No. 18-1976, -2023

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

GLAXOSMITHKLINE LLC and SMITHKLINE BEECHAM (CORK) LIMITED,

Plaintiffs-Appellants,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Cross-Appellant.

Appeal from the U.S. District Court for the District of Delaware (Stark, C.J.)
No. 1:14-cv-00878-LPS-CJB

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December 2, 2020

CERTIFICATE OF INTEREST

Counsel for Defendant-Cross-Appellant Teva Pharmaceuticals USA, Inc., William M. Jay, certifies the following:

1. Represented Entities. Provide the full names of all entities represented by undersigned counsel in this case. Fed. Cir. R. 47.4(a)(1).

Teva Pharmaceuticals USA, Inc.

2. Real Party in Interest. Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. Fed. Cir. R. 47.4(a)(2).

N/A

3. Parent Corporations and Stockholders. Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. Fed. Cir. R. 47.4(a)(3).

Teva Pharmaceuticals Holdings Coöperatieve U.S.; IVAX LLC; Orvet UK; Teva Pharmaceuticals Europe B.V.; Teva Pharmaceuticals Industries Ltd.

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

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5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). *See also* Fed. Cir. R. 47.5(b).

GlaxoSmithKline LLC et al. v. Glenmark Pharmaceuticals Inc., USA, No. 1:14-cv-877 (D. Del.)

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

N/A

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TABLE OF ABBREVIATIONS

’000 patent	U.S. Patent No. RE40,000 (Appx31-45)
ANDA	Abbreviated New Drug Application (generic drug application)
CHF	Congestive heart failure
GSK	Plaintiffs-Appellants GlaxoSmithKline LLC and SmithKline Beecham (Cork) Limited
Hatch-Waxman	Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (formally, Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585)
JMOL	Judgment as a matter of law
Post-MI LVD	Left ventricular dysfunction following myocardial infarction
Section viii	21 U.S.C. § 355(j)(2)(A)(viii)
Teva	Defendant-Cross-Appellant Teva Pharmaceuticals USA, Inc.

RULE 35(b) STATEMENT

1. Based on my professional judgment, I believe the panel decision is contrary to the following precedents of this Court:

Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348 (Fed. Cir. 2003); *AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370 (Fed. Cir. 2012); *Takeda Pharm. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625 (Fed. Cir. 2015); *Grünenthal GMBH v. Alkem Labs. Ltd.*, 919 F.3d 1333 (Fed. Cir. 2019); *Nat'l Presto Indus., Inc. v. W. Bend Co.*, 76 F.3d 1185 (Fed. Cir. 1996); *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263 (Fed. Cir. 2004); and *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315 (Fed. Cir. 2016).

2. Based on my professional judgment, I believe this appeal requires an answer to precedent-setting questions of exceptional importance:

The questions concern whether induced infringement can be used to nullify a provision of the Hatch-Waxman Amendments. Congress specified in Hatch-Waxman that when a drug is no longer patented and is FDA-approved for unpatented uses, a patent on one method of using the drug cannot be allowed to block the sale and use of the drug for the other, unpatented purposes. *See* 21 U.S.C. § 355(j)(2)(A)(viii). The statutory mechanism is a "carve-out": a generic manufacturer can adopt a "skinny label," deleting the patented indication and labeling the product only for unpatented indications, and avoid claims that the label induces infringement. The questions are: Can the generic manufacturer nonetheless

be held liable for induced infringement based on evidence that would be available in *every* carve-out case—the skinny label itself and product materials that describe the generic drug product as the AB-rated generic equivalent of the brand product, but do not even mention the patented method? And even if the generic manufacturer were found to have encouraged infringement, can it be held liable for infringement that it did not cause—*e.g.*, if the direct infringer undisputedly did not see the communication that supposedly encouraged infringement?

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INTRODUCTION

A divided panel has handed down this Court's most important infringement decision in years. After seven unchallenged years on the market, Teva was sued and found liable to GSK for $235 million in lost profits—for selling an unpatented drug labeled for unpatented uses. Teva followed the special pathway Congress created so generic drugs can enter the market while steering clear of method-of-use patents: it adopted a "skinny label"—one that included only the two unpatented indications and "carved out" GSK's patented method. But this Court held, over Chief Judge Prost's dissent, that Teva induced infringement *despite* the carve-out, because Teva described its skinny-labeled product as the generic equivalent of GSK's product. If that can be inducement, as the majority held, *every* skinny-labeled generic is at risk, and the carve-out statute is a dead letter.

Congress authorized carve-outs for a crucial purpose: ensuring "that one patented use will not foreclose marketing a generic drug for other unpatented ones." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 415 (2012). Otherwise a narrow method claim, like GSK's, could block generics long after the drug itself goes off-patent. But the panel's opinion "nullifies" the carve-out statute. Dissent 3. Commentators and analysts immediately recognized as much, describing

it as a "monumental,"[1] "major decision"[2] that "stretche[s]" inducement liability[3] in a "broad range of inducement cases" and threatens the viability of carve-outs.[4]

Under decades of precedent, merely marketing the skinny-labeled product does not induce infringement. Inducement requires proof that (1) a defendant affirmatively encouraged others to infringe, (2) during the term of the patent, and (3) the encouragement actually led to direct infringement. The panel created conflicts on all three prongs.

First, the panel emphasized that Teva expected some infringement would *occur*, but mere knowledge is "irrelevant" without action to *encourage* infringement. Teva marketed a product that it described the same way FDA and all generic

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[1] Zachary Silbersher, *Can Amarin Benefit from the* GSK v. Teva *Decision Regarding Induced Infringement for Off-Label Sales?*, Markman Advisors (Oct. 7, 2020), https://www.markmanadvisors.com/blog/2020/10/7/can-amarin-benefit-from-the-gsk-v-teva-decision-regarding-induced-infringement-for-off-label-sales.

[2] Kyu Yun Kim et al., *A Major Decision Evaluating the Effect of a Skinny Label in a Post-Launch, Non-Hatch Waxman Litigation, Jury Trial World*, mondaq (Oct. 15, 2020), https://www.mondaq.com/unitedstates/patent/994650/a-major-decision-evaluating-the-effect-of-a-skinny-label-in-a-post-launch-non-hatch-waxman-litigation-jury-trial-world.

[3] Kevin E. Noonan, GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc. (Fed. Cir. 2020), Patent Docs (Oct. 8, 2020), https://www.patentdocs.org/2020/10/glaxosmithkline-llc-v-teva-pharmaceuticals-usa-inc-fed-cir-2020.html.

[4] Dani Kass, *Generics Worry Fed. Circ. Blew Up 'Routine' Labeling Practice*, Law360 (Oct. 7, 2020), https://www.law360.com/articles/1317312/generics-worry-fed-circ-blew-up-routine-labeling-practice.

manufacturers do: as "AB-rated" to the brand product. That does not actively induce infringement of the patented method.

Second, the panel relied on supposed inducement from *before* the patent-in-suit issued, merely because Teva archived a press release on its website. Neither pre-patent nor passive activity can actively induce.

Third, the panel eliminated the critical causation element. The district court detailed overwhelming and uncontroverted testimony that Teva's actions had no impact on physicians' prescribing behavior. The majority did not dispute the one-sided evidence; it said that requiring proof of causation was "an incorrect legal standard." Op. 16.

Under the majority's redefinition of inducement, *every* generic on the market with a skinny label is at risk, and *no* generic will risk using a skinny label in the future. Copycat litigation has already begun: a generic that launched last month with a carve-out already faces a new inducement suit, seeking lost profits and an injunction. The full Court should take up these important issues, restore consistency to this Court's precedents, and save the carve-out statute from nullification.

BACKGROUND

I. Congress created "carve-outs" so that narrow method patents cannot block generic drugs from being sold for noninfringing uses.

Carve-outs are a key way of bringing low-cost generic drugs to market. Congress determined that method-of-use patents alone must not prevent the sale of

generic products for noninfringing uses. Accordingly, a generic company can submit a "Section viii statement" informing FDA that it will omit ("carve out") any reference to a patented indication from its product's labeling. *See* 21 U.S.C. § 355(j)(2)(A)(viii). This procedure prevents brand companies from "maintain[ing] de facto indefinite exclusivity over a pharmaceutical compound by obtaining serial patents for approved methods of using the compound." *AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1380 (Fed. Cir. 2012).

Congress knew that carve-outs "would result in some off-label infringing uses." *Takeda Pharm. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015). That is because when physicians prescribe drugs for patented uses, pharmacies may fill those prescriptions with generic versions (indeed, state law often requires it). *Id.* at 633. Hatch-Waxman "enable[s] the sale of drugs for non-patented uses" *even if* some off-label sales would naturally occur. *Id.* at 631.

II. Teva follows the carve-out procedure, but the panel majority sustains a $235 million jury verdict for induced infringement.

This case is about an off-patent drug, carvedilol (brand-name Coreg), with substantial noninfringing uses. The patent-in-suit covered only one narrow method of treating congestive heart failure (CHF), which represented less than 18% of carvedilol prescriptions. Op. 5, 18.

1. Carvedilol is FDA-approved for (1) managing hypertension, (2) treating mild-to-severe CHF, and (3) treating heart dysfunction following a heart

attack ("post-MI LVD"). Dissent 8. The patent on the carvedilol compound expired in 2007. Op. 3. GSK also obtained two patents claiming methods of treating CHF. Op. 4.

GSK spent nearly $1 billion promoting Coreg as "a heart failure drug." Appx11114-11115, Appx10508-10509. Using carvedilol became the "standard of care" for treating symptomatic CHF—detailed in textbooks, taught to medical students, and incorporated into the CHF guidelines of the American College of Cardiology and American Heart Association. Dissent 14; Appx10385, Appx11147-11152.

Teva and thirteen other manufacturers sought FDA approval to market generic carvedilol after the patent on the compound was set to expire. Teva originally submitted a Paragraph IV certification that GSK's method-of-treatment patents were invalid. GSK did not sue; it put one patent into reissue proceedings to narrow the claims, and it delisted the other from FDA's Orange Book. Dissent 9, 12.

In 2004, FDA tentatively approved Teva's ANDA with all three indications. But in 2007, with expiration of the compound patent approaching, Teva decided to carve out the CHF indication. Its "skinny label" included only the unpatented indications—hypertension and post-MI LVD. Dissent 8-9.

Eight companies launched skinny-labeled generic carvedilol in September 2007. GSK did not sue. By 2008, generic carvedilol was selling at $.02 and Coreg at $2.33 per pill, and GSK had less than 8% of the market. Dissent 12; Appx6769.

In 2008, GSK's patent reissued as the '000 patent. The new, narrower method claimed only *some* uses of carvedilol to treat CHF—*i.e.*, administered daily, with one of three specific ACE-inhibitors, for more than six months, for the specific purpose of decreasing mortality caused by CHF. Op. 5. Only a small fraction of carvedilol prescriptions—at most 17.1%—were for infringing uses. Op. 18. GSK did not then assert its reissue patent.

In 2011, after GSK's original method-of-use patents had been delisted, FDA directed Teva to amend its carvedilol label to add the information that had previously been carved-out, and Teva did so. Op. 6.

2. In 2014, eleven months before the '000 patent expired, GSK sued Teva for inducing infringement. Op. 6. GSK sought nearly $750 million in lost profits—ten times Teva's revenue from *all* carvedilol sales ($74.5 million, for a net loss of $13 million). Dissent 13 & n.3.

GSK sought to prove inducement to the jury through its expert, Dr. McCullough, who GSK represented would "absolutely" testify that he read and relied upon Teva's labels in making infringing prescriptions. Dissent 14. But on the stand, Dr. McCullough testified that he did not read Teva's label before he started

administering carvedilol, that nothing changed in his prescribing practices after generic launch, and that generic substitution happened "automatic[ally]" at pharmacies. Dissent 14-15.

The jury nonetheless awarded GSK $235 million in damages.

3. The district court (Stark, C.J.) granted Teva JMOL. Appx1-27 (313 F. Supp. 3d 582 (D. Del. 2018)). The court concluded that there was no evidence Teva's skinny label caused physicians to infringe, both because it did not encourage the patented method-of-use, and because both sides' physician witnesses testified that they did not read Teva's label before prescribing carvedilol. Appx13-15.

The court also examined the other materials GSK introduced: press releases (both predating the patent) announcing tentative and final FDA approval,[5] and product catalogs that described generic carvedilol as the AB-rated generic equivalent of Coreg. None included the elements of the claimed method. And as the district court recognized, accurately stating that generic carvedilol was AB-rated by FDA—found therapeutically equivalent, as labeled, to Coreg—did not even arguably advocate infringement of the patented method. Appx15-16.

[5] The 2004 press release announced FDA's "tentative approval," stating that "Carvedilol Tablets are the AB-rated generic equivalent of GlaxoSmithKline's Coreg® Tablets and are indicated for treatment of heart failure and hypertension." Appx6347. Only later did Teva carve-out CHF. Subsequently, the 2007 press release announced final approval of Teva's "Generic version of GlaxoSmithKline's cardiovascular agent Coreg® (Carvedilol) Tablets." Appx6342.

Furthermore, even if these materials could have encouraged infringement, the district court concluded, a "vast amount of evidence" from *both* parties' experts showed that they had not *caused* infringement. Appx20. GSK provided no evidence that physicians had relied on Teva's label, product guides, or press releases in prescribing carvedilol. And overwhelming evidence showed that doctors' prescribing decisions were driven by other sources, including GSK's promotion and cardiologists' standards of care. Appx18-21.

