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 (Hon. Leonard P. Stark), No. 1:14-cv-00878-LPS-CJB

PETITION FOR REHEARING EN BANC

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October 7, 2021

CERTIFICATE OF INTEREST

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

1. The full name of every party or amicus represented by me is:

Teva Pharmaceuticals USA, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

N/A

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by me are:

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

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in the court (and who have not or will not enter an appearance in this case) are:

Shaw Keller LLP: John W. Shaw, Karen E. Keller, David M. Fry

5. The title and number of any case known to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal:

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

6. Information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees):

N/A

October 7, 2021

/s/ *William M. Jay*
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TABLE OF ABBREVIATIONS

’000 patent	U.S. Patent No. RE40,000 (Appx31-45)
2020 Op.	Opinion in this case issued by this Court October 2, 2020, and withdrawn February 9, 2021
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
Op.	Opinion issued August 5, 2021, that is the subject of this petition for rehearing en banc
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:

HZNP Meds. LLC v. Actavis Labs. UT, Inc., 940 F.3d 680, 701-702 (Fed. Cir. 2019); *Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625 (Fed. Cir. 2015); *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1323-1324 (Fed. Cir. 2012); 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 inducement doctrine 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. Because inducement liability under § 271(b) requires "active encouragement" and intent to infringe, *carving out* patented indications allows a generic manufacturer to launch without risk of being liable for inducing infringement. The questions are:

a. Where a product has substantial noninfringing uses and the defendant has deleted instructions to practice the patented method from its labeling, may the plaintiff prove active inducement by claiming that several disparate sections of the labeling "met" or "satisfied" the individual elements of the patented method, or does proof of active inducement require proof that the defendant encouraged the patented method?

b. Active inducement and causation are distinct elements of inducement. If a jury finds active inducement, may the jury infer that the defendant's inducement *caused* direct infringement, even when undisputed evidence shows that the supposedly inducing materials did not influence anyone to infringe?

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INTRODUCTION

The divided panel sparked immense controversy with its deeply flawed 2020 decision on induced infringement. The panel warded off rehearing en banc temporarily by agreeing to reconsider. But the majority's new decision—reaching the same result—is more troubling, not less. It has upset the careful equilibrium that Congress developed to enable access to low-cost generic drugs. The full Court should step in.

Congress determined in Hatch-Waxman that once a drug itself is no longer patented, "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). Congress allowed generics to adopt "skinny labels"— omitting any patented indication—and come to market without being sued for infringing the carved-out method. Teva followed that pathway here. Yet in October 2020, the majority held that Teva induced infringement *despite* the carve-out, and was liable for $235 million in lost profits, simply because Teva described its skinny-labeled product—accurately—as the AB-rated generic equivalent of GSK's product. Chief Judge Prost's dissent and a host of critics—generic *and* brand manufacturers, law professors, and Congressman Waxman himself—all recognized that the decision placed *every* skinny-labeled generic at risk.

The majority then granted panel rehearing—but merely added a new rationale to reach the same result. It held that Teva's *skinny label* induced infringement, too—even though Teva had omitted everything that *GSK told FDA* corresponded to its patented method-of-use. The majority held that, because snippets of language in disparate portions of the label could "satisfy" each claim term if a doctor read them together, Teva can be held liable for inducement. This new opinion only "exacerbates" the problems created by the original. Dissent 38.

First, it eviscerates this Court's construction of § 271(b)'s "active encouragement" element. Inducement requires communications that clearly "encourage" or "instruct" an infringing use, rather than merely "mention" or "describe" that use.

Second, it eliminates 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 that one-sided evidence but held that juries can *infer* that encouragement causes direct infringement.

Third, the majority's decision creates extraordinary uncertainty for generic and biosimilar medicines. Nearly half the time, it is a skinny label that first enables a generic version of an unpatented drug with patented and unpatented uses. But

now, launching such a generic before every method-of-treatment patent expires will incur massive risk—and both consumers and competition will suffer.

