so effective it ***decreased the risk of death by 65%.*** C.A.App.2997–2998; C.A.App.10373–10374; C.A.App.11282. As a result, GSK was ordered to stop the trial early because it would have been unethical to withhold the life-saving drug from the patients receiving placebo. C.A.App.11282, C.A.App.10371–10373; C.A.App.3409. When inventor Dr. Ruffalo received the call that the trial had to be stopped, his first reaction was panic. "[O]h my God," he testified, "it killed people, just like everybody said, and it's my fault." C.A.App.11282. But when he learned the real reason for the call, he "cried for three hours . . . ." *Id.* Dr. Lukas, another inventor, recalled being "shocked" at the trial's extraordinary results. C.A.App.10374.

Based on these extraordinary results, in May 1997, FDA approved Coreg® to treat "mild to moderate" heart failure patients—the majority of the patients that were in that first trial—and GSK finally launched the drug, achieving immediate commercial success. C.A.App.10377–10379; C.A.App.10795. GSK then ran additional clinical trials with "severe" heart failure patients, and FDA approved Coreg® for

those patients, too, such that, by 2001, Coreg® was labeled for "the treatment of mild to severe chronic heart failure . . . ." C.A.App.10379–10381; C.A.App.11164. Today, this is indication 1.1 on Coreg®'s label. C.A.App.7664–7665.

But for patients who had recently suffered a heart attack and might only be in the earliest stages of heart failure, with few or no symptoms yet present, Coreg® was unavailable. In GSK's clinical trials, individuals who had suffered a major cardiovascular event within three months of the trials' start were excluded. C.A.App.11515.

Unfortunately, many recent heart attack victims have heart failure and need immediate care. Accordingly, GSK got back to work, and initiated clinical trials on the use of carvedilol for "post-MI LVD" patients. C.A.App.10382. These are patients who have suffered heart attacks (*i.e.*, myocardial infarctions, or MI) within 21 days, and have left ventricular dysfunction (LVD), meaning the left ventricle of the heart has a reduced ability to pump out blood, the main defining characteristic of heart failure. *Id.* LVD is quantified by the heart's "ejection fraction," which measures the amount of blood pumped out of the left ventricle with each beat. C.A.App.10602–10603. A normal ejection fraction is typically between 55%–70%; patients with an ejection fraction of less than 40% have congestive heart failure, regardless of whether they have developed any symptoms of the disease. C.A.App.10603; C.A.App.11132; C.A.App.11226.

These additional clinical trials were also successful, and, in March 2003, FDA approved Coreg® for reducing the risk of death in patients with this manifestation of heart failure, post-MI LVD with an ejection fraction below 40%, "with or without symptomatic

heart failure." C.A.App.7992; C.A.App.10382–10383. Today, this is indication 1.2 on Coreg®'s label. C.A.App.7665.

GSK's trailblazing work and investment in carvedilol changed the standard of care for heart failure patients. C.A.App.10667–10668; C.A.App.11267. As a result, heart failure is no longer the short-term death sentence it was just 25 years ago.

B. GSK's '000 Reissue Patent Covering the Use of Carvedilol to Reduce the Risk of Mortality From Heart Failure

Days after GSK's first carvedilol heart failure trial ended early based on extraordinary results, GSK filed a patent application covering the use of carvedilol to decrease mortality of heart failure patients. C.A.App.10373–10374. That application issued as U.S. Patent No. 5,760,069 (the '069 patent") on June 2, 1998, with an expiration date of June 7, 2015.

Rather than wait until this patent covering GSK's pioneering work expired, Teva wanted in on the carvedilol heart failure market early, in 2007, when the patent on the carvedilol molecule expired. And so in 2002 Teva applied for FDA approval to market a Coreg® copy. As part of this process, Teva provided GSK a "Paragraph IV" letter notifying GSK of Teva's generic drug application ("ANDA"). In this letter, Teva did not deny that its proposed generic copy of Coreg® would infringe the '069 patent. C.A.App.3003–3019. Instead, Teva asserted that the '069 Patent was technically invalid over the prior art, including GSK's own prior carvedilol publications. *Id.*

Instead of brushing off Teva's arguments, GSK took them seriously and asked the Patent Office to reconsider the '069 Patent in light of Teva's prior art in a "reissue" proceeding.

Reissue proceedings allow a patent owner to obtain substitute patent rights where, as a result of an error, original patent rights are potentially invalid. 35 U.S.C. § 251. Importantly, while patent owners must agree to surrender their original patent rights at the conclusion of the proceedings, those rights remain in force up and until the PTO issues the reissue certificate. 35 U.S.C. § 252.

GSK filed for reissue of the '069 patent in November 2003 to correct the mistake identified by Teva. *See, e.g.*, C.A.App.7015–7018; C.A.App.10968. The reissue proceeding progressed slowly, concluding in January 2008, when the PTO granted the '000 reissue certificate with newly worded claims. C.A.App.32; C.A.App.11039; C.A.App.10968. While narrower, these claims still covered GSK's pioneering invention of the use of carvedilol to prolong the life of heart failure patients, no matter the patient's specific heart failure symptoms or cardiac event history.[1] It is these claims the jury found Teva willfully infringed by marketing its generic copy of Coreg®.

II. TEVA'S BLATANT ATTEMPT TO END-RUN GSK'S PATENT RIGHTS

Because the reissue proceeding took so long, it overlapped with Teva's generic launch in September

[1] The re-issued claims require a heart failure patient be maintained on treatment with carvedilol for at least six months, a requirement absent from the original claims. C.A.App.45 (8:30–41); (C.A.App.261 (8:27–33).