The district court also concluded that GSK did not present substantial evidence to support causation after Teva amended its label, because GSK conceded that after the label amendment, physicians' practices and GSK's market share were unaffected. Appx24.

4. This Court disagreed, over Chief Judge Prost's 33-page dissent. For evidence of inducement, it pointed to Teva's labels (including the skinny label),[6] product catalogs, and pre-patent press releases, and to testimony that Teva expected to "get sales" resulting from CHF prescriptions. Op. 14, 16.

As to causation, the majority held that the district court "applied an incorrect legal standard," and that GSK was not required to prove that Teva actually influenced doctors. Op. 16. The majority stated that once a plaintiff proves that a

[6] The majority did *not* suggest that the skinny label actually instructed the patented method.

defendant marketed "an identical product" with the expectation that it would (sometimes) be used for "infringing activity, the criteria of induced infringement are met." *Id.*

Chief Judge Prost dissented. She observed 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 product] was approved, or could be used, to treat CHF." Dissent 8, 10. She explained that the majority contradicted longstanding circuit precedent holding that a generic label that carves out the patented method-of-use cannot induce infringement, Dissent 19-20; that inducement requires an affirmative act that *encourages* others to infringe an already-issued patent, Dissent 23-25; and that an inducer's communications must actually cause others to infringe to support inducement liability, Dissent 21, 27-32.

Chief Judge Prost recognized that the practical implications were enormous: the majority's decision both "nullifies Congress's statutory provision for skinny labels," by "creating infringement liability for any generic entering the market with a skinny label," and "discourages generics from entering the market in the first instance." Dissent 3, 17-19, 32-33.

ARGUMENT

I. The panel's multiple departures from longstanding precedent threaten any product with a carve-out.

The panel's decision contradicts multiple lines of settled precedent, eviscerates the Section viii carve-out statute, and throws inducement doctrine into disarray. Even a generic manufacturer that does "everything right" risks a jury verdict awarding up to six years of lost profits, and has no hope of summary judgment or JMOL. Dissent 2. The same evidence deemed "sufficient" here—*e.g.*, knowledge that third parties might infringe or truthful references to FDA's "therapeutic equivalence" rating—will be available in *any* carve-out case. The effects of these departures from precedent are seismic.

A. The panel's decision nullifies the carve-out statute.

The entire point of the carve-out statute is to allow access to generic drugs with non-infringing uses. "[O]ne patented use"—especially one as narrow as GSK's—cannot be allowed to block competitors from "marketing a generic drug for other unpatented ones." *Caraco*, 566 U.S. at 415. But by upholding massive liability for distributing an unpatented product, even *without* having encouraged the patented method, the panel enabled just such a block. Its holding directly contradicts this Court's carve-out precedent in multiple respects—without trying to distinguish it.[7]

[7] Commentators have noted that "[s]urprisingly, the majority's decision does not even discuss the statutory framework permitting skinny labeling." Paul Dietze et

1. Crucially, "mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003). For exactly that reason, this Court squarely rejected the notion that a carved-out product induces infringement based on "market realities"—*i.e.*, "even if [the] generic drug is formally approved only for unpatented uses, pharmacists and doctors will nonetheless substitute the generic for all indications." *AstraZeneca*, 669 F.3d at 1380. A generic manufacturer's "knowledge is *legally irrelevant*" if a physician writes an infringing prescription "without inducement." *Warner-Lambert*, 316 F.3d at 1364 (emphasis added). That is especially true "where a product has substantial noninfringing uses," as carvedilol did. *Id.* at 1365; Op. 18.

The majority flouted that rule. It focused on testimony that Teva "expect[ed]" to "get sales" representing carvedilol prescribed for the carved-out indication. Op. 14. And it wrongly equated that expectation with encouraging "direct infringing activity." Op. 16. That testimony is no different from the evidence of pharmacy substitution and other "market realities" advanced in *AstraZeneca* and *Warner-Lambert*, which this Court rejected because it "would, in practice, vitiate [Section

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al., *Fed Circ. Ruling Is Troubling for Generic Drug Manufacturers*, Law360 (Oct. 21, 2020), https://www.law360.com/articles/1320956/fed-circ-ruling-is-troubling-for-generic-drug-manufacturers; *accord* Silbersher, *supra* ("majority opinion strangely fails to address" the carve-out precedents).

viii] by enabling … infringement claims despite the [carve-out]." *AstraZeneca*, 669 F.3d at 1380; *see Warner-Lambert*, 316 F.3d at 1364-65 (rejecting inducement argument even "assuming that [the generic] is 'counting on' sales for off-label uses"); *Takeda*, 785 F.3d at 633. The panel's decision will equally "vitiate" Section viii: plaintiffs can offer this type of testimony in literally *every* carve-out case. Dissent 20, 32.

2. The panel struck a second blow to Section viii with its equally limitless view of active inducement. It relied on Teva's skinny label, without disputing that the CHF indication was fully carved-out, and on accurate descriptions of Teva's product as an AB-rated generic equivalent to Coreg. These facts will exist in *literally any carve-out case*. Again the panel refused to acknowledge, much less distinguish, the caselaw it shredded.

For a generic to induce infringement with a skinny-labeled product, it "must encourage, recommend, or promote infringement" of the patented method. *Takeda*, 785 F.3d at 631 (rejecting inducement claim where label mentioned but did not instruct the patented use); *accord Warner-Lambert*, 316 F.3d at 1364; *Allergan, Inc. v. Alcon Labs.*, 324 F.3d 1322, 1333-34 (Fed. Cir. 2003); *Grunenthal GMBH v. Alkem Labs. Ltd.*, 919 F.3d 1333, 1336 (Fed. Cir. 2019); *see also Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1321, 1324 (Fed. Cir. 2012). And in the rare case where this Court has found inducement, the key was the label's content

(which carved out too little); plaintiffs cannot rely "merely [on] the planned distribution of the generic drug." *AstraZeneca LP v. Apotex Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010). "This requirement of inducing acts is particularly important in the [generic-drug] context because [Hatch-Waxman] was designed to enable the sale of drugs for non-patented uses even though this would result in some off-label infringing uses." *Takeda*, 785 F.3d at 631.

The panel decision eviscerates that active-inducement requirement. First, Teva's skinny label did not mention the patented method, much less "encourage, recommend, or promote" its many elements. Instructing only "noninfringing use[s]" should weigh *against* liability. *Sanofi v. Watson Labs. Inc.*, 875 F.3d 636, 646 (Fed. Cir. 2017). Yet the panel held that the skinny label was evidence of liability. Op. 16 ("the FDA labels"); Dissent 17-20.

Second, Teva's press releases and product materials accurately described its product as an AB-rated generic equivalent of Coreg. Op. 6, 12, 15-16. That echoed FDA's press release touting approval of "generic versions of Coreg (carvedilol)." Dissent 10. FDA developed and must publicize the AB rating; as GSK's expert testified, it means that, *when administered as labeled*, the generic drug is therapeutically equivalent to the brand drug. Dissent 16, 26-27. The Patent Act does not subject generics to crippling liability for repeating FDA's findings. Dissent 27 n.9.

Indeed, descriptive *product* information cannot support liability for inducing infringement of a carved-out *method*. "Infringement only exists where there is evidence that goes beyond a product's characteristics or the knowledge that it may be put to infringing uses." *Takeda*, 785 F.3d at 639 (citation omitted).

The panel decision does not mention, much less apply, this line of cases.[8] Rather, it echoes the *Takeda dissent*, which *disagreed* with key premises in the Court's caselaw—that Hatch-Waxman was designed to allow generic launch with skinny labels even if some off-label infringement would result, and that a skinny label must promote infringement in order to induce. *See* 785 F.3d at 635-36 (Newman, J., dissenting); *see also Bayer*, 676 F.3d at 1329 (Newman, J., dissenting) (disagreeing with holding that label could not induce infringement without instructing the patented use).

If truthfully echoing FDA's description of a skinny-labeled product as "the AB generic equivalent of Coreg®" is enough for inducement liability, Op. 16, the carve-out statute truly has been "nullifie[d]." Dissent 3.

[8] In the cases the majority cited, the label or other instructions affirmatively induced infringement. Op. 11-12, 16-17; Dissent 17-18. The only cited skinny-label case involved an *inadequate* carve-out; the label still instructed infringement. Op. 12 (citing *AstraZeneca*, 633 F.3d at 1060); pp. 12-13, *supra*.

B. The panel's decision allows juries to find inducement from conduct predating the patent.

Even if Teva's press releases *had* encouraged infringement of GSK's narrow method, reliance on them creates a further conflict in circuit law. Until this decision, the rule was clear: "[a]s a matter of law § 271(b) does not reach actions taken before issuance of the adverse patent." *Nat'l Presto Indus., Inc. v. W. Bend Co.*, 76 F.3d 1185, 1196 (Fed. Cir. 1996). The panel held that that rule did not shield the 2007 press release because it was archived on Teva's website.[9] That squarely contradicts § 271(b)'s express requirement of "*active*[]" inducement: the inducing acts after patent issuance must be "'affirmative,'" not "passive." Dissent 23 (quoting *Takeda*, 785 F.3d at 632 n.4, and citing other cases).

C. The panel's decision hollows out inducement doctrine.

The majority opinion also throws this Court's inducement doctrine into disarray by eliminating the causation requirement this Court has long recognized.

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) (citations omitted). Talk is not enough; the infringer must both listen and be moved.

[9] The panel offered *no* justification for reliance on the 2004 press release—not even a website footer, for there was none. Op. 15.

The district court granted JMOL because overwhelming, uncontroverted evidence showed that Teva's actions did not influence doctors to do anything. Appx20. The majority never disputed the district court's assessment of the evidence. Rather, it held that the court had "applied an incorrect legal standard"—that "precedent makes clear that" no causation showing is required if a defendant provided and marketed "an identical product" with the expectation of infringing uses. Op. 16. If even skinny-labeled generics are treated as "identical" to the brand, every carve-out case can clear that low bar.[10]

This Court's precedent is indeed "clear," but in the opposite direction: plaintiffs must prove "that the [inducement] defendants' actions led to direct infringement." *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1274 (Fed. Cir. 2004); *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1329 (Fed. Cir. 2016). The majority provided no rationale for discarding

[10] Neither the majority nor the dissent thought the outcome should be different for the "skinny" and "full" label periods. Causation is why: as the dissent explained, if Teva did not induce infringement during the skinny-label period, GSK did not prove that the label change caused any infringement. GSK conceded that the amendment had no impact on GSK's market share, Appx12204-12205, and GSK's experts agreed that it had no impact on physicians' prescribing practices, Dissent 30-32; Appx10754.

that precedent—which it did not even mention—and excising the causation element.[11]

II. The grave harm to competition makes this decision exceptionally important.

This decision "is no small matter." Dissent 3. It "nullifies Congress's statutory provision for skinny labels," *id.*, which threatens future generic launches and exposes many current skinny-labeled products to new claims of infringement after years on the market. That would be "the death knell for carve outs."[12]

Already, many commentators and analysts have identified the decision as one of the most consequential—and harmful—on either infringement or Hatch-Waxman. They have called it a "very controversial"[13] and "major decision"[14] that "represents a fairly monumental change in the law of induced infringement" and "upset[s] the expected scope of liability for most generic launches with skinny labels."[15]

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[11] The majority cited *Power Integrations* only for the general proposition that circumstantial evidence can establish "the intent element." Op. 11.

[12] Brenda Sandburg, *Rx Drug Promotion: Potential Enforcement Worries*, Pink Sheet (Nov. 19, 2020), https://pink.pharmaintelligence.informa.com/PS143323/Rx-Drug-Promotion-Potential-Enforcement-Worries.

[13] Sandburg, *supra*.

[14] Kim, *supra*.

[15] Silbersher, *supra*; *see* Kass, *supra*.

And brand-name companies are proving them right. Following this decision, a generic that just launched with a carve-out now faces inducement litigation, relying on indistinguishable evidence—awareness of potential direct infringement, references to the "AB rating," and archived press releases announcing FDA approval—and demanding lost profits. Compl., ¶¶ 94-113, *Amarin Pharma, Inc. v. Hikma Pharm. USA Inc.*, No. 20-cv-1630 (D. Del. filed Nov. 30, 2020). Generics now face "drastically increase[d] … potential liability for launching with a skinny label,"[16] with "large and meaningful damages" from lost profits "more likely.[17]

As the Chief Judge recognized, this expansion of liability will "discourage[] generics from entering the market" with a skinny label if this decision is not promptly reconsidered. Dissent 33. Section viii is intended to let generics *avoid* the thirty months of litigation that a Paragraph IV certification triggers. But under this decision, Section viii becomes *riskier* than pre-launch Paragraph IV litigation, because of the massive damages exposure. Against that enormous down-side risk, the up-side may be just pennies per pill. *See* p. 6, *supra*. The result will be *less* access to low-cost drugs *even after* compound patents expire—precisely contrary to Congress's intent and patients' interests. Dissent 1.

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[16] Silbersher, *supra*.

[17] StreetInsider, GSK v. Teva *'Skinny Label' Ruling Positive for Amarin (AMRN) – Citi* (Oct. 5, 2020), https://bit.ly/2UmjyRE.