Commentators and analysts immediately recognized the new opinion as an "important, controversial decision"[1] that "changed everything,"[2] left "generics makers steeped in uncertainty,"[3] and "opened the floodgates for induced infringement."[4] Copycat litigation began immediately after the panel's original opinion. *See, e.g.*, *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 2021 WL 3396199 (D. Del. Aug. 3, 2021).[5] And with the "roadmap" paved by the new

[1] Khadijah M. Silver, *Teva's Generic Label Not Skinny Enough To Protect from $234M Damages to GSK*, MedCityNews (Aug. 6, 2021), https://medcitynews.com/2021/08/tevas-generic-label-not-skinny-enough-to-protect-from-234m-damages-to-gsk/.

[2] Sara W. Koblitz, *Ding Dong Is the Skinny Label (Effectively) Dead?*, FDA Law Blog (Sept. 7, 2021), https://www.thefdalawblog.com/2021/09/ding-dong-is-the-skinny-label-effectively-dead/.

[3] Dani Kass, *GSK Redo Doesn't Cure Generics' 'Skinny Label' Uncertainty*, Law360 (Aug. 9, 2021), https://www.law360.com/articles/1410679/gsk-redo-doesn-t-cure-generics-skinny-label-uncertainty.

[4] Koblitz, *supra*.

[5] *See also* Ian Lopez, *Teva Drug-Label Case Spurs Fresh Litigation as Judges Weigh Redo*, Bloomberg Law (Mar. 8, 2021), https://news.bloomberglaw.com/health-law-and-business/teva-drug-label-case-spurs-fresh-litigation-as-judges-weigh-redo (discussing follow-on cases).

decision, this follow-on litigation will become a wave of lawsuits against carve-outs that have been on the market unchallenged for years.[6]

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 narrow method patents cannot block generic drugs from being marketed for noninfringing uses.

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).

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

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[6] Daniel Knauss et al., *Fed. Circ. Tev Ruling May Shake Up Skinny Label Strategies*, Law360 (Sept. 1, 2021), https://www.law360.com/articles/1417824/fed-circ-teva-ruling-may-shake-up-skinny-label-strategies.

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

This case is about an off-patent drug, carvedilol (brand-name Coreg). The patent-in-suit covered one narrow method of treating congestive heart failure (CHF), which represented less than 18% of prescriptions. Op. 37.

1. Carvedilol is FDA-approved for (1) managing hypertension, (2) treating mild-to-severe CHF, and (3) treating dysfunction of the heart's left ventricle following a heart attack ("post-MI LVD"). Dissent 11. The patent on the carvedilol compound expired in 2007. Op. 5.

GSK also obtained two patents claiming methods of treating CHF. Op. 5; Dissent 10; Appx257-267. GSK consistently certified to FDA—under penalty of perjury—that *only* the CHF indication was claimed by its method-of-treatment patents. Dissent 11; Appx6894-6907; Appx7831-7834; Appx10888-10890.

Teva sought FDA approval to market generic carvedilol once the compound patent expired. Teva originally sought approval for all three indications, and 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 delisted the other from FDA's Orange Book. Op. 6; Dissent 10, 12. In 2004, FDA tentatively approved Teva's ANDA with all three indications.

In 2007, however, with expiration of the compound patent approaching, Teva decided to carve-out the CHF indication—as thirteen other generics were doing.

Dissent 11. FDA sent Teva a redlined label instructing what to carve-out, based on information GSK had provided to FDA about the material claimed by its method-of-treatment patents (as required by 21 C.F.R. § 314.53(c)(2)(O)). Teva did so, omitting more than 50 paragraphs, including the "Heart Failure" portions of the "Indications and Usage," "Dosage and Administration," "Adverse Reactions," "Pharmacodynamics," "Specific Populations," and "Clinical Studies" sections. Appx6908-6951.

Eight companies launched generic carvedilol, with skinny labels, in September 2007. GSK did not sue. By 2008, generic carvedilol was selling at $.02 and Coreg at $2.33 per pill, and GSK's market share was below 8%. 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. 6. GSK still did not sue.

In 2011, after GSK's original method-of-use patents were delisted, FDA directed Teva to amend its carvedilol label to add the information that had previously been carved-out. The amendment had no impact on physicians' prescribing practices—Teva and GSK maintained their respective market shares. Op. 7-8; Dissent 12-13.