2007. During those years, and even after, Teva engaged in a concerted effort to capture the lion's share of the market for the use of carvedilol to treat heart failure. These efforts include the conduct at the center of this case—Teva's manipulation of its generic drug label.

A. GSK's Proper Listing of the '069 and '000 Patents in the Orange Book and FDA's U-233 Use Code

When Teva first notified GSK of its ANDA in 2002, GSK had three patents listed in the Orange Book related to Coreg®. One was the '069 patent, which GSK had listed upon its issuance in 1998. At the time, applicants listed method of use patents under a 1994 FDA policy that encouraged, but did not require, NDA applicants to "submit to FDA information on the approved use claimed by the patent." 68 Fed. Reg. 36,676, 36,682 (June 18, 2003).

While that policy no longer exists, it had two critical aspects: 1) use codes appearing in the Orange Book were created entirely by FDA; and 2) use codes were ***only*** "intended to alert the ANDA and 505(b)(2) applicants to the existence of a patent that claims an approved use. They are not meant to substitute for the applicant's review of the patent and the approved labeling." *Id.* at 36,683. Additionally, the "patent certification forms" touted by Teva in its petition—and discussed in *Caraco*—did not exist under this policy; FDA first required those from NDA applicants in August 2003. *Id.* at 36,677 (the final rule "makes changes to the patent information required to be submitted and provides declaration forms for submitting that information to FDA . . . ."); 36,686, 36,707–709 (form 3542a), 36,710–712 (form 3542).

Accordingly, when Teva filed its ANDA in 2002, the Orange Book listed the '069 patent under the FDA-created use code U-233. C.A.App.7831. FDA's summary for that use code was "decreasing mortality caused by congestive heart failure." C.A.App.7833.

This has always been the use code summary for the '069 patent and, ultimately, the '000 reissue patent. Notably, FDA did not change the use code when it approved Coreg® for post-MI LVD patients in March 2003, which also occurred under the 1994 policy. Nor should it have. The indication approved by FDA for these patients explicitly instructs doctors to treat them with carvedilol "to decrease cardiovascular mortality," exactly as the use code describes. The main relevant clinical distinction between these patients and those with mild to severe heart failure is that post-MI LVD patients may or may not be symptomatic. As the approved indication for post-MI LVD patients states:

> 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 less than or equal to 40% (***with*** or without ***symptomatic heart failure***) [see Clinical Studies (14.2)].

C.A.App.7665 (emphasis added).

This use code did not change when FDA began requiring the patent information forms in August 2003. As an initial matter, Teva omits that the requirements for these forms, as first implemented in 2003, were very different than they are today. Today, an NDA holder wanting to list a method of use patent must identify every section and subsection of its label

that describes the method of used claimed by its patent. 21 C.F.R. § 314.53(c)(2)(i)(O)(2) (2019). FDA only adopted these requirements in ***2016***, almost 20 years after GSK first listed the '069 patent in the Orange Book. 81 Fed. Reg. 69,580, 69,599 (Oct. 6, 2016).

In August 2003, when FDA first required patent information forms, they were fairly sparse. They simply required the NDA holder to confirm that its patent claimed an approved use and to both identify and describe that approved use with reference to the approved labeling. 68 Fed. Reg. 36,686, 36,707–709, 36,710–712 (June 18, 2003). There was no requirement—nor room on the form—for the NDA holder to identify everything on its label related to the listed patent. *Id.* at 36,686. FDA did not impose an obligation to identify every section and subsection of the labeling that described the claimed method of use until 2016. 81 Fed. Reg. 69,599.

Teva also omits that there are two different types of patent information forms, Forms 3542 and 3542a, which have distinct purposes. Form 3542a is for use by NDA applicants when applying for approval (whether original, amended or supplemental). 21 C.F.R. § 314.53(c)(2)(i). Form 3542 is for use by NDA holders after receiving approval. 21 C.F.R. § 314.53(c)(2)(ii).

Critically, in first requiring these forms in 2003, FDA announced it would ***only*** use Form 3542, and not Form 3542a, for Orange Book listing purposes. *See* 68 Fed. Reg. 36,707. As the forms and their instructions explicitly state: "[t]he information submitted in the declaration form submitted upon or after approval will be the only information relied upon by FDA for listing a patent in the Orange Book" (form)

(C.A.App.6894; 68 Fed. Reg. 36,707); "[o]nly information from form 3542 will be used for Orange Book publication purposes" (instructions) (C.A.App.6897). Consistent with this, Form 3542a does not even request of the applicant a proposed use code, while Form 3542 does. *Compare* C.A.App.6894–6896 (form 3542a) *with* C.A.App. 6880–6882 at 6882 (form 3542 with box 4.2b "Use Code").

But, even with these new forms, FDA remained clear that use codes developed based thereon were no substitute for the generic filer's independent evaluation: "[use codes] are not meant to substitute for the applicant's review of the patent and the approved labeling." 68 Fed. Reg. 36,683 (June 18, 2003).

Under these then-applicable policies, FDA never asked GSK to provide a patent information form in connection with the post-MI LVD indication, whether at the time the requirement arose in August 2003, five months ***after*** the post-MI LVD indication had been approved, or anytime thereafter. During this time, GSK continuously sold Coreg® with the post-MI LVD indication on the label, and applications for generic copies of Coreg®, including Teva's, remained pending. If there had been any issue with use code U-233 during this time frame, in relation to the post-MI LVD indication, surely it would have been raised by FDA or the highly motivated generic companies. Instead, there was silence from FDA, and no generic company ever told GSK that a generic copy of Coreg® labeled with the post-MI LVD indication would not infringe the then-existing '069 patent.