* * * *

At a minimum, given the decision's catastrophic impact on FDA's generic-drug program and GSK's use of FDA's AB rating to prove inducement, the Court should not deny rehearing without first inviting the federal government's views. *E.g.*, *Guarantee Co. of N. Am., USA, Inc. v. Ikhana, LLC*, 959 F.3d 1354, 1354 (Fed. Cir. 2020).

CONCLUSION

Rehearing en banc should be granted.

Respectfully submitted.

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December 2, 2020

ADDENDUM

United States Court of Appeals for the Federal Circuit

GLAXOSMITHKLINE LLC, SMITHKLINE BEECHAM (CORK) LIMITED,
Plaintiffs-Appellants

v.

TEVA PHARMACEUTICALS USA, INC.,
Defendant-Cross-Appellant

2018-1976, 2018-2023

Appeals from the United States District Court for the District of Delaware in No. 1:14-cv-00878-LPS-CJB, Chief Judge Leonard P. Stark.

Decided: October 2, 2020

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ANDREW CURTIS NICHOLS, Winston & Strawn LLP, Washington, DC, for amicus curiae Association for Accessible Medicines. Also represented by GEORGE C. LOMBARDI, KURT A. MATHAS, Chicago, IL; JEFFREY FRANCER, The Association for Accessible Medicines, Washington, DC.

Before PROST, *Chief Judge*, NEWMAN and MOORE, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* NEWMAN.

Dissenting opinion filed by *Chief Judge* PROST.

NEWMAN, *Circuit Judge*.

GlaxoSmithKline LLC and SmithKline Beecham (Cork) Ltd. (collectively, "GSK") charged Teva Pharmaceuticals USA, Inc. with infringement of GSK's Reissue Patent No. RE40,000 ("the '000 patent"). Trial was

held in the United States District Court for the District of Delaware; the jury found the patent valid and infringed, and assessed damages. The jury also found that the infringement was willful. The district court then granted Teva's motion for judgment of non-infringement as a matter of law.[1] GSK appeals the JMOL, and Teva conditionally cross-appeals the damages verdict. No appeal is taken from the verdict of patent validity.

On appellate review, we reverse the grant of JMOL and reinstate the jury verdicts, for the verdicts are supported by substantial evidence. We remand to the district court for appropriate further proceedings.

BACKGROUND

The GSK patents

This litigation concerns the medicinal product having the common name "carvedilol." United States Patent No. 4,503,067 ("the '067 patent") was issued in 1985 for carvedilol and related compounds; this patent expired on March 5, 2007.

The FDA initially approved carvedilol for treatment of hypertension and the product was marketed with the brand name Coreg®. Scientists continued to study carvedilol, and discovered its efficacy in treating congestive heart failure. In May 1997, the FDA approved carvedilol for the additional treatment of congestive heart failure. The method was patented in United States Patent No. 5,760,069 ("the '069 patent") entitled "Method of Treatment for Decreasing Mortality Resulting from Congestive Heart Failure." The '069 patent was issued on June 2, 1998, and describes and claims treatment with a

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[1] *GlaxoSmithKline LLC v. Teva Pharm. USA, Inc.*, 313 F. Supp.3d 582 (D. Del. 2018) ("Dist. Ct. Op.").

combination of carvedilol and one or more of an angiotensin-converting enzyme ("ACE") inhibitor, a diuretic, and digoxin.[2] The '069 patent was listed in the FDA's Orange Book with use code U-233, "decreasing mortality caused by congestive heart failure." J.A. 6868. The FDA in 2003 approved this Coreg® combination for use by patients suffering from left ventricular dysfunction following a myocardial infarction.

Teva's generic carvedilol, and reissue of the '069 patent

In March 2002, Teva applied for FDA approval of its generic carvedilol, certifying in the Abbreviated New Drug Application ("ANDA") under Paragraph III of the Hatch-Waxman Act that its product would not be launched until the '067 patent expired in March 2007. Teva also made a Paragraph IV certification that the '069 patent was "invalid, unenforceable, or not infringed," and, on May 24, 2002, Teva sent GSK a Paragraph IV notice stating that the claims of the '069 patent are invalid for anticipation or obviousness. Teva received FDA "tentative approval" for this ANDA in 2004, "for treatment of heart failure and hypertension," to become effective on expiration of the '067 patent. Teva, on June 9, 2004, issued a press release to this effect. Press Release, Teva Pharm. Ind. Ltd. *Teva Announces Tentative Approval of Carvedilol Tablets*, Business Wire (June 9, 2003).

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[2] A 65% reduction in mortality was observed in the clinical trial, whereby the FDA terminated the clinical trial so that the patients on placebo could receive the treatment. Milton Packer, M.D. *et al.*, *The Effect of Carvedilol on Morbidity and Mortality in Patients with Chronic Heart Failure*, 334 NEW ENG. J. MED. 1349, 1349 (1996) (reporting 65% reduction in risk of death in clinical trials).

GSK on November 25, 2003 filed an application to reissue the '069 patent, as provided in 35 U.S.C. § 251. The '000 patent was issued on January 8, 2008; the italicized text in claim 1 illustrates the limitations added by reissue:

> 1. A method of decreasing mortality caused by congestive heart failure in a patient in need thereof which comprises administering a therapeutically acceptable amount of carvedilol in conjunction with one or more other therapeutic agents, said agents being selected from the group consisting of an angiotensin converting enzyme inhibitor (ACE), a diuretic, and digoxin,
>
> *wherein the administering comprises administering to said patient daily maintenance dosages for a maintenance period to decrease a risk of mortality caused by congestive heart failure, and said maintenance period is greater than six months.*

'000 patent, col. 8, ll. 30–40 (emphasis added). On expiration of the '067 patent in 2007, Teva launched its generic carvedilol. Teva's label dated "8/2007" states:

> 1 INDICATIONS AND USAGE
>
> 1.1 Left Ventricular Dysfunction following Myocardial Infarction . . .
>
> 1.2 Hypertension . . .

The label stated that "Carvedilol 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)." J.A. 5508. Teva's

press releases and marketing materials state that its carvedilol is "an AB Rated generic of Coreg® Tablets."[3]

In 2011 the FDA required Teva to amend its carvedilol label to be "identical in content to the approved [GSK Coreg®] labeling (including the package insert and any patient package insert and/or Medication Guide that may be required)." Dist. Ct. Op. at 587. Teva amended its label to include the indication for treatment of heart failure, as required by the FDA. Dist. Ct. Op. at 587.

GSK's suit for infringement

On July 3, 2014, GSK filed suit for induced infringement of the '000 patent. As defendants, GSK named Teva and Glenmark Pharmaceuticals USA, the two largest providers of generic carvedilol. The action against Glenmark was severed and stayed.

Trial was to a jury. Teva presented the defenses of patent invalidity and non-infringement. Teva argued that since it had omitted ("carved out") from its initial (2007) label the indication and prescribing information for treatment of congestive heart failure, citing the carve-out authorization in 21 U.S.C. § 355(j)(2)(A)(viii), then Teva could not be found to induce prescribing physicians to infringe the '000 patent, at least not before Teva amended its label to include all of the information that the FDA had approved for Coreg®.

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[3] The "AB rating" is an FDA coding system "to allow users to determine quickly whether the Agency has evaluated a particular approved product as therapeutically equivalent to other pharmaceutically equivalent products first letter) and to provide additional information on the basis of FDA's evaluations (second letter)." U.S. Food & Drug Admin., *Approved Drug Products with Therapeutic Evaluations* (FDA Orange Book, preface).

Teva also argued that to establish liability for induced infringement, GSK is required to prove that Teva directly communicated with the direct infringers and "caused" them to directly infringe the method in the '000 patent. The district court instructed the jury that:

> Teva cannot be liable for induced infringement where GSK does not show that Teva successfully communicated with and induced a third-party direct infringer and that the communication was the cause of the direct infringement by the third-party infringer.

Jury instruction 4.2.4. The jury was instructed that proof of induced infringement may be based on circumstantial evidence:

> GSK is not required to present hard proof of any direct infringer physician stating, for example, that she read Teva's labels or other Teva materials and that these labels or other Teva materials caused her to prescribe Teva's generic carvedilol in an infringing manner. GSK must prove that Teva's actions led physicians to directly infringe a claim of the '000 patent, but GSK may do so with circumstantial – as opposed to direct – evidence.

Jury instruction 4.2.4.

Both sides presented witnesses, documents, and argument. The jury found that Teva induced infringement of claims 1–3 during the period starting January 8, 2008 (the date of the '000 patent's issuance) to April 30, 2011 (the last day before Teva amended its label); and that Teva induced infringement of claims 1–3 and 6–9 during the amended label period starting May 1, 2011 and ending June 7, 2015 (the date of expiration of the '000 patent). The jury assessed damages based on a combination of lost profits and royalty, and found that the infringement was willful.

Grant of judgment as a matter of law

The district court granted Teva's motion for JMOL, stating that the verdict of induced infringement was not supported by substantial evidence because "GSK failed to prove by a preponderance of the evidence that ***'Teva's*** alleged inducement, as opposed to other factors, actually ***caused*** the physicians [i.e., as a class or even at least one of them] to directly infringe,' by prescribing generic carvedilol and to do so for the treatment of mild to severe CHF." Dist. Ct. Op. at 591 (emphases and bracketed text in original). The district court explained that: "Without proof of causation, which is an essential element of GSK's action, a finding of inducement cannot stand." *Id.*

The district court referred to the many sources of information available to prescribing physicians, such as the American Heart Association, the American College of Cardiology, and various publications. The court stated that GSK's Coreg® label and promotion of carvedilol had already informed physicians about the uses of Coreg®. Dist. Ct. Op. at 594. Cardiologists testified that they knew of the various uses of carvedilol before the FDA required Teva to amend its label. The court stated that "even in September 2007, when generic companies (including Teva) began selling carvedilol, doctors relied on guidelines and research, as well as their own experience, in addition to GSK marketing." *Id.*

The district court concluded that: "A reasonable factfinder could only have found that these alternative, non-Teva factors were what caused the doctors to prescribe generic carvedilol for an infringing use." *Id.* at 597. The court ruled: "In sum, substantial evidence does not support the jury's finding on causation, and therefore does not support its verdict that Teva is liable for induced infringement, during both the skinny and full label periods." *Id.*

GSK appeals, arguing that the district court erred in law and in fact, and that the jury's finding of induced infringement was supported by substantial evidence, and should be sustained.

DISCUSSION

Standards of review

For procedures not unique to patent law, the district court is subject to the standards of the regional circuit and is reviewed on that basis. The Third Circuit holds that when trial is to a jury, the district court should grant JMOL "sparingly" and "only if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability." *Marra v. Phila. Hous. Auth.*, 497 F.3d 286, 300 (3d Cir. 2007); *see also Moyer v. United Dominion Indus.*, 473 F.3d 532, 545 n.8 (3d Cir. 2007) (same).

The Third Circuit provides that a "court may grant a judgment as a matter of law contrary to the verdict only if 'the record is critically deficient of the minimum quantum of evidence' to sustain the verdict." *Acumed LLC v. Advanced Surgical Servs., Inc.*, 561 F.3d 199, 211 (3d Cir. 2009). The Federal Circuit has well recognized such a requirement for jury trials, stating, for example: "To prevail on a renewed motion for JMOL following a jury trial, a party must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusion(s) implied by the jury's verdict cannot in law be supported by those findings." *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1326 (Fed. Cir. 2016). *See also, e.g.*, *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1309 (Fed. Cir. 2009) (infringement is a question of fact, and a jury verdict thereon is reviewed for support by substantial evidence); *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1225 (Fed. Cir. 2014) ("A jury verdict will be set aside only

if the jury instructions were legally erroneous and the errors had prejudicial effect." (internal quotations omitted)).

We review the district court's grant of JMOL on this basis.

A

INDUCED INFRINGEMENT

The patent infringement statute includes 35 U.S.C. § 271(b):

> Whoever actively induces infringement of a patent shall be liable as an infringer.

GSK argues that the district court erred in law and fact. GSK states that Teva's marketing of carvedilol with knowledge and intent of its infringing use, and promotion of its generic product as the same as Coreg®, meet the legal requirements of active inducement of infringement. GSK states that there was substantial evidence whereby a reasonable jury could so find.

Teva responds that the district court correctly ruled that Teva could not be liable for inducing infringement, because cardiologists already knew of carvedilol and its uses, and Teva did not directly "cause" them to infringe.

GSK states that the district court erred in law, as shown in long-established and clear precedent that induced infringement may be shown by evidence that the accused inducer promoted the infringing use with knowledge that such use directly infringes the patent claims. GSK cites, *e.g., Toshiba Corp. v. Imation Corp.,* 681 F.3d 1358, 1365 (Fed. Cir. 2012) ("[W]here an alleged infringer designs a product for use in an infringing way and instructs users to use the product in an infringing way, there is sufficient evidence for a jury to find direct infringement."); *Lucent*, 580 F.3d, at 1318 ("Microsoft not only designed the accused products to practice the claimed invention, but also

instructed its customers to use the accused products in an infringing way."): *Ericsson,* 773 F.3d, at 1220, 1222 (finding induced infringement where alleged inducer advertised compliance with an infringing standard).