2. In 2014, shortly before the '000 patent expired, GSK sued Teva for inducing infringement. Op. 8. GSK sought nearly $750 million in lost profits. Appx12281-12282.

GSK sought to prove inducement through its expert, Dr. McCullough, whom GSK's counsel "walk[ed] through" Teva's label seeking to establish direct infringement by physicians. Appx10617. "[M]ov[ing] on to inducement," Dr. McCullough testified that Teva encouraged infringement by stating, in product guides, press releases,[7] and marketing materials, that carvedilol was the "AB-rated" generic equivalent of Coreg without expressly *disclaiming* approval for the patented CHF indication. Appx10631-10644.

GSK offered no expert testimony regarding causation but avoided mid-trial JMOL by representing that, if recalled, Dr. McCullough would "absolutely" testify that he had read and relied on Teva's label. Dissent 20; Appx10958-10962. Dr. McCullough then said exactly the opposite—that he did *not* read Teva's label before administering generic carvedilol, and that generic substitution happened "automatic[ally]" at pharmacies. Dissent 20; Appx11662-11663. Indeed, he said,

[7] The 2004 press release announced FDA's "tentative approval," before the carve-out. Appx6347. The 2007 post-carve-out press release announced final approval of Teva's "Generic version of GlaxoSmithKline's cardiovascular agent Coreg® (Carvedilol) Tablets." Appx6342.

he *would not have* used Teva's product to treat CHF, because the skinny label was "missing too much information" about the CHF indication. Appx11660-11661.

The jury nonetheless awarded GSK $235 million in damages.

3. The district court 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-experts testified that they did not read Teva's label before prescribing carvedilol. Appx13-15. Furthermore, a "vast amount of evidence" from *both* parties showed that doctors' prescribing decisions were driven not by Teva but by, for example, GSK's promotion and cardiologists' standards of care. Appx18-21. And GSK conceded that after Teva amended its label, physicians' practices and GSK's market share stayed the same. Appx24.

4. In October 2020, this Court disagreed, over then-Chief Judge Prost's dissent. For evidence of inducement, the majority pointed primarily to product catalogs accurately describing Teva's generic pills as the AB-rated generic equivalent of Coreg, pre-patent press releases, and testimony that Teva expected to "get sales" resulting from CHF prescriptions. 2020 Op. 14, 16.[8] The opinion remarkably failed to mention, much less apply, the line of precedents holding that a

[8] http://www.cafc.uscourts.gov/sites/default/files/opinions-orders/18-1976.OPINION.10-2-2020_1663180.pdf.

skinny labeled does not "actively encourage" infringement of the carved-out method.

5. That decision sparked "widespread" criticism and confusion—from generic *and brand* manufacturers, law professors, and Congressman Waxman himself, all of whom filed amicus briefs in support of rehearing en banc. Dissent 13.

In response, the majority and issued a new opinion—reaching the same result on a new rationale. The majority now said that skinny-label precedents were inapplicable because Teva's skinny label was not a "true section viii carve-out." Op. 28 n.7. The majority emphasized that Dr. McCullough "compared" each claim element to (disparate) portions of Teva's skinny label and testified that the label "mention[ed]" or "me[t]" each limitation. Op. 14-15; Appx10623-10631. "But he never testified that the skinny label encouraged, recommended, or promoted practicing the claimed method." Dissent 18. Indeed, the cited testimony was about *direct* infringement, not inducement. Dissent 18 n.13; p. 7, *supra*.

Regarding causation, the majority held that the jury could have "infer[red]" from evidence of the other two inducement elements—affirmative encouragement and direct infringement—that Teva "actually induced doctors to infringe," despite overwhelming, uncontradicted evidence that Teva did not cause infringement. Op. 36.

Judge Prost again dissented, noting that the majority's "new opinion does little to assuage, and even exacerbates, concerns raised by the original." Dissent 38. She observed that Teva "played by the rules, exactly as Congress intended"—carving-out the patented CHF indication based on information GSK provided to FDA and including only the two unpatented indications. Dissent 2. In nonetheless holding Teva liable, the majority's new opinion "effectively eliminat[ed]" the affirmative-encouragement requirement, and "eviscerate[ed] the causation prong of inducement." Dissent 3. Where there was previously clarity and "equilibrium to the skinny-label system," there is now confusion and uncertainty. Dissent 35, 37. That uncertainty discourages generics from using carve-outs, which "throw[s] a wrench into Congress's design for enabling quick public access to generic versions of unpatented drugs with unpatented uses." Dissent 3.