While GSK ultimately did submit the two patent information forms raised by Teva in its petition, GSK did so in relation to events having nothing to do with the contested post-MI LVD indication. The first is a

Form 3542a for the '069 patent GSK submitted on September 1, 2006, in connection with GSK's application for pediatric exclusivity. C.A.App.6889–6907. The second is a Form 3542 GSK submitted on February 6, 2008 to note the issuance of the '000 reissue patent in place of the already-listed '069 patent. C.A.App.6873–6887.

Notably, while Teva claims it relied on these forms, there is no evidence in the record Teva ever obtained or saw them before this case. We nonetheless address these forms, so the record before this Court is clear.

Plainly, from a timing perspective, only the 2006 form could possibly have any relevance to Teva's initial launch in September 2007. But that form was a Form 3542a, ***not*** a Form 3542, and thus had nothing to do with any Orange Book listing, the already existing FDA use code in the Orange Book, or Teva's carve-out label. As FDA made clear, only information in a Form 3542 would ever be used for Orange Book purposes. But even still, nothing on GSK's 2006 Form 3542a reasonably suggests that the post-MI LVD indication was not covered by the then existing '069 patent. Rather, GSK described the approved use covered by the patent as "Treatment of Mild-To-Severe Heart Failure . . . To Increase Survival," which embraces all heart failure patients covered by the patent and referenced on the approved label for Coreg®. C.A.App.6895.

As for the Form 3542 GSK submitted in February 2008 for the '000 reissue patent, that form repeats the above description of the patented use, and, in the additional box not present on Form 3542a, adds that the use code should remain the same as it always had

been since FDA created it in 1998: "Decreasing Mortality Caused by Congestive Heart Failure." C.A.App.6881–6882. But as noted, GSK submitted this form six months ***after*** Teva's launch, so it had nothing to do with Teva's carve-out label or decision to launch its infringing product. And while GSK misled no one about the scope of its patent rights, the timing makes it impossible for GSK to have even theoretically done so, let alone be responsible for Teva's (or FDA's) actions. GSK complied with FDA regulations and policies, and misled no one.

B. Teva's Game-Playing With Its Generic Label to Ensure It Obtained All Uses of Coreg® for Heart Failure

For its part, what did Teva do to comply with FDA's policies over the years in relation to the post-MI LVD indication that appears on its label? Nothing.

At trial, Teva presented no evidence it ever independently evaluated the '069 patent or the '000 reissue patent as required by FDA policy. Far from doing "everything right," as Teva proclaims, it did nothing at all.

Instead, Teva intended and did everything to ensure it would secure sales of carvedilol for all heart failure patients, regardless of how its product was labeled. This began with Teva's initial ANDA in 2002, labeled for all indications. C.A.App.10530. After FDA approved Coreg® for post-MI LVD heart failure patients, Teva also added that indication. *See, e.g.*, C.A.App.5508; C.A.App.10622–10623. Tellingly, Teva did ***not*** revise its Paragraph IV notice to state that this added indication did not infringe the '069 patent.

Then, in 2004, FDA granted Teva tentative approval. C.A.App.7788–7792. Immediately, Teva began priming the market for the launch of its generic copy, encouraging doctors to use the product just like Coreg® to treat heart failure. Teva trumpeted in a press release, distributed to cardiologists, that its "Carvedilol Tablets are the AB-rated generic equivalent of Glaxo SmithKline's Coreg® Tablets and are indicated for treatment of heart failure" and would be available in 2007. C.A.App.6347. This press release also referenced GSK's total Coreg® sales, the vast majority of which were for heart failure, evidence Teva planned on capturing all sales including those for the patented use. *Id.*

As for GSK's then-existing '069 patent, Teva seemed content to rely on invalidity arguments. But, as its desired launch date drew near, and it appeared the reissue proceeding might fix GSK's patent, Teva apparently got cold feet and hatched a new strategy, based on a Hatch-Waxman Act "section viii statement." As described by the Court in *Caraco*, these statements "assert[] that the generic manufacturer will market the drug [only] for one or more methods of use not covered by the brand's patents." *Caraco*, 566 U.S. at 406. Generic manufacturers that employ them "propose labeling for the generic drug that 'carves out' from the brand's approved label the still-patented methods of use." *Id.*

But there was a problem with Teva's strategy: its "carve-out" was incomplete. Rather than carve-out both indications covering Coreg®'s heart failure uses, Teva only carved out the first one, leaving the indication that instructs doctors to use carvedilol to "reduce cardiovascular mortality" in post-MI LVD patients

with an ejection fraction of ≤40% and with symptomatic heart failure.[2] C.A.App.5508.

Also remaining on the label was language warning of the risk of "worsening heart failure" when patients first use the product, as well as data from GSK's clinical studies showing carvedilol reduced mortality in the post-MI LVD heart failure patients. C.A.App.5510; C.A.App.5512–5513. Compounding matters, Teva did no analysis to support its carve-out; instead, it copied a carve-out FDA apparently negotiated with another generic manufacturer. C.A.App.7793.