In *Global-Tech Appliances, Inc. v. SEB S.A.,* 563 U.S. 754 (2011), the Supreme Court explained that copying of a patented product is evidence of inducing infringement. *Id.* at 770–71. The Court had applied the principles of induced infringement to copyright issues in *MGM Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913 (2005), stating that "active steps . . . taken to encourage direct infringement, such as advertising an infringing use or instructing how to engage in an infringing use, show an affirmative intent that the product be used to infringe." *MGM* at 936 (citations omitted, ellipsis in original). The Court held that inducement to infringe is not negated when the direct infringers already knew of the infringing subject matter. *Id.*

Precedent has also established that "[a] plaintiff may . . . prove the intent element [of induced infringement] through circumstantial evidence, just as with direct infringement." *Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, 824 F.3d 1344, 1347 (Fed. Cir. 2016) (ellipsis in original). *See also Power Integrations*, 843 F.3d at 1335 ("Indeed, we have affirmed induced infringement verdicts based on circumstantial evidence of inducement (e.g., advertisements, user manuals) directed to a class of direct infringers (e. g., customers, end users) without requiring hard proof that any individual third-party direct infringer was actually persuaded to infringe by that material."); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1272 (Fed. Cir. 1986) ("Circumstantial evidence is not only sufficient, but may also be more certain, satisfying and persuasive than direct evidence").

These principles have been applied to the circumstances of FDA-regulated products; *see, e.g., Eli*

Lilly & Co. v. Teva Parenteral Meds., Inc., 845 F.3d 1357, 1369 (Fed. Cir. 2017) ("[E]vidence that the product labeling that Defendants seek would inevitably lead some physicians to infringe establishes the requisite intent for inducement."); *Sanofi v. Watson Labs. Inc.,* 875 F.3d 636, 645 (Fed. Cir. 2017) (finding induced infringement where the label "directs medical providers to information identifying the desired benefit for only patients with the patent-claimed risk factors" and "[t]here was considerable testimony that this label encourages . . . administration of the drug to those patients"); *AstraZeneca LP v. Apotex, Inc*., 633 F.3d 1042, 1060 (Fed. Cir. 2010) (finding induced infringement where "despite being aware of the infringement problem presented by the proposed label, Apotex nonetheless proceeded with its plans to distribute its generic drug product"); *Mentor H/S, Inc. v. Med. Device All., Inc.*, 244 F.3d 1365, 1379 (Fed. Cir. 2001) (finding induced infringement where the defendant "sold the [accused] device with the intention that doctors would use it to perform the patented method").

The jury received evidence that Teva's promotional materials referred to Teva's carvedilol tablets as AB rated equivalents of the Coreg® tablets. *See, e.g.*, Teva June 9, 2004 press release (J.A. 6347) (describing Teva's carvedilol as the "AB-rated generic equivalent of GlaxoSmithKline's Coreg® tablets.") *See also* Teva Spring 2008 Product Catalog (J.A. 6221); Teva's 2011 Generic Product Reference Guide (J.A. 6072) stating "AB Rated and bioequivalent to Coreg® Tablets". There was evidence that Teva's 2007 press release remained on Teva's website, and trial exhibit PTX 1301.0002 is a screenshot bearing the date "4/14/2015," with the caption "Sept. 06, 2007 1:55 PM 'Teva Announces Approval and Shipment of Generic Coreg® Tablets.'" (J.A. 6353). The record shows a screenshot dated 4/22/2015 captioned "Carvedilol Tablets [-] Generic of Coreg® Tablets" (PTX 860) (J.A. 4245–4246). In evidence were Teva's Monthly Prescribing Reference, 2012 and 2013

editions, which state that they provide "high-quality educational tools to serve as convenient, authoritative references in daily use" and are designed to be "a trusted tool in [the clinician's] clinical armamentarium." J.A. 6203. Also in evidence was the 2012 edition of Teva's *Health Systems Pharmacy Drug Reference* (J.A. 6192, *et seq.*).

Witnesses for both sides testified that cardiologists knew of carvedilol and the uses established for Coreg®. GSK's witness, Dr. McCullough, testified that doctors are "completely reliant" on information provided by the generic producers, and that doctors receive Teva's product catalogs, visit its website, and read its product guides. Trial Tr. June 19, 2017, at 1662. Dr. McCullough testified that he saw the 2004 press release, in which "Teva is telling doctors that they had received tentative approval for generic carvedilol, and that its final approval is anticipated in 2007." *Id.* at 1656. He testified that Teva was telling him, as a physician, that Teva was "expecting to have a generic version of GlaxoSmithKline Coreg that is AB rated, and that it is indicated for the treatment of heart failure." *Id.* at 1657.

Dr. McCullough discussed Teva's September 6, 2007 press release announcing that the FDA "has granted final approval for the company's Abbreviated New Drug Application (ANDA) to market its generic version of GlaxoSmithKline's cardiovascular agent Coreg® (Carvedilol) Tablets." Dr. McCullough told the jury that this release "indicates that we should be able to prescribe generic carvedilol for heart failure." Trial Tr., June 19, 2017, at 1659. He testified that "we're completely reliant on what [the generics] provide to us." *Id.* at 1662.

Dr. McCullough testified that Teva's Spring 2008 catalog lists Teva's carvedilol tablets next to Coreg® tablets and uses the phrase "AB rating," and that this would lead a doctor to believe that "they're therapeutically

interchangeable." Trial Tr., June 14, 2017, at 634–635. He stated that as to Teva's carvedilol "we had lots of information . . . that indicated that . . . it was a complete replacement. That in fact the two, the drug was the same, and all the information regarding it was the same." Trial Tr., June 19, 2017, at 1663. Dr. McCullough testified that if he just wrote Coreg on a prescription, the patient would get the generic unless he explicitly wrote "dispense as written" or "DAW." *Id.* at 1162..

Teva argued that it could not be liable for induced infringement because it had deliberately omitted, or "carved out" from its 2007 label, reference to congestive heart failure. Teva's Rule 30(b)(6) witness, Director of New Products Jennifer King, explained:

> Question: So is the expectation of Teva that when you carve out a particular indication, that Teva will still get sales of that drug for that indication once it's launched its product?
>
> Answer: It's a legal strategy, not a commercial strategy.
>
> ***
>
> Question: And so to make it specific to the issues here, if Teva has carved out congestive heart failure, but not hypertension and not post MILVD, Teva still expects to get sales where the doctor prescribed carvedilol for congestive heart failure, correct?
>
> Answer: Yes, unless the doctor feels strongly.
>
> Question: Writes brand only?
>
> Answer: Yes.

Trial Tr., June 13, 2017, at 488.

In response to the question whether "[b]ased on what Teva said in 2004 and 2007, any time after that . . . , did

you ever come to believe that Teva's generic carvedilol had not been approved for the treatment of heart failure?" Dr. McCullough answered: "No, I never knew it." Trial Tr., June 19, 2017, at 1661.

GSK also presented an expert witness on the regulatory process, Professor Erika Lietzan, who explained the drug approval process, and explained that the AB-rating means that "if the generic drug is used in accordance with its label, you would expect it to have the same clinical effect" as the brand drug. Trial Tr., June 13, 2017 at 534, 542. She introduced Teva's product catalogs that "list the AB ratings and they compare Teva's carvedilol with Coreg on that table with carvedilol on the left and Coreg on the right," id. at 582–83 (J.A. 10582–83). She stated that the FDA's "general position is that if you compare one product to another by name, you are implying the use of the product." *Id.* at 545.

Teva argued that the 2004 and 2007 press releases should not be considered as evidence of inducement because the '000 patent was not issued until January 8, 2008. Teva Br. 40, citing *Nat'l Presto Indus., Inc. v. West Bend Co.*, 76 F.3d 1185, 1196 (Fed. Cir. 1996) ("§271(b) does not reach actions taken before issuance of the adverse patent"). However, the evidence before the jury was that the 2007 press release remained on Teva's website throughout the life of the '000 patent with the caption "Sept. 06, 2007 1:55 PM 'Teva Announces Approval and Shipment of Generic Coreg® Tablets.'" Trial exhibit PTX 1301.0002 bearing the date "4/14/2015,"

The jury was correctly instructed that it could find inducement if 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." Jury instructions 4.2. The jury properly could consider Teva's continued affirmative

promotion of its carvedilol tablet as the AB generic equivalent of Coreg® which could be used as a cardiovascular agent, well after the issuance of the '000 patent. This evidence included the press release on Teva's website after issuance of the '000 patent, and the promotional catalogs circulated by Teva between 2008 and expiration of the '000 patent in 2015. The record includes Dr. McCullough's expert testimony that doctors are "completely reliant" on this type of promotional material from the generic producer. The jury found Teva liable for induced infringement during the period of the '000 patent.

The district court granted Teva's motion for JMOL, stating that "there is not legally sufficient evidence to support a finding that Teva, by listing its carvedilol as AB rated to Coreg® in product catalogs and reference guides, encouraged infringement." Dist. Ct. Op. at 594. The court's reason was that "physicians already knew how to use carvedilol for treating CHF" and thus infringement was not "caused" by Teva. *Id.* The district court applied an incorrect legal standard, for precedent makes clear that when the provider of an identical product knows of and markets the same product for intended direct infringing activity, the criteria of induced infringement are met. There was ample record evidence of promotional materials, press releases, product catalogs, the FDA labels, and testimony of witnesses from both sides, to support the jury verdict of inducement to infringe the designated claims for the period of the '000 reissue patent.

Precedent has recognized that the content of the product label is evidence of inducement to infringe; *see Vanda Pharm. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1129 (Fed. Cir. 2018) (holding that "[t]he contents of the label itself may permit the inference of specific intent to encourage, recommend, or promote infringement"); *Sanofi,* 875 F.3d at 646 ("The content of the label in this case permits the inference of specific intent to encourage the infringing use."). These rulings comport with

precedent on causation in tort liability, as in, *e.g., Tinnus Enter., LLC v. Telebrands Corp.,* 846 F.3d 1190, 1204 (Fed. Cir. 2017) (approving "the use of instruction manuals to demonstrate direct infringement by customers in the context of induced infringement"); *Golden Blount, Inc. v. Robert H. Peterson Co.*, 438 F.3d 1354, 1363 (Fed. Cir. 2006) ("[T]he instructions packaged with each device teach the infringing configuration.").

Applying the standards of law and precedent, there was substantial evidence to support the jury's verdict of inducement to infringe the '000 patent. We remark that our colleague in dissent applies an incorrect standard of review, for this court on appeal of a jury verdict does not find facts afresh, contrary to the substantial evidence standard. For example, the dissent finds that neither "Teva's press releases [nor] its product catalogs encourage doctors to practice the patented method," Diss. Op. at 22, although Dr. McCullough testified that doctors do read press releases and product catalogs, and even Teva's expert, Dr. Zusman, conceded that "it's possible" that doctors read these materials. Trial Tr., June 16, 2017 at 1238–1241.

Nor is this appeal a policy debate about whether GSK made enough money from carvedilol in past years, and therefore should not be permitted to enforce its patent on its discovery of this novel method of prolonging life for persons with congestive heart failure. The implications of the dissent's position are vast, and if enforcement of patents on new discoveries varies with the extent to which the patentee has profited from past discoveries, this is a

policy matter for Congress, not a factor in judicial review of jury verdicts.[4]

We conclude that there was substantial evidence to support the jury's findings of induced infringement, throughout the term of the '000 patent, on the entirety of the documentary and testimonial record concerning liability before and after Teva amended its label. The grant of JMOL is reversed; we remand for entry of judgment on the verdict.

B

DAMAGES

The jury received the calculation of GSK's damages expert that 17.1% of generic carvedilol sales during the period of infringement were for the method claimed in the '000 patent. Teva does not dispute this calculation. The jury assessed damages of $234,110,000 based on lost profits, plus royalty payments of $1,400,000. The verdict amount is about half of that presented by GSK's damages expert. Teva does not challenge quantum, but argues that, on correct instructions, Teva would have incurred no damages, or at most only a reasonable royalty.

Teva argues that the jury should have been instructed that GSK must prove that, for every infringing sale made by Teva, the direct infringer would have purchased the prescribed carvedilol as GSK's Coreg® branded product, and not from another generic producer. The district court had declined to present that instruction, explaining:

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[4] The dissent's proposed restriction on enforcement of patents on new uses of known products is a matter of public interest, for, as observed by *amicus curiae* Biotechnology Innovation Organization: "Developing innovative new uses of known substances has great societal value, but often requires significant time and expense." BIO Br. 1.

> The undisputed evidence is that [Teva's] generic carvedilol is interchangeable with the generic carvedilol of the non-party manufacturers; therefore, the generic carvedilol of these non-party manufacturers is an ***infringing alternative*** – and ***not*** a non-infringing alternative. These non-parties' products, thus, would not exist in the but-for world, which must be constructed to include "likely outcomes with ***infringement factored out of the economic picture."*** *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1350 (Fed. Cir. 1999) (emphasis added).

Memorandum Order (June 9, 2017) (emphasis in original). The district court recognized: "It is undisputed that, at all times relevant to the lost profits analysis, there were generic carvedilol tablets available from at least eight different generic manufacturers that were approved by the [FDA]," *id.* n.3, and stated that "[i]t doesn't matter whether the ***sales*** by other generic suppliers would be non-infringing, because the ultimate ***use*** of those products by doctors ***would*** be infringing and thus not a permissible consideration." *Id.* (emphasis in original).

Teva argues that it was incorrect to require the jury to ignore the reality of the marketplace, in which there were other producers of generic carvedilol who had not been sued for infringement. Teva states that the district court incorrectly instructed that: "The use of the acceptable substitutes also must not infringe the patent because they did not include all the features required by the patent. For example, the use of generic carvedilol supplied by companies other than Teva was not an acceptable non-infringing substitute." Jury instruction 6.3.3.