ARGUMENT

I. The panel's departures from precedent throw inducement doctrine into disarray.

The panel's decision contradicts settled precedent, eviscerates the carve-out statute, and throws inducement doctrine into disarray. Because "the background facts here will seemingly persist in most skinny-label cases," Dissent 35, the effects of the decision will be seismic.

A. The panel's decision rejects the previously clear line between "encouraging" and merely "describing" an infringing use.

The panel sustained massive liability on the theory that, even after carving out the CHF indication as FDA instructed, Teva's label still mentioned the elements of the patented method. Until now, this Court's cases had rejected that type of inducement-by-hidden-message. Mentioning claim elements is not enough; inducement requires encouraging the entire method.

1. Merely selling an unpatented product that can be (or even is) used in an infringing manner cannot give rise to inducement liability. *See, e.g.*, *Takeda*, 785 F.3d at 630. Inducement therefore requires a clear showing of "active steps taken to encourage direct infringement," *id.* (citation omitted). That rule is "particularly important" in the prescription-drug context, because Congress designed Hatch-Waxman expressly to encourage the launch of off-patent generics labeled for unpatented indications—"even though this would result in *some* off-label infringing uses." *Id.* at 631; Dissent 30.

Accordingly, this Court has drawn a consistent line between "encouraging" and merely "describing" an infringing use—the latter is insufficient to show inducement. *See, e.g.*, *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1323-1324 (Fed. Cir. 2012) (affirming Rule 12(c) dismissal where claim elements "may be *described* outside the Indications and Usage section of the FDA-approved

label" but the label "fails to *recommend* or *suggest*" the patented method-of-treatment (emphases added)); *HZNP Meds. LLC v. Actavis Labs. UT, Inc.*, 940 F.3d 680, 701-702 (Fed. Cir. 2019) (affirming summary judgment where label mentioned and "*describe[d]*" each claim element but did not "*require*," and therefore "encourage," the patented method (emphases added)); *see also Takeda*, 785 F.3d at 631 ("[m]erely 'describing' an infringing mode is not the same as 'recommending', 'encouraging,' or 'promoting' an infringing use, or suggesting that an infringing use 'should' be performed" (citations and brackets omitted)).

That is why the focus of the label-inducement inquiry is supposed to be the "Indications and Usage" section, which explicitly *instructs* therapeutic uses. *See Bayer*, 676 F.3d at 1319-1324; *BTG Int'l Ltd. v. Amneal Pharms. LLC*, 352 F. Supp. 3d 352, 391-392 (D.N.J. 2018) ("The Federal Circuit held ... [in *Bayer*], it is the Usages and Indications section that does the real work."). It is also how FDA says labels should be read. 21 C.F.R. § 201.57(c)(2)(iv) ("Indications or uses must not be implied or suggested in other sections of the labeling"). Once Teva deleted the CHF indication from that section, plus 50 paragraphs of CHF-related material, Dr. McCullough testified that he would not have prescribed Teva's product to treat CHF based on that label: it was "missing too much information." Appx11660-11661.

2. The majority's inducement analysis throws this previously clear doctrine into disarray by embracing precisely the "scholarly scavenger hunt" that

courts have consistently rejected. *Takeda Pharms. USA, Inc. v. W.-Ward Pharm. Corp.*, 72 F. Supp. 3d 539, 548 (D. Del. 2014) (citation omitted), *aff'd*, 785 F.3d 625 (Fed. Cir. 2015). The majority did not identify any *instruction* or *encouragement* of the patented method-of-treatment in Teva's label. Instead, it looked to testimony that disparate portions of the label "mention" or "meet" individual claim limitations. Op. 14-15, 17, 24; Dissent 18-19; Appx10622-10631.

For example, addressing the first claim element (decreasing mortality caused by CHF), Dr. McCullough noted sections of the label where "there's a mention" of "heart failure," including one that was expressly agnostic about whether patients even *had* heart failure. Appx10623; *see* Appx5508 (directing use of carvedilol to treat post-MI LVD patients "with or without symptomatic heart failure").