None of these stratagems had anything to do with GSK's actions. Unlike today, when GSK would have identified each section of its label for consideration by FDA, GSK was cut out of this process, the opposite of Teva's erroneous claim GSK somehow informed FDA and the public which parts of its label should be carved out to avoid infringement. As noted, by the time Teva concocted its carve-out strategy, GSK had not yet provided the Form 3542 Teva now claims it relied upon.

Teva went forward with the carve-out label, and launched its product on September 6, 2007. In its press release announcing this launch, Teva nowhere mentions its product has a carve-out label, but instead communicated to doctors its product should be used to treat all heart failure patients. C.A.App.6342. This press release explicitly stated that Teva was selling a

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[2] Both experts agree a patient with an ejection fraction of ≤40% with symptoms is suffering from heart failure. C.A.App. 11226 (Dr. Zusman); C.A.App.11131–1132 (Dr. Zusman); C.A.App.10622–10631 (Dr. McCullough); C.A.App.10696 (Dr. McCullough).

"Generic version of GlaxoSmithKline's cardiovascular agent Coreg®," which GSK's expert testified was shorthand to doctors to use the drug to treat heart failure. C.A.App.11660.

And, just like the 2004 release, the 2007 release included Coreg®'s total revenue, demonstrating Teva still intended to capture the entire heart failure market. In fact, Teva included heart failure revenue despite personnel explicitly questioning whether it was right to do so. C.A.App.10973–10974. This press release remained on Teva's website throughout the entire infringement period. C.A.App.6353.

Teva's subsequent marketing materials built upon those press releases and reinforced that its generic product should be used exactly like Coreg®, including for the patented use. Teva's product catalogs directly compared Teva's product to Coreg® without limitation, including by stating it was "AB"-rated to "Coreg®." *See, e.g.* C.A.App.6221; C.A.App.6270.

Teva's 2009 product guide was even more explicit, referring to Coreg® as the "Brand Equivalent" of Teva's product. C.A.App.6324. As explained to the jury by GSK's regulatory expert, according to FDA, such direct comparisons—where the generic not only refers to an "AB" rating but also invokes the name of the branded drug (Coreg®)—communicates both products are approved for all the same uses. C.A.App.10545. All of these efforts by Teva achieved its intended goal—capture the lion's share of the market for Coreg®, including for the patented use.

Having largely destroyed the market for Coreg® with its launch in 2007, Teva applied the coup de grâce in 2011. Teva amended its label to add back the indication for "mild-to-severe" heart failure and the

corresponding clinical trial data and reports, which it previously omitted. Teva's "full" label, as well as related Monthly Prescribing References for Healthcare Professionals, now told doctors to use the product for all types of heart failure, as its other promotional materials had done for years. C.A.App.5531–5553; C.A.App.6192–6208.

And, just as in 2007, Teva's 2011 efforts to comply with FDA policy and regulations were non-existent. As GSK's and Teva's experts agreed, Teva's change to the "full" label in 2011 should have been accompanied by a Paragraph IV notification. C.A.App.10571–10572; C.A.App.11049–11050. Instead? Silence from Teva, and its capture of the market GSK worked for 15 years to create was complete.

III. THE PROCEEDINGS BELOW

A. The Trial Proceedings

After unsuccessfully trying to rebuild the branded market for Coreg® with an improved carvedilol product, GSK ultimately sued Teva in 2014 to recover at least some of its damages. In its complaint, GSK alleged Teva willfully induced infringement of the '000 reissue patent through its sale and marketing of its generic carvedilol. The case went to trial in June 2017.

In the main, Teva did not try the case based on the issues described in its petition—i.e., that GSK's Orange Book listings were somehow the cause of Teva's infringement. That defense, which Teva has put forward as an equitable estoppel defense, will be tried on remand in the District of Delaware.

Instead, in an attempt to avoid liability, Teva challenged validity and also raised a novel causation

theory: that generic drug providers should not be held responsible for inducing patent infringement because branded companies, when they first make the market, teach doctors how to use the drug according to their patented methods. Under this theory, the cause of doctors' infringement with Teva's product was not Teva, but, bizarrely, GSK.

As for Teva's carve-out label, the primary role it played at trial was a mundane one—Teva challenged it actually instructed the patented method during the partial or full label period. C.A.App.11152–11154. To keep the two separate, the jury rendered its liability verdict in two time periods: a) the carve-out, or partial label, period, from 2007–2011; and b) the full-label period, from 2011 to patent expiry in 2015. C.A.App.205–206.

Far from communicating to the jury that Teva launched its product because it had purportedly carved out "all of the language" GSK "identified as covering its patented uses," as Teva's Question Presented claims, Teva relied on the reissue proceedings. Counsel for Teva told the jury in opening that Teva launched in 2007 because the re-issue proceeding resulted in a "gap" in patent coverage, and thus Teva was free to launch—and destroy GSK's market—without fear of liability. C.A.App.10324; C.A.App.10343. But, as the jury was instructed, there was no "gap" that resulted from reissue. GSK's patent rights were continuously in force from 1998 forward. C.A.App.166; C.A.App.11832–11833. When forced to confront this in closing, Teva's counsel cavalierly dismissed his earlier claims with a shrug and a glib "My bad." C.A.App.11891.