Teva also argues that the "prerequisite for lost profits" is "but-for causation," and not the *Panduit* factors on which the jury was instructed. Teva Reply Br. 4. Teva points out that pharmacies are allowed or required to substitute

generic products unless explicitly ordered otherwise, and that this would deprive GSK of all profits on its higher priced Coreg®.

GSK responds that the district court correctly held that generic carvedilol is not a non-infringing alternative, and that the court correctly stated that "the law is clear that a lost profits analysis must be based on a world in which infringement of the asserted patent does not exist, and therefore it does not allow for infringing alternatives to be available in the hypothetical 'but for' world." Memorandum Order (June 9, 2017), citing *Grain Processing*, 185 F.3d at 1350). *See generally Micro Motion, Inc. v. Kane Steel Co.*, 894 F.2d 1318, 1322 (Fed. Cir. 1990) ("There is precedent for finding causation despite an alternative source of supply if that source is an infringer or puts out a noninfringing product that is an unacceptable alternative, or has insignificant sales."). The district court correctly instructed the jury that the availability of carvedilol from other generic producers is not a "non-infringing substitute.")

We have considered all of Teva's arguments, and conclude that the jury instructions are in conformity to law. The damages verdict is not otherwise challenged, and is sustained.

CONCLUSION

We vacate the district court's grant of JMOL and reinstate the jury verdicts of infringement and damages. We remand for appropriate further proceedings, including consideration of GSK's post-trial motion based on the verdict of willful infringement.

VACATED AND REMANDED

Each party shall bear its own costs.

United States Court of Appeals for the Federal Circuit

GLAXOSMITHKLINE LLC, SMITHKLINE BEECHAM (CORK) LIMITED,
Plaintiffs-Appellants

v.

TEVA PHARMACEUTICALS USA, INC.,
Defendant-Cross-Appellant

2018-1976, 2018-2023

Appeals from the United States District Court for the District of Delaware in No. 1:14-cv-00878-LPS-CJB, Chief Judge Leonard P. Stark.

PROST, *Chief Judge*, dissenting.

Through the decades, many, including my colleagues, have spoken on the importance of patents in incentivizing innovation. The calls for robust patent protection have been particularly passionate in the pharmaceutical space. The critical balance of those patent rights, however, is public access to the innovation once patents have expired. Indeed, Congress designed the generic approval system with the express purpose of speeding the introduction of generic drugs to the market as soon as patents allow. Today, the Majority's decision undermines this balance by allowing a drug marketed for unpatented uses to give rise to liability

for inducement and by permitting an award of patent damages where causation has not been shown.

This case is about whether Teva induced infringement of GSK's reissue patent, RE40,000, by marketing its generic carvedilol of for *unpatented* uses through a "skinny label." The clear answer: Teva did not.

Congress provided for skinny labels for exactly these circumstances, *see* 21 U.S.C. § 355(j)(2)(A)(viii), such that the lone method covered in the '000 patent would not foreclose access to more affordable carvedilol. And Teva acted exactly as Congress intended. Teva waited until GSK's patent covering the carvedilol compound expired to launch its product covering two unpatented indications—hypertension and post-MI LVD. So, when GSK's '000 reissue patent later issued—reciting a narrow method of treating a third indication, CHF—Teva's skinny label did not even suggest using its product according to the patented method.

At the FDA's direction, Teva amended its label years later to include the patented method, but there was still no inducement via the full label. Nothing changed in the market, and doctors' prescribing decisions were not affected. By that time, GSK could not rely on Teva's ANDA as an artificial act of infringement. Thus, to prove induced infringement, GSK had to show that Teva actually caused doctors to directly infringe the '000 patent. It failed to do so.

The jury returned a verdict in favor of GSK, finding that Teva had induced infringement of the '000 patent by marketing both its skinny and full labels. The district court thereafter applied the law to the evidence presented at trial. In a thoughtful and thorough opinion, the court concluded that there was not legally sufficient evidence to show that Teva infringed the '000 patent and granted JMOL for Teva. The Majority, with little explanation, reverses that decision by misapplying the law and misconstruing the facts.

The district court got it right: no evidence established that Teva *actually caused* the doctors' infringement for either label. No communication from Teva *encouraged* doctors to use generic carvedilol to practice the patented method. And no evidence showed that doctors relied on Teva's label. Indeed, *GSK's own expert admitted that he had not read Teva's label* before prescribing generic carvedilol. Rather than suggest inducement, the record established that doctors relied on other sources of information, not Teva, in making their decision to prescribe carvedilol. And in any case, the record showed that the switch from Coreg® to generic carvedilol occurred "automatically," often without doctors' knowledge at all.

The Majority nonetheless reinstates the jury's verdict of inducement based on its conclusion that the district court applied the incorrect legal standard. Respectfully, the Majority is wrong. According to the Majority, the "content" of Teva's skinny label alone is sufficient to prove induced infringement—even though Teva's skinny label did not encourage, promote, recommend, *or even suggest* the patented method. Maj. 16. This holding is no small matter: it nullifies Congress's statutory provision for skinny labels—creating liability for inducement where there should be none. Contrary to Congress's intent, the Majority thereby allows one patented method to discourage generics from marketing skinny labels—thus, slowing, rather than speeding, the introduction of low-cost generics.

The legal insufficiency of GSK's evidence should not be shielded by the jury's verdict. While juries must be afforded deference, it is central to our judicial system that their verdicts conform to the limits of the law. Where, as here, a verdict is not supported by legally sufficient evidence, judges are given the authority—indeed, the responsibility—to enter judgment as a matter of law. The role of judges as gatekeepers preserves the integrity of our juries' verdicts; it does not diminish them. In this case, the district court's judgment of noninfringement justly upheld the

law, because GSK's evidence of inducement was legally insufficient to support the jury's verdict.

Because I believe the Majority's holding is counter to Congress's intent and incorrectly concludes that the jury's verdict was supported by substantial evidence, I respectfully dissent.

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There is a lot to be said about the law and about this case. I try to do so here. Section I briefly describes Congress's complex statutory scheme governing pharmaceutical approval, including Congress's design for skinny labels. Section II reviews the facts and procedural background of this case. Section III rejects the Majority's nullification of Congress's provision for skinny labels. Finally, Section IV discusses the evidence in this case and how that evidence fails to provide substantial evidence for the jury's verdict.

I. THE STATUTORY BACKGROUND

Congress contemplated the very circumstances this case presents, and plainly intended for the opposite outcome. It facilitated generic drug approval as soon as patents would allow and, through 21 U.S.C. § 355(j)(2)(A)(viii), specifically provided generics a pathway to approval that avoids any infringement of a brand's patents.

When Congress passed the Hatch-Waxman Act in 1984, it designed a complex statutory scheme to regulate drug approval. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585. One essential purpose was to "speed the introduction of low-cost generic drugs to the market." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk*, 566 U.S. 399, 405 (2012); *see also* H.R. Rep. No. 98–857, pt. 1, at 14–15 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2647–48 ("The purpose . . . is to make available more low cost

generic drugs by establishing a generic drug approval procedure . . . .").

According to Congress's scheme, the FDA regulates the manufacture, sale, and labeling of prescription drugs. The process begins when a brand manufacturer submits a new drug application ("NDA"). The NDA must include, among other things, proposed labeling describing the use, or uses—often called "indications"—for which the drug may be marketed. *See* 21 U.S.C. § 355(b)(1).

Once the FDA has approved the brand manufacturer's drug, a generic company may seek permission to market its version of the drug by filing an abbreviated new drug application ("ANDA"). The ANDA substantially relies on the information in the brand's NDA. The scheme is designed to minimize the barriers to entry for generic drugs. Even the generic's proposed labeling essentially copies the brand label. *See* 21 U.S.C. § 355(j)(2)(A)(i), (v). The generic is not required to provide information about clinical trials and investigations, but it must demonstrate that its generic version is bioequivalent to the branded drug. *See* 21 U.S.C. § 355(j)(2)(A)(iv).

Related to the approval process, the FDA publishes the Orange Book,[1] which identifies drug products that have been approved as safe and effective. The Orange Book is updated to identify generic versions once an ANDA has been finally approved. It reports a therapeutic equivalence rating that signals whether the generic drug can be expected to have the same clinical effect and safety profile when administered as labeled. *Orange Book Preface*, at

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[1] Formally, "Approved Drug Products with Therapeutic Equivalence Evaluations." *See* U.S. Food & Drug Admin., Preface to *Approved Drug Products with Therapeutic Equivalence Evaluations* (40th ed. 2020) ("*Orange Book Preface*").

§ 1.2. Relevant to this case, for example, a therapeutic equivalence rating of "AB" means that the generic version of the brand drug meets necessary bioequivalence requirements. *Orange Book Preface*, at § 1.7.

The FDA cannot approve a generic drug that would infringe a patent. To determine whether an ANDA would infringe, the FDA relies on the brand manufacturer to file with its NDA information for any patents that cover a compound or method of use described in the brand label. The FDA does not attempt to verify the accuracy of the submitted patent information but publishes it in the Orange Book and applies it in approval decisions.

Congress, however, provided the generic manufacturer two pathways to show that its proposed label will not infringe an Orange-Book-listed patent. The first and most-commonly used pathway is to file one of four certifications explaining that the generic label will not infringe the Orange-Book-listed patent. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV). For example, a "paragraph III certification" states that the generic label will not infringe because the generic will not launch its product until the Orange-Book-listed patent expires. *Id.* § 355(j)(2)(A)(vii)(III). And a "paragraph IV certification" states that a generic label will not infringe because the Orange-Book-listed patent "is invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug." *Id.* § 355(j)(2)(A)(vii)(IV).

Even though the FDA may approve a label for which a generic has certified that it will not infringe, Congress made it an artificial act of infringement to file an ANDA covering an Orange-Book patented drug or method. *See* 35 U.S.C. § 271(e)(2)(A); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670–71, 676 (1990); *cf.* 35 U.S.C. § 271(a) (imposing patent-infringement liability generally only when an infringer makes, uses, offers for sale, sells, or imports an invention). The brand may therefore bring an

infringement action based solely on the generic's ANDA and proposed label.

The second pathway, available in circumstances where at least one indication on the brand label is no longer patent protected, allows the generic to "carve out" other still-patented indications from its label. *See* 21 U.S.C. § 355(j)(2)(A)(viii) ("section viii"); 21 C.F.R. § 314.94(a)(8)(iv). The resulting label is commonly called a "skinny label." When the ANDA is finally approved, the generic will be limited to the indications included on its skinny label but will nonetheless be able to launch its product *without infringing* the remaining method patent.

Congress therefore specifically designed the statutory scheme governing drug approval such that one patented use would not foreclose a generic from marketing a drug for other unpatented uses. *Caraco Pharm.*, 566 U.S. at 415; *see also Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1359–60 (Fed. Cir. 2003) (quoting the legislative history and concluding that "Congress recognized that a single drug could have more than one indication and yet that the ANDA applicant could seek approval for less than all of those indications"). As I address in more detail below, the Majority's holding in this case directly undermines Congress's design. *See infra* § III.

II. THE FACTUAL AND PROCEDURAL BACKGROUND

A. *Carvedilol: An unpatented compound useful for unpatented methods of treatment*

Carvedilol—the drug at the center of this suit—is well studied and well understood. By 2007, the compound itself was not patent protected, nor were multiple uses of it.

Carvedilol is a beta-blocker, which is a class of drugs that have been used since the 1960s to treat certain heart conditions. Carvedilol in particular was developed in the 1980s and was covered by U.S. Patent No. 4,503,067, which issued in 1985 and expired in 2007. The '067 patent

claimed the carvedilol compound and a method of using carvedilol to treat hypertension and angina pectoris. *See* '067 patent claims 1–18.

By the early 1990s, research revealed that beta-blockers could also be useful for treating a different condition called congestive heart failure ("CHF"), which prevents the heart from being able to deliver enough oxygenated blood to the body. GSK filed an NDA that included indications for both hypertension and CHF. GSK's NDA was approved in 1997 under the brand name Coreg®. Later, in 2003, a third indication, often called "post-MI LVD," was approved and added to Coreg®'s label, covering patients that had recently suffered heart damage from a heart attack.

After the initial approval of its NDA, GSK was issued two method patents, U.S. Patent Nos. 5,760,069 and 5,902,821, related to using carvedilol to treat CHF. GSK listed the '069 and '821 patents, along with the '067 patent, in the FDA's Orange Book. Once the '067 patent expired in March 2007, no Orange-Book-listed patent covered the hypertension or post-MI LVD indications.

B. *Generic carvedilol: Teva launches its low-cost generic for unpatented uses based on a skinny label*

The record shows that Teva did everything right—proceeding precisely as Congress contemplated. Teva launched its low-cost generic carvedilol for unpatented uses using a skinny label. And Teva did not encourage doctors to use generic carvedilol to practice the one still-patented use.

When Teva initially filed its ANDA, it sought approval for all three approved indications—CHF, hypertension, and post-MI LVD. At the same time, Teva filed certifications explaining that it would not infringe any of GSK's three Orange-Book-listed patents. With respect to the '067 patent, Teva filed a paragraph III certification, notifying GSK that it would not market its generic carvedilol

until the '067 patent expired. And with respect to the '069 and '821 patents, Teva filed a paragraph IV certification, notifying GSK that it would not infringe the method-of-use patents because they were invalid and unenforceable. Upon receiving the certifications, unlike the typical Hatch-Waxman case, GSK did not sue Teva based on any of the Orange-Book-listed patents. Instead, seemingly acknowledging the deficiencies in its patent, GSK filed a reissue application for the '069 patent.