Addressing the coadministration requirement (administering carvedilol with an ACE inhibitor, diuretic, or digoxin), Dr. McCullough pointed to a section describing a clinical trial of heart-attack patients, a minority of whom also had "symptoms of heart failure." Appx5523. He testified that "ACE inhibitors and diuretics are certainly mentioned there," Appx10625, among numerous "[b]ackground treatment[s]" that trial participants were already taking. Appx5523. But he never said—because he could not—that any patient with heart failure was administered carvedilol together with an ACE inhibitor or digoxin, much less that the label *encouraged* it.

This approach sharply departs from circuit precedent. *HZNP* squarely held that a label "describing" *every claim step*, but not "requir[ing]" that each step be taken, "does not encourage infringement" *or* create "material issues of fact." 940 F.3d at 702.[9] Similarly, *Bayer* expressly rejected the notion that "mention[ing]" claim limitations in disparate portions of labeling equals "recommend[ing] or suggest[ing]" an infringing use, 676 F.3d at 1322. And *Takeda* warned that a mention of an infringing use "cannot be combined with *speculation* about how physicians may act to find inducement." 785 F.3d at 632 (emphasis added).

In all of these cases, this Court focused on the *legal* distinction between "describing" an infringing mode and "encouraging" it. The majority has now eviscerated that distinction. Indeed, it echoes the *dissents* in these cases, which *disagreed* with key premises in the Court's caselaw—that Hatch-Waxman was designed to allow skinny-labeled generics to launch even if some off-label infringement would result, and that a skinny label must promote infringement to induce. *See Takeda*, 785 F.3d at 635-36 (Newman, J., dissenting); *Bayer*, 676 F.3d

[9] The method in *HZNP* had three steps. Op. 17. The label directed patients to perform the first and, *if* they chose to perform the third, to perform the second as well. "This does not encourage infringement, particularly where the label does not *require*" anything more than the first. 940 F.3d at 702 (emphasis added). And the label mentioned the "not require[d]" third step much more directly than Dr. McCullough testified that Teva's skinny label mentions the carved-out elements here.

at 1329 (Newman, J., dissenting); *HZNP*, 940 F.3d at 709 (Newman, J., dissenting).

B. The panel's decision nullifies inducement's causation requirement.

To induce infringement means "to influence" the infringer—"to prevail on" someone to commit the act of infringement. *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 760 (2011) (citation omitted). Talk is not enough; the infringer must both listen and be moved.

The district court granted JMOL because overwhelming, uncontroverted evidence showed that Teva's actions did not influence doctors. Appx20. Every doctor who testified—including GSK's witnesses—said he *did not read*, and therefore could not have been moved by, Teva's generic label before prescribing carvedilol. Dissent 20. The majority nonetheless held that the jury could reasonably "infer that when Teva distributed and marketed a product with labels encouraging an infringing use, it actually induced doctors to infringe." Op. 36. In other words, there is no need to *prove* causation. Instead, if a label *was capable of* causing infringement, the jury can simply *assume* causation, even where undisputed evidence from both sides directly contradicts that assumption. As Judge Prost recognized, the majority's opinion effectively holds "that there is no independent causation element for inducement; intentional encouragement might always suffice to infer causation too." Dissent 34. That means failure to prove causation will never keep a case from reaching a jury.

The majority's causation holding squarely conflicts with precedent requiring plaintiffs to prove that the inducer "actually caused" infringement, *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1330 (Fed. Cir. 2016), and traditional tort principles requiring proof of causation that does not rely on "pure speculation and conjecture," Dissent 31 (quoting *Restatement (Second) of Torts* § 433B cmt. a). The majority invokes the jury's factfinding role, Op. 36, but there were no disputes of material fact on causation. Instead, overwhelming direct evidence *negated* that element, while not a shred of direct evidence *supported* it. And unsupported speculation will not do. *See, e.g.*, *Mirror Worlds, LLC v. Apple Inc.*, 692 F.3d 1351, 1353 (Fed. Cir. 2012) (jury verdict cannot rely on inference contrary to the record); *Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1260 (Fed. Cir. 2010) (jury "was not free to disregard the overwhelming record evidence" of non-infringement "and instead to 'infer' that" infringement "might" be possible). Without evidence of causation, the district court rightly granted JMOL.