B. The Jury's Inducement Verdict and the District Court's JMOL

After hearing all of this, the jury found Teva willfully induced infringement by selling its generic carvedilol with both its partial label and full label, awarding GSK $235 million in damages. Pet.App.9a–10a; C.A.App.207; C.A.App.211. The jury thus sided with GSK that Teva's partial label was not a true carveout, and encouraged infringement, including the indication which instructs doctors to use carvedilol to reduce cardiovascular mortality in post-MI LVD heart failure patients. *See* Pet.App.27a. Indeed, the jury heard experts for GSK *and* Teva agree that the post-MI LVD patients with a left ventricular ejection fraction of ≤40% and symptoms of heart failure were all suffering from heart failure. Pet.App.16a, 18a–19a; C.A.App.10602–10606, 10622–10623, 11226. The verdict also means the jury rejected Teva's defense that it did not cause infringement.

The district court upended the jury's liability verdict at JMOL. On JMOL, Teva argued the jury could not reasonably have found Teva caused doctors to infringe. The district court agreed. Pet.App.160a–161a; *see also* Pet.App.95a. In addition, in a footnote the district court treated the fact question of whether the post-MI LVD indication instructs the claimed use "as though it were a legal one for it to decide *de novo*." Pet.App.21a–22a; C.A.App.15–16 at n.9. And, improperly slotting itself in as the fact-finder, "decided the post-MI LVD portion of Teva's label was insufficient to find that the [partial] label instructed an infringing use." Pet.App.21a; C.A.App.15–16 at n.9.

C. The Federal Circuit Reinstates the Jury's Verdict, Twice

At the Federal Circuit, a majority panel reversed the district court's JMOL decision and reinstated the jury's verdict, finding it supported by substantial evidence. Pet.App.90a. The primary issue addressed on appeal was Teva's novel causation argument that had persuaded the district court to grant its JMOL request. Pet.App.96a. Whereas the majority found causation supported by substantial evidence, in the dissent's view it was lacking, including based on the dissent's belief—contrary to the jury's verdict—that Teva had marketed "its generic carvedilol for *unpatented* uses through a 'skinny label.'" Pet.App.110a–11a (emphasis in original).

Emboldened by the dissent's favorable take on its "skinny" label, Teva sought rehearing, contending the majority's decision "could be broadly read to impose liability on ANDA filers that carved out patented uses under section viii when seeking approval to market generic drug products, in direct contravention of the Hatch-Waxman Act." Pet.App.10a–11a. Several amici supported Teva. The Federal Circuit granted the petition for panel rehearing, vacating its earlier judgment and opinion. Pet.App.11a.

The rehearing grant had a distinct purpose: to make clear that Teva's "skinny" label did *not* reflect only *un*patented uses, and thus assuage concerns the decision would have far-reaching consequences to the section viii carve-out regime.

Indeed, the Federal Circuit's subsequent per curiam decision, again reinstating the jury's verdict of willful induced infringement, explains that the panel "agreed to rehear this case to make clear how the facts

of this case place it clearly outside the boundaries of the concerns expressed by *amici*" that the prior decision "upset the careful balance struck with section viii carve-outs." Pet.App.11a. It did so with a concise message about the rare nature of the facts of this case that Teva still refuses to come to terms with—that its "skinny" label did not carve out the patented use:

> This is a case in which substantial evidence supports a jury finding that the patented use was on the generic label at all relevant times and that, therefore, Teva failed to carve out all patented indications. This narrow, case-specific review of substantial evidence does not upset the careful balance struck by the Hatch-Waxman Act regarding section viii carve-outs.

Pet.App.12a.

The rehearing decision explains why the evidence supports the jury's inducement verdict in both the partial and full label periods. Most relevant to the issues Teva raises here, the decision reviews the substantial evidence supporting the jury's conclusion that the post-MI LVD indication left on Teva's partial label encourages the patented use of decreasing mortality caused by congestive heart failure. Pet.App.15a–16a. And, it rightly calls out that *Teva's* expert conceded the post-MI LVD indication covers patients with congestive heart failure. Pet.App.16a.

The rehearing decision also addressed the impact GSK's submissions to FDA for Orange Book listing had on the jury. Simply put, none. Pet.App.22a–25a. This makes sense. While the jury did not hear about, nor did the rehearing decision (or dissent) reflect, the various policies in place at the relevant time concern-

ing Orange Book listings and use code drafting outlined above, the jury *did* hear and the rehearing decision *did* recognize, a critical fact that was in play when the relevant events occurred: that *ANDA applicants like Teva have an obligation to analyze Orange-Book listed patents to determine how to prepare their carve-out labels*. Pet.App.24a–25a. From Teva's petition, one would never guess that Teva's counsel rightly *conceded* during oral argument that GSK's FDA submissions "are 'not absolutely dispositive of infringement.'" Pet.App.23a.

The rehearing decision also dispensed with Teva's attempts to liken its partial label to others found not to induce infringement. Pet.App.16a–21a. In so doing, it rejected Teva's claim that GSK's expert had merely "cobbled together" disparate portions of the label to drum up infringement instructions, and that such piecing together of the label cannot give rise to inducement liability. Pet.App.17a–18a. As the jury had done, the majority read the actual label, rather than rely on Teva's distorted description, finding "[a]ll of the claim limitations were contained in the Indication section (which amounted to a single sentence), the Clinical Study section (to which doctors were directly referred by the Indication section), and the Dosage and Administration section (which immediately follows the Indication section and which says how much and how often to give the carvedilol)." Pet.App.17a–18a.