Meanwhile, in 2004, the FDA granted *tentative* approval for Teva's ANDA application. Teva issued a press release, announcing the "tentative approval . . . for Carvedilol Tablets" and stating that "Carvedilol Tablets are the AB-rated generic equivalent of GlaxoSmithKline's Coreg® Tablets and are indicated for treatment of heart failure and hypertension." J.A. 6347. Though Teva was surely encouraged by the FDA's tentative approval, neither it nor any other generic could yet enter the market; therefore, GSK remained the only manufacturer of carvedilol for several more years.

Before Teva's carvedilol product was finally approved, Teva amended its ANDA and proposed label to carve out the CHF indication according to 21 U.S.C. § 355(j)(2)(A)(viii). Thus, in September 2007, when the FDA finally approved Teva's ANDA as an AB-rated version of GSK's Coreg®, Teva's skinny label was only indicated for hypertension and post-MI LVD—neither of which was covered by any patent.

Both Teva and the FDA announced the approval of generic carvedilol with a press release. Teva's short press release stated that it had been granted "final approval for the company's [ANDA] to market its Generic version of GlaxoSmithKline's cardiovascular agent Coreg® (Carvedilol) Tablets." J.A. 6342. Teva also announced that it would immediately begin shipping its product but did not suggest that its product should be used to treat CHF. *See id.*

The FDA's press release, which was published a day earlier, went further than Teva's. It named fourteen generic manufacturers, including Teva, and announced that it had approved "the first generic versions of Coreg (carvedilol)." J.A. 7116. All fourteen AB-rated generics were approved based on skinny labels indicated only for hypertension and post-MI LVD. The FDA's release stated that "Coreg is a widely used medication that is FDA-approved to treat high blood pressure, mild to severe chronic heart failure and left ventricular dysfunction following a heart attack." *Id.* The FDA also stated that "[t]he labeling of the generic products may differ from that of Coreg because parts of the Coreg labeling are protected by patents and/or exclusivity." *Id.* Thus, it was the FDA, not Teva, that informed the public that the approved generic carvedilol products could be used for treating CHF.

Upon approval, Teva and seven other AB-rated generics began selling carvedilol. By that time, GSK had already profited from a monopoly in the carvedilol market for a decade, earning it $7.1 billion. Without competition, GSK was selling Coreg® for roughly $1.50 per pill. Generic carvedilol, in contrast, entered the market at a dramatically lower cost—only 3.5 cents per pill.

In marketing its generic carvedilol, Teva *never* stated that it was approved, or could be used, to treat CHF. In fact, the record suggests Teva hardly marketed its generic at all. Teva publicly acknowledged that it sold generic carvedilol in product catalogs, which were produced for pharmacists and described basic identifying information for all Teva products. In these catalogs, Teva listed carvedilol tablets with the appropriate identifying information and reported that the therapeutic equivalence rating was "AB" and the "Brand" was Coreg® Tablets. J.A. 6214, 6221 (2008 Product Catalog); J.A. 6054, 6056, 6072 (2011 Product

Catalog).[2] Teva's product catalogs explained that therapeutic equivalence ratings are codes that "are published in the FDA's Orange Book" for "[d]rug products the FDA considers therapeutically equivalent to other pharmaceutically equivalent products." J.A. 6256. With respect to an "AB" rating, in particular, the catalog stated that an "AB" code identifies "[p]roducts meeting necessary bioequivalence requirements." *Id.* Teva also published prescribing references that were distributed to doctors and included the same basic information. *See* J.A. 6192, 6200. Notably, from the time the generic product was approved, the FDA likewise reported the equivalence rating for Teva's carvedilol product in the Orange Book. J.A. 6865–67.

In 2008, after Teva and the other generics had already launched their products, the reissue proceedings of the '069 patent finally resulted in the '000 patent. The '000 patent recited a narrowed method of treating CHF using carvedilol, now additionally requiring treatment in combination with another therapeutic agent in daily maintenance dosages for a period greater than six months to decrease a risk of mortality. Claim 1 of the '000 patent recites:

> 1. A method of decreasing mortality caused by congestive heart failure in a patient in need thereof which comprises administering a therapeutically acceptable amount of carvedilol in conjunction with one or more other therapeutic agents, said agents being selected from the group consisting of an angiotensin converting enzyme inhibitor (ACE), a diuretic, and digoxin,

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[2] The 2011 product catalog does not include a date of publication but includes a 2010 copyright. *See* J.A. 10545 at ll. 18–21.

> *wherein the administering comprises administering to said patient daily maintenance dosages for a maintenance period to decrease a risk of mortality caused by congestive heart failure, and said maintenance period is greater than six months.*

J.A. 45 at col. 8 ll. 30–40 (italics reflects claim narrowing during reissue).

After the '000 patent's issuance in 2008, GSK quickly removed both of its original patents from the Orange Book and listed the '000 patent. GSK, however, did not assert the '000 patent against any generic based on their ongoing sales of generic carvedilol under the approved skinny labels. Thus, the carvedilol market continued relatively unchanged, with GSK selling Coreg® under its label with three indications at an *increased* price of $2.33 per pill, and the generics offering carvedilol labeled for only hypertension and post-MI LVD at a *decreased* price of 2.5 cents per pill.

Years later, in 2011, the FDA directed Teva to revise its label to include the CHF indication. Teva complied. Teva did not issue a press release or otherwise notify doctors of the change to its label. Indeed, Teva did not change anything about how it marketed its generic carvedilol; it continued to sell its product in the same manner that it had done since approved. *See* J.A. 6054. GSK still did not allege that Teva's sales of its generic product infringed the '000 patent.

C. *The trial: GSK fails to prove that Teva actually induced doctors to infringe the patented method*

GSK finally sued Teva in the U.S. District Court for the District of Delaware in 2014, more than six years after the FDA's approval of Teva's ANDA and less than one year before the expiration of the '000 patent. GSK did not (and could not) bring an ordinary Hatch-Waxman case relying on Teva's ANDA as an artificial act of infringement, but

instead alleged for the first time that Teva had induced infringement of the '000 patent by selling its generic carvedilol under both its skinny and full labels. GSK sought nearly $750 million dollars in damages from Teva.[3]

GSK's lawsuit ultimately led to a seven-day jury trial in 2018. GSK had to show that Teva's inducement actually caused doctors' direct infringement of the patented method. GSK failed to do so for either Teva's skinny or full label. GSK was given multiple opportunities, but still could not show that any affirmative act by Teva had caused doctors to prescribe generic carvedilol according to the patented method.

Specifically, at trial, GSK failed to produce testimony purporting to show that Teva's label induced infringement of the claimed method by even a single doctor. The parties agreed that when Teva launched, its skinny label did not instruct doctors to prescribe generic carvedilol to treat CHF. *See* J.A. 10584 at ll. 4–6; *see also* J.A. 10542 at ll. 19–23. There was no dispute that the only two uses included on Teva's label were hypertension and post-MI LVD—uses that were not patented. *See* J.A. 10545 at ll. 9–14 (GSK's expert, Dr. Lietzan, testifying that in 2008, Teva's carvedilol tablets and Coreg® "were approved for different uses," and "[m]ore precisely, the Teva product was not approved for one of the uses that the Coreg product was approved for").

With respect to both Teva's skinny and full labels, GSK failed to present evidence showing that doctors relied on

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[3] Between September 2007, when Teva launched its product, and June 2015, when the '000 patent expired, Teva sold only $74.5 million of generic carvedilol total (i.e., for any use). Given Teva's costs, however, Teva sold generic carvedilol at a net loss of $13 million. J.A. 10875 at l. 22 to 10876 at l. 12.

the label in making prescribing decisions. To the contrary, GSK's expert, Dr. McCullough, testified that *he had not read* the labels of other generic carvedilol products, and that he read Teva's label only "in [the] context of [his] work on this case." J.A. 10671 at ll. 3–9. He repeatedly stated that when generic carvedilol launched, he "didn't actively switch" patients from Coreg® to the generic product, but that he "continued to prescribe [Coreg®]" and it was "automatically switched" by pharmacists, often without his knowledge. J.A. 10674 at l. 25 to 10675 at l. 9; *see also* J.A. 11662 at ll. 13–20; J.A. 10678 at l. 1 to 10679 at l. 7.

While Teva's label did not seem to influence doctors' prescribing decisions, numerous other industry materials did. Dr. McCullough testified that in prescribing carvedilol to treat CHF, he was informed by prescribing guidelines established by the American Heart Association and the American College of Cardiology, medical research studying carvedilol, and even GSK's own Coreg® label and the promotional materials advertising it. J.A. 10676 at l. 2 to 10677 at l. 25.

No one reviewing the record should ignore what happened on the fourth day of trial. Following Dr. McCullough's testimony, Teva moved for JMOL that GSK had not demonstrated induced infringement of the '000 patent. GSK's counsel argued in response that it had shown inducement through Teva's label. GSK stated unequivocally, "[n]o label, no inducement." J.A. 10962 at l. 7; *see also* J.A. 10962 at ll. 8–10 ("[Teva's label is] the only way the doctors know how to prescribe it or why they would prescribe it for congestive heart failure."). But when the district court asked GSK whether Dr. McCullough or any other doctor had testified that they had even read Teva's carvedilol label, GSK agreed they had not. J.A. 10959 at ll. 9–14.

GSK asked for the opportunity to put Dr. McCullough back on the stand, representing that "he would absolutely

give" the relevant testimony. J.A. 10959 at ll. 15–20. He didn't. Instead, when the district court let him back on the stand, Dr. McCullough testified that *he had not read Teva's label* before he started prescribing generic carvedilol. J.A. 11662 at l. 25 to 11663 at l. 3. Dr. McCullough reasserted his testimony that *substitution of Coreg® for generic carvedilol was automatic*. J.A. 11662 at ll. 13–24.

D. *JMOL: The district court gets it right*

At the conclusion of trial, the jury was instructed that to prove inducement, GSK had to show by a preponderance of the evidence that, among other elements, Teva took some affirmative act that actually caused doctors' subsequent direct infringement. J.A. 11798 at ll. 1–3; *see also* J.A. 11802 at ll. 9–16. The jury was asked to determine whether Teva induced infringement of the '000 patent based on its skinny and full labels separately. It found that Teva induced infringement of the '000 patent based on both labels. The jury also found that GSK was entitled to $234.1 million in lost profits and $1.4 million in reasonable royalty damages. Following the verdict, however, amid other post-trial motions, Teva filed a renewed motion for JMOL, again arguing that GSK had not presented legally sufficient evidence to support a finding of inducement. The district court agreed and granted Teva's motion. *See GlaxoSmithKline LLC v. Teva Pharm. USA, Inc.*, 313 F. Supp. 3d 582 (D. Del. 2018).

The district court granted JMOL in favor of Teva because "neither sufficient nor substantial evidence supports the jury's finding of inducement." *Id.* at 591. In reaching its decision, the district court carefully considered the evidence that GSK had presented at trial. And it concluded that this evidence failed to show that even a single doctor, much less a class of doctors, was induced to infringe the '000 patent based on Teva's actions. *Id.* at 590–91. It was not disputed that Teva's label, at launch, did not include treating CHF or the method claimed in the '000 patent.

The record also showed that Dr. McCullough had not even read Teva's label and that his prescribing behavior, like other doctors, had not changed when generic carvedilol entered the market. *Id.* at 594–95.

The court also recognized that Teva had reported the FDA's AB rating for Teva's generic carvedilol, communicating that it was therapeutically equivalent to GSK's branded carvedilol. *Id.* at 593–94. But it rejected GSK's view that communicating therapeutic equivalence with Coreg® caused any infringement of GSK's '000 patent. *Id.* at 593. The district court stated:

> As both parties showed at trial, being AB rated signifies that a generic drug is therapeutically equivalent to a branded drug. The undisputed evidence demonstrates that a generic drug cannot be listed as "AB rated" generally, as "AB rated" is a relative term; it necessarily requires a comparison between the generic drug and some branded reference drug.

Id. (internal citations omitted). The district court also cited testimony from GSK's expert, Dr. Lietzan, confirming that AB rating reports therapeutic equivalence only "if the generic drug is used *in accordance with the label*." *Id.* (emphasis in original). Thus, the district court concluded that "there is *not* legally sufficient evidence to support a finding that Teva, by listing its carvedilol as AB rated to Coreg®," encouraged infringement. *Id.* at 594 (emphasis added).

Even though no direct evidence was presented at trial that Teva induced infringement of the '000 patent, *see* J.A. 10960 at ll. 6–9, the district court correctly considered whether circumstantial evidence supported the jury's verdict. *GlaxoSmithKline LLC*, 313 F. Supp. 3d at 595. The district court concluded it did not. It stated:

> [G]iven the dearth of evidence that doctors read and understand and are affected by labels, and given the vast amount of evidence that doctors'

> decisions to prescribe carvedilol during the relevant periods were influenced by multiple non-Teva factors[, an inference that Teva induced infringement] was an unreasonable one for the jury to have drawn.

Id. The district court therefore granted JMOL that Teva had not infringed the '000 patent during either the skinny or full label periods. *Id.* at 595, 597–98. GSK appealed.