II. The grave harm to competition and uncertainty the majority's decision creates make this case exceptionally important.

As the dissent observes, this case is "far from … a disagreement among reasonable minds about the individual facts." It is a "signal[] that [the circuit's] law on [inducement] has gone awry." Dissent 3. Commentators have agreed—calling

the decision an "important, controversial decision"[10] that leaves the skinny-label statute effectively "dead."[11] And copycat litigation against other carve-outs has already begun.

The reason is simple: "the background facts here will seemingly persist in most skinny-label cases." Dissent 35. Needing only to find claim elements "mentioned" in the label, brands will regularly find *something* in the skinny label that gets their case to the jury—as the progress of the first copycat case shows. *Amarin*, 2021 WL 3396199, at *6-8 (R&R recommending denial of motion to dismiss).[12] Under the majority's opinion, those defendants will be unable to avoid trial or obtain JMOL, no matter how weak the plaintiff's causation evidence. And plaintiff will always be able to adduce evidence that the generic truthfully described itself as AB-rated, Op. 27-28—which *every generic* necessarily does, which is why there was such an outcry after the panel's prior opinion rested on that evidence. Dissent 13.

The carve-out statute cannot function if every carve-out leads to a jury trial. When inducement liability required clear evidence of affirmative encouragement,

[10] Silver, *supra*.

[11] Koblitz, *supra*.

[12] By contrast, before this case, claims like GSK's were routinely dismissed on the pleadings. *E.g.*, *Novartis Pharms., Corp. v. Wockhardt USA LLC*, 2013 WL 5770539, at *9 (D.N.J. Oct. 23, 2013).

generics could launch in confidence that their skinny labels do not induce infringement, just as Congress intended. But now, the risk of generic launch with a carve-out label is far too great given that the lost-profits damages a jury can award (hundreds of millions of dollars) dwarfs the profits a generic earns (pennies per pill—or worse, a net *loss*, Appx10875-10876). *See* 2020 Dissent 10.

Nor is this regime workable for FDA. Generics cannot write their own labels to avoid infringement. Rather, the brand identifies what parts of its own labeling its method-of-use patents claim, 21 C.F.R. § 314.53(c)(2)(O), and FDA relies on the brand's description when it proposes carved-out labeling. But the panel opinion makes clear that following FDA's instructions, based on the brand's explicit claims, is no safe harbor. And brands will now have every incentive to write their labels to facilitate claims of inducement after a carve-out.

Because of the massive damages exposure, Section viii will now be *riskier* than pre-launch Paragraph IV litigation. Brand manufacturers can lie in wait for years after generic launch, then sue to recover their lost market share. Indeed, they began using that strategy immediately after the majority's 2020 opinion, suing generic manufacturers that launched with a skinny label and even one health insurer. *See* Lopez, *supra*; *Amarin*, 2021 WL 3396199.

That daunting prospect will be too risky for generic manufacturers. The majority's "opaque" decision will create enormous, competition-killing uncertainty,

"leaving [generics] in the dark about what might expose them to liability," Dissent 3, and discouraging them from entering the market.

Losing the carve-out mechanism will cost the entire health-care system. When a brand drug has both patented and unpatented uses, the first generic launch relies on a skinny label nearly half the time.[13] Without carve-outs, generic approval will take years longer. The result will be "billions and billions" in lost drug savings for patients and the federal government.[14]

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

[14] Kass, *supra*.

CONCLUSION

Rehearing en banc should be granted.

Respectfully submitted.

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October 7, 2021

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, Judge Leonard P. Stark.

Decided: August 5, 2021

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

Opinion for the court filed per curiam.

Dissenting opinion filed by *Circuit Judge* PROST.

PER CURIAM.