The dissent's contrary take, parroted by Teva in its petition, is built on an assumption unsupported by the factual record—that GSK's FDA submissions are somehow responsible for the words in Teva's partial label. Pet.App.64a. In the dissent's view, because

GSK did not recite the post-MI LVD indication verbatim in its Form 3542a—which states it will *not* be used for Orange Book listing purposes (C.A.App.6893–6894)—GSK had put a stake in the ground that the post-MI LVD indication was not a patented use. Pet.App.57a–58a, 62a, 65a. The dissent then bases its entire analysis on this incorrect view of "the carve-out backdrop" of this case. Pet.App.64a, 66a. Moreover, the dissent—like the district court—wrongly played fact-finder, relying on its own interpretation of Teva's press releases, notwithstanding expert testimony to the contrary, and also improvidently attacked the *circumstantial*, as opposed to direct, nature of GSK's inducement evidence. Pet.App. 69a–74a, 80a–81a. The dissent further doubled down on lack of causation, concluding, that even when Teva outright copied GSK's entire label Teva did not induce infringement. Pet.App.76a–77a.

None of the dissent's concerns or arguments present a sound reason for this Court's review. We explain why below.

REASONS FOR DENYING THE PETITION

When viewed through the lens of the actual facts and regulatory landscape, Teva's petition collapses. The decision below does not have the far-reaching consequences Teva and amici lament because its outcome turns on the application of a specific set of facts to a properly stated rule of law. The decision below—like others before it addressing carve-out labels—has not had, and will not have, a chilling effect on the generic drug industry.

Moreover, review of the decision below would involve considering long-since-changed FDA regula-

tions that have no bearing on how the carve-out process operates today. And, the challenged aspect of the decision below is not even case dispositive, since over 70% of the damages occurred during Teva's full label period.

At bottom, Teva is asking this Court to rescue it from an adverse factual finding of substantial liability based on a fanciful Question Presented. Denial is appropriate.

I. THIS CASE PRESENTS NO BASIS FOR THE COURT TO REVIEW ANY ASPECT OF INDUCED INFRINGEMENT

The law of inducement is not in jeopardy. The record demonstrates both the jury and appellate court applied the correct construct of induced infringement, and that the liability determination is amply supported. In suggesting otherwise, Teva ignores the substantial evidence supporting the finding that its carve-out, or partial, label encourages a patented use, and that its inducement liability was also predicated on marketing messages beyond its labels.

A. Both the Jury and Federal Circuit Correctly Applied the Well-Settled Concept of "Active Inducement" in Determining Teva's Liability

"Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). Though first codified in the 1952 Patent Act, this concept of induced infringement had long been recognized at common law. *Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 545 U.S. 913, 935–36; *see also id.* at 942 (Ginsburg, J., concurring). To illustrate, at common law, a "patent defendant who not

only expected but invoked infringing use by advertisement" was liable for infringement. *Id.* at 935 (brackets omitted).

As explained in *Grokster*, "[t]he rule on inducement of infringement as developed in the early cases is no different today." *Id.* at 936. "[A]ctive steps" taken by the accused infringer "to encourage direct infringement" are required to establish inducement liability, and such steps may be shown through "advertising an infringing use or instructing how to engage in an infringing use." *Id.*; *see also id.* at 937 ("The classic instance of inducement is by advertisement or solicitation that broadcasts a message designed to stimulate others to commit violations.").

Global-Tech paints the same picture based on the statute's plain language. It explains, "[t]he term 'induce' means '[t]o lead on; to prevail on; to move by persuasion or influence.'" *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 760 (quoting Webster's New International Dictionary (2d ed. 1945)). It continues, "[t]he addition of the adverb 'actively' suggests that the inducement must involve the taking of affirmative steps to bring about the desired result." *Id.*

Inducement liability must thus be grounded in actions that encourage and foster using a product to infringe rather than for using it for some lawful reason. *Grokster*, 545 U.S. at 936–37.

This well-settled law is exactly what the jury considered in determining Teva's infringement liability. The jury instruction on "Induced Infringement" included the "active steps" requirement:

> Teva is liable for active inducement of a claim only if GSK proves by a preponderance of the evidence each of the following:

> . . .
>
> 2. that Teva took some affirmative action, or that Teva continued to take an action that began before the '000 patent issued, after the '000 patent was issued on January 8, 2008, intending to cause the physicians to directly infringe by administering Teva's carvedilol product;
>
> . . . .

C.A.App.168.

An additional jury instruction, entitled "Affirmative Actions Intended to Cause Infringement," communicates the same point. C.A.App.171. It provides in relevant part that, "to find inducement, you must find that Teva intended others to use its products in at least some ways that would infringe the asserted claims of the '000 patent, *took affirmative acts to encourage direct infringement*, and that those actions actually caused the direct infringement of the asserted claims of the '000 patent." *Id.* (emphasis added). Yet further, the jury knew "[i]t is not enough for the accused inducer to lead another to engage in conduct that happens to amount in infringement. Rather, to induce infringement, the accused inducer must persuade another to engage in conduct that the inducer knows – or believes with high probability, but deliberately avoided confirming – is infringement." C.A.App.172.

These jury instructions correctly communicate what is required to find liability for "active inducement," including based on the statute's plain language, *Grokster* and *Global-Tech*. In fact, Teva has *never* challenged them.

In reviewing the jury's verdict for substantial evidence, the Federal Circuit recognized and applied these same, long-standing principles. It explained that inducement liability only attaches where the accused infringer takes "active steps" to encourage infringement. Pet.App.12a–13a; *see also id.* at 28a–29a. The Federal Circuit then applied that requirement. For example, it concluded that "substantial evidence in this case supports the jury's determination that Teva's partial label contained information encouraging each claimed step and the preamble" and also "finding that Teva's partial label was evidence that Teva instructed physicians to use its carvedilol in an infringing way." Pet.App.20a, 27a. It also made clear that Teva's other marketing materials, in addition to its labels, support inducement. Pet.App.36a–37a, 42a. The requirement of active steps to encourage infringement was thus unquestionably central to the decision below.