III. THE MAJORITY NULLIFIES CONGRESS'S PROVISION FOR SKINNY LABELS

The Majority's holding that the content of Teva's skinny label can itself establish inducement nullifies Congress's provision for skinny labels. The Majority is wrong as a matter of law.

The Majority states that "precedent makes clear that when the provider of an identical product knows of and markets the same product for intended direct infringing activity, the criteria of induced infringement are met." Maj. 16. Then, citing *Vanda Pharmaceuticals, Inc. v. West-Ward Pharmaceuticals International Ltd.*, 887 F.3d 1117, 1129 (Fed. Cir. 2018), and *Sanofi v. Watson Laboratories Inc.*, 875 F.3d 636, 646 (Fed. Cir. 2017), the Majority explains that the content of an FDA-approved label can establish inducement to infringe. Maj. 16. The Majority, however, does not distinguish between Teva's skinny and full labels. As applied to Teva's skinny label, the Majority's holding therefore has the effect of nullifying Congress's provision for skinny labels.

Contrary to the Majority's suggestion that Teva provided and marketed an "identical product," *see* Maj. 16, Teva did not launch its product with a label that was

identical to GSK's.[4] This case is therefore not analogous to either *Vanda* or *Sanofi*, where a brand manufacturer alleged patent infringement based on the generic's ANDA that included a virtually identical label. Unlike those cases, here, Teva's skinny label is insufficient to prove infringement.

When Teva launched its product, Teva's carvedilol label did not suggest that it was approved to treat CHF at all, much less the '000 patent's narrow method of treating CHF by administering "daily maintenance dosages" for at least "six months" in conjunction with another therapeutic agent. J.A. 10584 at ll. 4–6; *see also* J.A. 10542 at ll. 19–23; J.A. 10695 at l. 21 to 10696 at l. 1. And there is *no dispute* that the only two uses included on Teva's label, i.e., hypertension and post-MI LVD, *were not patented*. J.A. 10545 at ll. 9–14. Teva's skinny label therefore did not infringe.

To hold otherwise, as the Majority does, undermines Congress's provision for skinny labels by substantially nullifying section viii. According to the Majority, a generic company that carves out from its label a patented method of use can nonetheless be found to infringe that patented method based on the content of the FDA-approved label. *See* Maj. 16. By finding inducement based on Teva's skinny label, which was not indicated for—and did not otherwise describe—the patented method, the Majority invites a

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[4] It is worth repeating—Teva's generic product included the same drug compound, carvedilol, but that drug compound was no longer patent protected. Nor were two approved indications of carvedilol patent protected. Teva did not infringe any patent by marketing a generic product for those uses. Teva's product that was approved and marketed through its skinny label was not identical to Coreg® because, unlike Coreg®, Teva's product was not approved to treat CHF patients according to the patented method.

claim of inducement for almost *any generic* that legally enters the market *with a skinny label*. That is directly contrary to Congress's intent. *See, e.g.*, *Caraco Pharm.*, 566 U.S. at 405–06, 415; *Medtronic*, 496 U.S. at 670–71, 676.

The Majority's holding is also contrary to our caselaw. In *Warner-Lambert v. Apotex Corp.*, we considered whether an ANDA applicant infringed a patented method by seeking approval for a label that did not include an indication for that method. 316 F.3d 1348. In that case, the patented use was not an approved use in the brand label. We explained that "Congress recognized that a single drug could have more than one indication and yet that the ANDA applicant could seek approval for less than all of those indications." *Id.* at 1360. We held that the generic label was neither an artificial act of infringement under § 271(e)(2)(A) nor an act of inducement under § 271(b). *Id.* at 1363. With respect to inducement, we explained, "the request to make and sell a drug labeled with a permissible (non-infringing) use cannot reasonably be interpreted as an act of infringement (induced or otherwise) with respect to a patent on an unapproved use, as the ANDA does not induce anyone to perform the unapproved acts required to infringe." *Id.* at 1364–65.

The same is true in yet another one of our cases. In *Takeda Pharmaceuticals U.S.A. v. West-Ward Pharmaceutical Corp.*, we considered whether a drug's label induced infringement of a patented method for which it was not indicated. 785 F.3d 625 (Fed. Cir. 2015). Takeda argued that the label induced infringement of the patented method of treating acute gout flares by instructing that "[i]f you have a gout flare while taking [the drug], tell your healthcare provider." *Id.* at 632 (first alteration in original). Takeda argued that this instruction would "inevitably" lead physicians to use the drug for the treatment of acute gout flares. *Id.* We concluded that it did not induce infringement. We explained that "vague label language cannot be combined with speculation about how physicians may act to find

inducement," and held that to induce infringement of a patented method, a "label must encourage, recommend, or promote infringement." *Id*. at 631–32.

Like the labels in *Warner-Lambert* and *Takeda*, Teva's label is not itself a basis for infringement. Teva's skinny label did not "encourage, recommend, or promote infringement" of the '000 patent. In fact, Teva's skinny label did not even suggest the patented method; it said absolutely nothing about CHF. It is legal error for the Majority to hold otherwise.

Contrary to the Majority's suggestion, it does not matter that Teva "deliberately," or intentionally, carved the CHF indication from its label. *See* Maj. 14. Far from abusing the system, Teva was acting in accordance with Congress's goals for it. The Supreme Court has explained that skinny labels provide a "mechanism for a generic company to identify [unpatented uses], so that a product with a label matching them can quickly come to market." *Caraco Pharm.*, 566 U.S. at 415. It is not gamesmanship for Teva to exercise this mechanism. Nor is it infringement.

Finally, to the extent the Majority finds liability for induced infringement based on Teva's expectation that "off-label" sales of generic carvedilol would occur, *see* Maj. 13–15, we have repeatedly rejected the argument that knowledge of off-label infringing uses establishes inducement. *See Takeda*, 785 F.3d at 631 ("The requirement of inducing acts is particularly important in the Hatch-Waxman Act context because the statute was designed to enable the sale of drugs for non-patented uses even though this would result in some off-label infringing uses."); *Warner-Lambert*, 316 F.3d at 1364 ("[M]ere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven."); *see also Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1276 n.6 (Fed. Cir. 2004).

IV. THE MAJORITY MISAPPLIES THE LAW AND MISCONSTRUES THE FACTS

To prove inducement under 35 U.S.C. § 271(b), GSK was required to show causation. That is, GSK had to show that doctors relied on Teva's inducing communications in directly infringing the claimed method. *See Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1330–32 (Fed. Cir. 2016); *Takeda*, 785 F.3d at 631–32; *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1219 (Fed. Cir. 2014). It failed to do so.

GSK failed to prove causation based on either Teva's skinny or full label. I address the skinny and full label periods below.[5] I also discuss uncontroverted evidence that showed that other sources, not Teva, influenced doctors' decisions to prescribe generic carvedilol according to the patented method during both periods.

A. *The Skinny Label Period: GSK fails to show that Teva actually caused doctors to directly infringe the patented method*

The Majority's conclusion that substantial evidence supports the jury's verdict of inducement during the skinny label period is contradicted by the record. Simply put, GSK cannot show that Teva's skinny label alone induced infringement of the '000 patent, and GSK failed to show that any other communication from Teva to doctors actually caused doctors to directly infringe the patent method.

During the skinny label period, GSK primarily relied on Teva's label as the basis for its claim that Teva induced

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[5] Teva's skinny label period runs from January 8, 2008, when the '000 patent issued, until April 30, 2011. The full label period runs from May 1, 2011, when Teva amended its label at the FDA's direction, until June 7, 2015, when the '000 patent expired.

doctors to practice the claimed method. *E.g.*, J.A. 10692 at ll. 7–10. Critically, as just discussed, Teva's skinny label did not teach the patented method and could not induce infringement of the '000 patent. *See supra* § III.

Moreover, regardless of what Teva's skinny label encouraged, GSK failed to show that doctors actually relied on Teva's label in deciding to prescribe generic carvedilol. GSK's expert Dr. McCullough expressly testified that he had not read Teva's label before prescribing generic carvedilol, J.A. 11662 at l. 25 to 11663 at l. 3, and also that he had not read any other generic carvedilol label, J.A. 10671 at ll. 3–9. Dr. McCullough was also unequivocal that his prescribing behavior did not change once generic carvedilol was launched, *e.g.*, J.A. 10674 at l. 25 to 10675 at l. 9.

The Majority nonetheless summarily concludes that there is substantial evidence to support the jury's verdict. Because even GSK's counsel admitted there is no direct evidence of inducement in the record, *see* J.A. 10960 at ll. 6–9, the Majority's conclusion is necessarily based only on circumstantial evidence. During the skinny label period, the Majority generally cites product catalogs and press releases published by Teva. *See* Maj. 12–16 (citing J.A. 6221, 6072 (product catalogs) and 6347, 6353 (press releases)).

Teva's documents fail to provide substantial evidence of inducement. First, Teva's press releases are not affirmative acts of inducement that occurred after the '000 patent issued. Second, no reasonable juror could conclude that Teva's press releases or its product catalogs encourage doctors to practice the patented method. Third, GSK failed to produce any evidence establishing that doctors relied on these materials in making their prescribing decisions. Indeed, in contrast to GSK's legally insufficient evidence, other uncontroverted evidence showed that other sources, not Teva, influenced doctors' decisions to prescribe generic carvedilol according to the patented method.

1. *Teva's press releases fail to provide substantial evidence of inducement because they were published before the '000 patent issued*

Teva published two releases before the '000 patent issued. The first was published in 2004 and announced the *tentative* approval of Teva's generic product. J.A. 6347. The second was published in 2007 and announced that Teva's generic product had been approved and that Teva would immediately begin shipping its product. J.A. 6353. Importantly, both of these press releases were published *before* the '000 patent issued in 2008 and therefore cannot alone be acts of infringement. *Nat'l Presto Indus., Inc. v. W. Bend Co.*, 76 F.3d 1185, 1196 (Fed. Cir. 1996) ("[W]hen no patent has issued at the time of the inducement there can not be a violation of § 271(b).").

The Majority nonetheless exhumes Teva's press releases to establish infringement because they remained on Teva's website after the '000 patent's issuance. Maj. 15–16. The continued presence of the press releases, however, is not probative evidence of inducement. Our caselaw is clear that inducement requires "an affirmative act to encourage infringement." *E.g.*, *Takeda*, 785 F.3d at 632 n.4; *Microsoft Corp. v. DataTern, Inc.*, 755 F.3d 899, 904 (Fed. Cir. 2014); *see also Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 918 (2005); *see also* J.A. 11797 at ll. 7–8, 13–18 (jury instructions). In this case, passive maintenance of the pre-issuance press releases is not an affirmative act of inducement.[6]

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[6] To the extent the Majority means to argue that the press releases are probative evidence of continued inducement because they were maintained on Teva's website, that argument also fails. Not only is passive maintenance not an affirmative act, but further, the "continued infringement" argument was not made to the jury. It therefore

Moreover, with respect to the 2004 press release, I am particularly unpersuaded that it could be probative evidence of inducement given that it reports only "tentative approval." J.A. 6347; *see also* J.A. 11656 at ll. 22–24 (Dr. McCullough testifying that the 2004 press release announced only "tentative approval" and what was "expected" in the future). The FDA does "not include drug products with tentative approvals in the Orange Book because a drug product that is granted *tentative approval is not an approved drug* product." *Orange Book Preface*, at § 1.1 (emphasis added). The suggestion that a practicing physician would (or should) rely on an announcement for "tentative approval" in making prescribing decisions over three years in the future seems unlikely.

2. *Teva's documents did not encourage doctors to practice the patented method*

Moreover, GSK did not produce any evidence during the skinny label period upon which a reasonable juror could conclude that Teva *encouraged* doctors to prescribe carvedilol to practice the patented method.

Teva's press releases and product catalogs, like its skinny label, do not promote treating CHF at all. For example, the 2007 press release said nothing of CHF. J.A. 6373; *see also* J.A. 10671 at ll. 11–14 (GSK's expert Dr. McCullough testifying that the release "said nothing about what indications were or weren't on the label"). The product catalogs likewise said nothing about the product's indications. Instead, the catalogs merely included carvedilol in a table that reported basic product information, like

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could not have provided substantial evidence for its verdict. At most, the jury saw a copy of the press releases taken from Teva's website with a footer indicating that they had been printed from the website in 2015. J.A. 6346–47, 6352–53.

physical description, units of sale, and therapeutic equivalence. *See* J.A. 6221. The Majority, purportedly "[a]pplying the standards of law and precedent," focuses on whether doctors read these materials. Maj. 17. But the question is not just whether these materials were read (though there is scant evidence even of that, *see infra* § IV.A.3); the question is whether these materials can reasonably be viewed as having *encouraged infringement*. And they simply cannot.

Moreover, for Teva to have induced infringement of the '000 patent, Teva must have induced infringement of "every single step" of the claimed method, *Ericsson*, 773 F.3d at 1219—including the steps that GSK added to secure its reissue patent and thereby extend its carvedilol coverage.[7] Thus, *even if* Teva's documents suggested using its carvedilol products to treat CHF, which they do not, such a suggestion would not be enough to induce infringement of the '000 patent. *See* J.A. 10695 at l. 21 to 10696 at l. 1 (Dr. McCullough agreeing that not every CHF patient treated with carvedilol infringes the claimed method).