GlaxoSmithKline LLC and SmithKline Beecham (Cork) Ltd. (collectively, GSK) sued Teva Pharmaceuticals USA, Inc. in the United States District Court for the District of Delaware for infringement of claims of GSK's Reissue Patent No. RE40,000. After the jury's verdict of infringement and its award of damages, the district court granted Teva's renewed motion for judgment as a matter of law of noninfringement. *GlaxoSmithKline LLC v. Teva Pharm. USA, Inc.*, 313 F. Supp. 3d 582 (D. Del. 2018) (*Dist. Ct. Op.*). GSK appeals the JMOL, and Teva conditionally cross-appeals the jury's damages award. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

For the reasons below, we vacate the grant of JMOL, reinstate the jury's verdict and damages award, and remand for appropriate further proceedings.

BACKGROUND

GSK markets and sells the medicinal product carvedilol, a beta-blocker, under the brand name Coreg®. The Food and Drug Administration (FDA) has approved carvedilol for three indications of use. By 1997, the FDA had approved carvedilol for treatment of hypertension and congestive heart failure (CHF). Then, in 2003, the FDA approved carvedilol for a third use: to reduce cardiovascular

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[*] Chief Judge Kimberly A. Moore assumed the position of Chief Judge on May 22, 2021.

[**] Circuit Judge Sharon Prost vacated the position of Chief Judge on May 21, 2021.

mortality in patients suffering from left ventricular dysfunction following a myocardial infarction, i.e., the "post-MI LVD" indication.

When GSK began investigating carvedilol's use for treating CHF, beta-blockers were contraindicated for that use. This was because beta-blockers slow the heart rate and reduce the heart's ability to pump blood, a potentially deadly combination for patients with heart failure. Very few doctors or companies, therefore, saw the potential for investigating beta-blockers for treating CHF. Despite this skepticism, GSK spent years investigating, and conducting trials of, carvedilol for the treatment of heart failure. And at the time, the only known treatment for improving mortality rates in CHF patients was with angiotensin-converting enzyme (ACE) inhibitors. Still, even with ACE inhibitors, patients continued to die from heart failure at high rates. It was not until the FDA approved GSK's Coreg® that using a beta-blocker to treat CHF became the standard of care for reducing mortality in heart failure patients.

The carvedilol compound was patented in 1985. *See* U.S. Patent No. 4,503,067, expiration date March 5, 2007. In 1998, U.S. Patent No. 5,760,069 issued, which claimed a method of administering a combination of carvedilol and one or more of an ACE inhibitor, a diuretic, and digoxin to decrease mortality caused by CHF in a patient.

In March 2002, Teva filed an Abbreviated New Drug Application (ANDA) for FDA approval of its generic carvedilol for all three indications. It certified, under Paragraph III of the Hatch-Waxman Act,[1] that it would not launch its product until the '067 patent on the carvedilol compound expired in March 2007. *See* 21 U.S.C.

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[1] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. 98–417, 98 Stat. 1585 (1984).

§ 355(j)(2)(A)(vii)(III). Teva also certified, under Paragraph IV, that the '069 patent was "invalid, unenforceable, or not infringed." *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). On May 24, 2002, Teva sent GSK a Paragraph IV notice stating that the claims of the '069 patent are anticipated or would have been obvious. GSK did not sue Teva upon receipt of the notice, and on November 25, 2003, GSK applied for reissue of the '069 patent under 35 U.S.C. § 251. Teva received FDA "tentative approval" for its ANDA in 2004, "for treatment of heart failure and hypertension." J.A. 7437. The approval was to become effective when the '067 patent expired in 2007.

On January 8, 2008, the PTO issued Reissue Patent No. RE40,000, and GSK notified the FDA on February 6, 2008. *See* J.A. 6880–82. The '000 patent, asserted in this case, claims a method of decreasing mortality caused by CHF by administering carvedilol with at least one other therapeutic agent. *See, e.g.*, '000 patent, col. 1, ll. 17–25. Claim 1 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,
>
> *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.*

(emphasis in original). The '000 patent is listed in the FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the

Orange Book, as a patent claiming a method of using Coreg®.