Also central to the decision was the understanding that inducement will not follow where there is "mere knowledge of infringing potential or of actual infringing uses" and an absence of active encouragement to infringe—in other words, "legitimate commerce." *Grokster*, 545 U.S. at 937. The Federal Circuit made clear it considered this in explaining that GSK's inducement expert "did not testify that Teva's actions merely describe infringement; he testified that Teva's actions encouraged infringement." Pet.App.27a; *see also id.* at 37a.

What this all demonstrates is the law of induced patent infringement was correctly stated and applied below. No additional look by this Court is warranted. *See* Sup. Ct. R. 10 (providing that even

when a properly stated rule of law is *mis*applied, review is rare).

B. The Factual Finding Below that Teva's Partial Label Encourages Infringement Does Not Conflict with Relevant Decisions of This Court

The factual nature of the issue of induced infringement disposes of Teva's claim that the decision below erases the line between encouragement to infringe (inducement) and the mere description of an infringing use.

"Infringement is a question of fact." *Stilz v. United States*, 269 U.S. 144, 147 (1925). A central fact question the jury decided was whether Teva's partial label instructed the patented use, notwithstanding Teva's carve-out attempt. The jury's verdict answered that question affirmatively. Teva tries to skirt that problem in its petition in two ways, neither of which pass muster.

First, Teva rides the dissent's bandwagon that its carve-out approach is non-infringing because it traces back to GSK's representations to FDA. This proposition falls apart when the applicable FDA regulations are considered, and because the jury rejected that position. The jury found that even in the face of GSK's FDA submissions, Teva failed to carve-out the patented use and heed its affirmative responsibility—confirmed by its regulatory expert (Pet.App.24a–25a)—to ensure its actions would not constitute infringement.

Second, Teva re-asserts its rejected factual argument that what was left in its carve-out label does not amount to encouragement to infringe because, at best, the infringing use is merely described or inadvertently

mentioned in its partial label. But again, whether this is so is a fact question for the jury to decide. The jury decided against Teva. Lower court decisions addressing different labels and finding no infringement are no basis to cast aside the jury's fact finding. Just as this case turns on its facts, so did the ones Teva invokes.

In *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625 (Fed. Cir. 2015), the patentee tried to prove a label encouraged the patented use of a drug to treat acute gout flares based on the label's statement "that '[i]f you have a gout flare while taking [the drug], tell your healthcare provider.'" *Id.* at 630. The court held that based on the record before it, the patentee had demonstrated "there may be some infringing uses" of the drug, but there was insufficient evidence of intentional encouragement to infringe. *Id.* at 633–34. That this case and *Takeda* both involve a carve-out label does not mean they should be decided the same, as Teva advances. Pet. at 30–31; *see also* Pet.App.13a (lower decision citing *Takeda*). Different facts compel a different result here, as already explained.

Same for *HZNP Medicines LLC v. Actavis Lab'ys UT, Inc.*, 940 F.3d 680 (Fed. Cir. 2019). There, the patented method involved three steps. There was no inducement because the label only required the first step. The district court serving as the fact finder found insufficient evidence the label encouraged performing the last two steps. *Id.* at 702. By contrast here, substantial evidence demonstrated Teva's partial label encouraged *all* steps of the claimed method. Pet.App.20a.

In *Bayer Schering Pharma AG v. Lupin Ltd.*, 676 F.3d 1316, 1322–24 (Fed. Cir. 2012), the label in question was deemed to lack information demonstrating

the safety and efficacy of two of the three simultaneous effects recited in the patented method, and so failed to recommend achieving that claimed combination of effects. That is not the case here. Pet.App.18a.

As the appellate court rightly stated, "[t]he jury was entitled to credit expert testimony regarding the label's instructions on who should take what drug, when, why, and how, and to reject the dissent's claim that the label describes rather than instructs as to an infringing use." Pet.App.29a n.6; *see also* Pet.App.18a.

Thus "inadvertent description" has not been deemed to satisfy § 271(b) per the decision below, as Teva claims. Pet. at 31. The issue of inducement vs. mere description was and remains a fact question. Teva's dissatisfaction with this case's outcome on the factual record—which plainly supports the conclusion Teva did *not* carve out the patented use, unlike in *Takeda*—is no compelling basis for review. *See* Sup. Ct. R. 10 (providing that even "where the asserted error consists of erroneous factual findings," review is rare).

II. THE SPECIFIC FACTS OF THIS CASE LIMIT ITS REACH AND COUNSEL AGAINST REVIEW

Certiorari should be denied for the additional reason that this case concerns regulatory issues long since mooted. FDA's rules concerning disclosure of patent information and use codes for Orange Book listing have dramatically changed since GSK first listed its patent in 1998. If the patent were listed today, GSK would submit a Form 3542 with a use code and specifically identify whether the patent covered all or just a portion of each approved use as well as each section and subsection of the label that describes

the method of use. 21 C.F.R. § 314.53(c)(2)(i)(O)(2) (2019). None of this information was required in 1998, 2003 or 2008. Indeed, in 1998, FDA merely "requested, but [did] not require[] NDA applicants [to] submit to FDA information on the approved use claimed by the patent." 68 Fed. Reg. 36,682 (June 18, 2003).