Without a disclosure of the claimed method, the Majority seems to rely on references to Teva's "AB rating" or therapeutic equivalence as evidence of inducement. *See* Maj. 12–16. These statements, however, cannot be legally sufficient to prove inducement. As recognized by the Majority, *see* Maj. 6 n.3, and clarified in Teva's publications,

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[7] As previously noted, the specific method steps of the '000 patent's very narrow method required administering to a CHF patient a therapeutically acceptable amount of carvedilol in conjunction with one or more particular therapeutic agents, wherein the administering comprises daily maintenance dosages for a maintenance period to decrease a risk of mortality caused by CHF, and wherein said maintenance period is greater than six months. *See* J.A. 45 at col. 8 ll. 30–40.

see J.A. 6256, therapeutic equivalence is a designation provided by the FDA relating to the safety and efficacy of the drug compound.[8] *See also* J.A. 10533 at l. 24 to 10534 at l. 1. Indeed, in closing arguments to the jury, GSK's counsel acknowledged that "the fact that Teva said they were AB rated isn't enough to prove inducement . . . . [W]e have to show you more than just the AB rating." J.A. 11849 at ll. 1–8. The Majority, however, seems quite content with the AB rating. Maj. 12 (mentioning the AB rating), 13 (noting use of the phrase "AB rating"), 15 (recounting GSK's expert's testimony of what an "AB rating" means, and observing that Teva's product catalogs included that term), 15–16 ("The jury properly could consider Teva's continued affirmative promotion of its carvedilol tablet as the AB generic equivalent of Coreg® . . . .").

Further, Orange Book determinations of therapeutic equivalence are not made for unapproved indications. *See GlaxoSmithKline*, 313 F. Supp. 3d at 593; *see also Orange Book Preface*, at § 1.2; J.A. 10543 at ll. 1–10. GSK's expert Dr. Lietzan testified that AB rating "is an indication that the product is therapeutically equivalent when used as labeled" and that "it doesn't reflect a decision of the therapeutic equivalence with respect to the off-label uses." J.A. 10583 at ll. 1–4; *see also* J.A. 10542 at ll. 13–14 ("AB

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[8] To the extent the Majority believes that Teva had an affirmative duty to inform doctors that it was not approved for one indication, respectfully, that is not the law. We expressly rejected this argument in *Takeda*. *See* 785 F.3d at 632 n.4 (rejecting Takeda's argument that Hikma's label needed to contain a "clear statement to show that it was avoiding the patented indication"). There, we stated that "[the patentee] needs to show that [the alleged infringer] took affirmative steps to induce, not affirmative steps to make sure others avoid infringement." *Id.*; *see also Grokster*, 545 U.S. at 918; *Microsoft*, 755 F.3d at 904.

rating means that [the drug is] therapeutically equivalent as labeled . . . ."). Thus, Teva's reporting of equivalence information cannot be evidence of inducing infringement for a method that the generic is not indicated to treat.[9]

3. *No evidence suggests that doctors relied on communications by Teva in prescribing carvedilol according to the patented method*

Even if the product catalogs or press releases encouraged doctors to prescribe generic carvedilol according to the patented method, which they do not, GSK failed to show that doctors would have relied on those materials in making prescribing decisions.

With respect to Teva's product catalogs, GSK's expert Dr. McCullough was not even able to say that they would have been seen by doctors, much less relied on. *See* J.A. 10686 at ll. 5–7 ("Q: So you are testifying that this [2008 Product Catalog] was actually given to doctors or you just don't know? A: I don't know that. I think it's possible."). If the doctors never even received Teva's product guides, they cannot be evidence that Teva caused infringement. *Power Integrations*, 843 F.3d at 1330–31.

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[9] To be approved as a generic, Teva's primary requirement was to show that its carvedilol product is bioequivalent, or therapeutically equivalent, to Coreg®. Teva was not required to be approved for all of indications. Thus, even were it correct that by reporting its "AB rating" Teva communicated that its generic carvedilol should be used for an indication not approved on its label, it would nonetheless stretch the bounds of reason to restrict Teva from accurately reporting that equivalence information upon approval. In fact, the Orange Book publicly reports the very same information, and has done so since Teva's generic was approved. *See* J.A. 6866–67.

Similarly, with respect to the press releases, no testimony suggested that doctors were in the habit of searching websites for past-published press releases to influence their prescribing behavior. Indeed, no record evidence even implies that doctors saw Teva's press releases when they were published, must less after the '000 patent issued in 2008. To the extent pharmaceutical press releases were considered at all, the record suggests that doctors only checked their email for new announcements to inform them "when drugs are going generic." J.A. 11655 at ll. 20–24.

Though circumstantial evidence may be sufficient evidence to prove inducement in some cases, this is not one of them. Beyond Teva's skinny label—which does not encourage doctors to practice the patented method—the only other evidence the Majority cites—i.e., press releases and product catalogs—are documents that do not describe the patented method, and for which little evidence, if any at all, even *hints* they were ever considered by doctors during the allegedly infringing period. The inferences required to reach a finding of inducement exceed the bounds of reason.

GSK failed to present evidence demonstrating that Teva caused the doctors' direct infringement of the '000 patent during the skinny label period. Without causation, GSK failed to prove inducement.

4. *Uncontroverted evidence in the record establishes that other sources, not Teva, induced doctors to prescribe carvedilol according to the patented method*

In contrast to the absence of evidence suggesting that Teva induced infringement, uncontroverted record evidence establishes that it was other sources, and not Teva's label or other documents, that induced doctors to prescribe carvedilol according to the claimed method. *See Integra Lifesciences I, Ltd. v. Merck KGaA*, 496 F.3d 1334, 1345 (Fed. Cir. 2007) ("The rule that a jury verdict is reviewed for support by 'substantial evidence' does not mean that the

reviewing court must ignore the evidence that does not support the verdict.").

In particular, the record confirmed that doctors prescribed carvedilol according to the claimed method based on the prescribing guidelines established by the American Heart Association and the American College of Cardiology, medical research studying carvedilol, and even GSK's own Coreg® label and GSK's promotional materials advertising it. *E.g.*, J.A. 10676 at l. 2 to 10677 at l. 25; J.A. 11151 at l. 3 to 11153 at l. 22; J.A. 11164 at l. 11 to 11172 at l. 12; J.A. 11296 at l. 17 to 11297 at l. 3.

The record additionally showed that the day before Teva published its 2007 press release, the FDA had published its own press release, J.A. 7116, which detailed even more about using carvedilol to treat CHF than did Teva's (indeed, Teva's said nothing about it). And the record showed that doctors would have actually relied on the FDA's release in making prescribing decisions. *See* J.A. 10670 at ll. 9–11; *see also Takeda*, 785 F.3d at 631 (finding insufficient evidence of induced infringement in part because before the generic's alleged inducement, the FDA had previously informed healthcare providers to prescribe the drug according to the claimed method).

Further still, the record showed that substitution of generic carvedilol for Coreg® often happened without doctor involvement at all. At trial, Dr. McCullough repeatedly testified that when the generics launched, he "didn't actively switch" patients from Coreg® to the generic product, but that he "continued to prescribe [Coreg®]" and it was "automatically switched." J.A. 10674 at l. 25 to 10675 at l. 9; *see also* J.A. 10675 at ll. 6–9; J.A. 11662 at ll. 13–20; J.A. 11176 at ll. 4–13; J.A. 11177 at ll. 10–16 (Teva's expert Dr. Zusman testifying). The switch did not occur because doctors relied on Teva's marketing materials. In fact, the switch did not even occur with the doctors' knowledge. *See* J.A. 10678 at l. 1 to 10679 at l. 7.

In sum, the district court's JMOL of noninfringement during the skinny label period should be affirmed. Teva did not induce infringement of the '000 patent during the skinny label period. And the record does not include legally sufficient evidence to support the jury's verdict.

B. *The Full Label Period: GSK fails to show that Teva actually caused doctors to directly infringe the patented method*

GSK also failed to prove causation during the full label period. No evidence suggests that any affirmative act by Teva actually caused doctors to directly infringe the patented method. Specifically, no evidence suggests that doctors relied on Teva's full label in making their prescribing decisions.

During the full label period, GSK primarily relied on Teva's label as evidence of inducement. Of course, unlike the skinny label, Teva's full label included an indication for the treatment of CHF. But because GSK could not rely on Teva's ANDA as an artificial act of infringement, GSK was required to show actual inducement, including that doctors actually relied on Teva's full label in making its prescribing decisions. *See Warner-Lambert*, 316 F.3d at 1363. GSK failed to do so.

As previously described, GSK's evidence showed that doctors, including the very doctor it chose to put on the stand, did not rely on generic labels in making prescribing decisions. *See* J.A. 10671 at ll. 3–9. Though GSK was given multiple opportunities to prove causation, *e.g.*, J.A. 10962 at ll. 7–10; J.A. 10959 at ll. 9–20, GSK's expert Dr. McCullough testified that he did not read Teva's label before prescribing generic carvedilol, J.A. 11662 at l. 25 to 11663 at l. 3, and he testified that his decision to prescribe carvedilol never changed, J.A. 10674 at l. 25 to 10675 at l. 9. Indeed, when Dr. McCullough was asked about Teva's amendment from a skinny to a full label, he specifically

testified that the change had no effect on his prescribing habits:

> Q: You agree that at least in your practice, there's no difference in your prescribing habits from when Teva had its skinny label to after Teva amended to have its full label; right?
>
> A: I would agree with that.

J.A. 10699 at ll. 6–10. If Teva's full label did not influence doctors' prescribing habits—i.e., if Teva did not induce doctors to directly infringe the patented method—then Teva cannot be liable for inducement.

The only other evidence that GSK offered from the full label period similarly fails to provide a basis for inferring causation. GSK introduced evidence of prescribing references that were distributed after Teva amended its label to the full label. *See* Maj. 12–13 (citing J.A. 6192–94).[10] But the limited testimony at trial did not establish that doctors relied on these references in making prescribing decisions. Dr. McCullough was asked whether the prescribing references "encourage[ed] the sales of Teva's product"—he stated "no." J.A. 10680 at ll. 9–16.

While the evidence failed to show that doctors relied on Teva's full label (or any other communication by Teva during the full label period), the record was consistent with the skinny label period demonstrating other sources, not Teva, influenced doctors' decision to prescribe generic carvedilol according to the patented method. *See supra* § IV(A)(4).

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[10] The Majority states that "[a]lso in evidence was the 2012 edition of Teva's *Health Systems Pharmacy Drug Reference*." Maj. 13. Despite the suggestion that this is an additional document, it is the same as Teva's 2012 Monthly Prescribing Reference that was mentioned in the immediately preceding sentence.

Specifically, the record confirmed that information from the American Heart Association and American College of Cardiology, as well as medical research, and even GSK's own marketing, encouraged doctors to prescribe carvedilol according to the '000 patent. *E.g.*, J.A. 10676 at l. 2 to 10677 at l. 25; J.A. 11151 at l. 3 to 11153 at l. 22; J.A. 11164 at l. 11 to 11172 at l. 12; J.A. 11296 at l. 17 to 11297 at l. 3.

The record also demonstrated that many generic carvedilol sales occurred without the doctors' knowledge at all. *See supra* § IV(A)(4). That is, even after Teva amended its label, doctors merely prescribed carvedilol, and it was pharmacies that dispensed generic carvedilol. *See* J.A. 10674 at l. 25 to 10675 at l. l. 9; J.A. 10678 at l. 2 to 10679 at l. 7.

In sum, to the extent the doctors prescribed generic carvedilol to treat patients according to the claimed method, no evidence shows that they did so because of any action taken by Teva. The district court's JMOL of noninfringement during the full label period should therefore be affirmed. Teva did not induce infringement of the '000 patent during the full label period. And the record does not include legally sufficient evidence to support the jury's verdict.

V. CONCLUSION

The Supreme Court has explained that one of Congress's essential purposes in designing a procedure for generic approval was to "speed the introduction of low-cost generic drugs to the market." *Caraco Pharm.*, 566 U.S. at 405. The Majority's holding undermines this purpose by creating infringement liability for any generic entering the market with a skinny label, and by permitting infringement liability for a broader label that itself did not actually cause any direct infringement. Congress did not intend either of these consequences.

Indeed, far from "speed[ing] the introduction of low cost generic drugs," this result discourages generics from entering the market in the first instance. Teva did everything right—using a skinny label, taking care not to encourage infringing uses—and yet, given today's result, it was ultimately more costly for Teva to sell an unpatented drug for unpatented uses than it would have been to stay out of the market altogether: Teva only sold $74 million worth of carvedilol during the allegedly infringing period (mostly for unpatented uses) but now owes $234 million in damages for sales made for a single indication. This irony reflects the fact that Teva's product was dramatically less expensive—costing less than 4 cents per pill as compared with Coreg®'s price of at least $1.50 per pill.

Simply put, allowing such an outcome undermines Congress's design for efficient generic drug approval. Teva entered the market according to this design and refrained from encouraging doctors to practice the '000 patent's method. Teva should not be liable for inducement.

For these reasons, I respectfully dissent.

CERTIFICATE OF SERVICE

I hereby certify that on December 2, 2020, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit using the Court's CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the CM/ECF system.

/s/ *William M. Jay*
William M. Jay

CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitation of Fed. R. App. P. 35(b)(2)(A) because it contains 3,895 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and Fed. Cir. R. 32(b)(2).

I further certify that this petition complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced 14-point Times New Roman typeface using Microsoft Word 2010.

/s/ *William M. Jay*
William M. Jay