Moreover, this case does not concern any overriding statutory issue like *Caraco*. *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399 (2012). There an NDA holder submitted an overly broad use code that prevented approval of a section viii carveout label even though it was undisputed the label would not induce the infringing use. The Court reversed the Federal Circuit and remanded, holding that "Caraco may bring a counterclaim seeking to 'correct' Novo's use code 'on the ground that' [Novo's method of treatment patent] 'does not claim . . . an approved method of using the drug'— indeed, does not claim two." 566 U.S. at 426. As the Court noted, "[a]n overbroad use code . . . throws a wrench into the FDA's ability to approve generic drugs as the statute contemplates." *Id.* at 419. The Court went on to say, "[a] fix is in order, but it must come from Congress or FDA." *Id.* at 428.

FDA heard the Court and proposed changes to the Orange Book listing process and proposed a process for challenging use codes submitted by NDA holders. 80 Fed. Reg. 6,802 (Feb. 6, 2015). FDA reiterated that its "role in patent listing is ministerial and does not involve substantive review of patents" and that use codes are meant to alert applicants but not meant to substitute applicant's review of the patent and ap-

proved labeling. *Id.* at 6,828. After receiving comment, FDA implemented these changes in 2016. 81 Fed. Reg. 69,580, 69,643–69,644 (Oct. 6, 2016).

Here, there is no suggestion that the FDA-created use code listed for Coreg® was overbroad. More importantly, FDA's post-*Caraco* rule changes further highlight that the regulatory scheme today and going forward is dramatically different from the scheme during the relevant time of this dispute. The Court should not expend resources reviewing antiquated FDA rules, the results of which will have no impact on the future.

Nor does this case present any conflict between Hatch-Waxman's "same labeling" requirement and § 271(b), as an amici suggests. *See* Brief of 42 Professors, 6–8. The Hatch-Waxman Act does not, and cannot, override patent rights, as confirmed by the "same labeling" provision itself. That provision expressly allows labeling edits when "aspects of the listed drug's labeling are protected by patent." 21 C.F.R. § 314.127(a)(7) (2016). Amici's reliance on a copyright infringement case is thus inapposite—the "same labeling" provision contains no exemption for copyrighted material.

Lastly, the record in this case is not yet complete. The case has been remanded to the district court for further proceedings, including resolution of equitable defenses relating to the Orange Book listing. And contrary to the Petition, the section viii issue presented is not case dispositive. As described above, Teva amended its label in 2011 to add back the carved-off portions. The jury and appellate court found this full label, along with all of Teva's other acts, induced infringement from that point forward. Pet.App.37a–39a. In fact, GSK presented evidence at trial that

more than 70% of its damages arose during the full label period. A ruling on since-replaced FDA rules would not negate Teva's liability for the full label period.

In sum, this case is an exceptionally poor vehicle for considering inducement in the context of section viii carve-out labels. The fact-bound result flowed from the application of well-settled inducement law to unique facts under a long-replaced regulatory scheme. A future dispute under then-applicable FDA rules, to the extent such a case ever gets to the Court, would be a far superior vehicle to address inducement in the context of a section viii label. Moreover, this case's incomplete record coupled with Teva's liability for the full label period—barely mentioned in the Petition—further support denial of the Petition.

III. THE SECTION VIII CARVE-OUT REGIME IS NOT IN DANGER, NOR WILL EVERY CARVE-OUT SITUATION PRESENT UNDUE RISK OF INFRINGEMENT LIABILITY

The doomsday scenario for section viii carve-outs Teva's petition portrays falls apart for a simple reason: the jury found, on the record before it, that Teva's partial label did not properly carve out GSK's patented use. The fact-bound nature of this case is why the decision below does not spell the end of carve-outs. As long as generics fully and truly carve out the patented use, they can continue to enjoy the carve-out statute's protection.

A decade-old Federal Circuit case addressing an attempted carve-out label proves the point. In *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1056 (Fed. Cir. 2010), the generic was deemed not to have carved out enough from its FDA-approved label to avoid the

patented use. Yet that decision had no chilling effect on carve-outs, as Teva's statistics show.[3]

Nor has this decision. The Federal Circuit first reinstated the jury's verdict in October 2020. In the nearly two years since then, GSK is aware of only one other case asserting a carve-out label failed to carve out the patented use, and thus could give rise to inducement liability. Teva's petition thus oversells the idea that every carve-out will lead to a jury trial. Pet. at 33.

Moreover, as explained above, today a patent-holder must provide much more information to FDA that FDA will use to assess a carve-out label. The patent-holder's role in this process undercuts Teva's claim that carve-out launches are now accompanied by prohibitive risk and will have grave consequences to the market. Additionally, the rules now provide a fast and convenient mechanism for testing the patent information provided by the brand for Orange Book listing. *See*, 21 CFR 314.53(f).

But, at bottom, the Hatch-Waxman Act's carve-out provision was never meant to snuff out patent rights and give failed attempts to carve-out a patented use a free pass just because a generic company might get it wrong. Such instances are few and far between, and this Court's inducement law need not be changed simply to account for the rare exception. In addition, the facts here don't even fit the exception. Contrary to what Teva and amici argue, Teva's carve-out was not the result of any genuine effort to avoid patent

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

rights, but rather was one of expediency, made at the last minute, without any assessment of GSK's patent rights. No responsible generic or biosimilar company's efforts under section viii could possibly be threatened by the actual circumstances of this case.

CONCLUSION

Teva's petition should be denied.

Respectfully submitted,

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