Just before Teva launched its generic carvedilol in 2007, it certified to the FDA that its label "will not include the indication defined in use code U-233" until the expiration of the '069 patent. J.A. 6176; *see* 21 U.S.C. § 355(j)(2)(A)(viii) (section viii). Patent use code U-233 corresponded to "decreasing mortality caused by congestive heart failure." J.A. 7833. Teva's label dated "8/2007" thus included only two indications: the post-MI LVD indication and the hypertension indication. J.A. 5506, 5508. Teva's press releases and marketing materials, however, touted its generic carvedilol as "indicated for treatment of heart failure and hypertension," as the "Generic version of [GSK's] cardiovascular agent Coreg®," and as an "AB-rated generic equivalent of [GSK's] Coreg® Tablets."[2] J.A. 6347, 6353.

In 2011, following GSK's delisting of certain patents from the Orange Book, including the '069 patent and U.S. Patent No. 5,902,821, the FDA instructed Teva to "revise [its] labeling to include the information associated with patent '821 (delisted) and the associated Use Code (U-313)." J.A. 5557. It told Teva to submit labeling "that is identical in content to the approved [GSK Coreg®] labeling (including the package insert and any patient package insert

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[2] The FDA assigns an "AB rating" for a drug that is considered therapeutically equivalent to another drug. FDA, Orange Book Preface § 1.7 (41st ed. current as of Jan. 21, 2021), https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface. A therapeutically equivalent drug is one that "can be expected to have the same clinical effect and safety profile when administered to patients under the conditions *specified in the labeling*." *Id.* § 1.2 (emphasis added); *see also* 21 C.F.R. § 314.3(b) (same).

and/or Medication Guide that may be required)." J.A. 5557. The FDA also requested Teva "provide information regarding [its] position on [the '000 patent]." *Id.*

Teva amended its label to include the indication for treating patients with chronic heart failure by administering carvedilol to increase survival and to reduce the risk of hospitalization. J.A. 5532. In addition, the post-MI LVD and hypertension indications remained on the label. In response to the FDA's request for information regarding its position on the '000 patent, Teva told the FDA it believed it need not "provide certification to [the '000 patent]" because it received final approval of its ANDA before the '000 patent issued. J.A. 5554.

On July 3, 2014, GSK sued Teva and Glenmark Pharmaceuticals USA, the two largest suppliers of generic carvedilol, in the District of Delaware, alleging that each had induced infringement of the '000 patent. The action against Glenmark was severed and stayed.

During a seven-day jury trial, Teva argued the asserted claims of the '000 patent were invalid and not infringed. Teva argued it could not have induced infringement, at least prior to 2011, because it had "carved out" the indication and prescribing information for treatment of congestive heart failure in its 2007 label under section viii. Teva also argued that it could not be liable for inducement for any time period because it did not cause others to infringe the method claimed in the '000 patent.

The district court instructed the jury to assess whether Teva induced infringement during two distinct time periods: the "partial label" period and the "full label" period. J.A. 171. The partial label period was from January 8, 2008, through April 30, 2011, when Teva's label had the post-MI LVD and hypertension indications but not the chronic heart failure indication. *Id.* The full label period was from May 1, 2011, through June 7, 2015, when Teva's

label had all three indications, including the chronic heart failure indication. *Id.*

The jury found the '000 patent was not invalid, that Teva induced infringement of claims 1–3 during the partial label period, and that Teva induced infringement of claims 1–3 and 6–9 during the full label period. The jury assessed damages based on a combination of lost profits and a reasonable royalty and found Teva's infringement willful.

The district court granted Teva's renewed motion for JMOL, stating that substantial evidence did not support the verdict of induced infringement because GSK failed to prove that Teva's alleged inducement, as opposed to other factors, actually caused physicians to directly infringe by prescribing generic carvedilol for the treatment of mild to severe CHF. *Dist. Ct. Op.* at 591. The district court explained that "[w]ithout proof of causation, which is an essential element of GSK's action, a finding of inducement cannot stand." *Id.*

The district court also determined no reasonable juror could have found induced infringement based on the post-MI LVD indication in Teva's partial label, which GSK had argued instructed practice of the claimed method. *Id.* at 592 n.9. Although the district court acknowledged there is some overlap with CHF patients and post-MI LVD patients, it reasoned "the two indications are distinct and require different clinical testing and different FDA approvals to treat." *Id.* It further reasoned infringement required carvedilol be "prescribed to treat the risk of mortality ***caused by CHF***." *Id.* (emphasis in original). The district court concluded a reasonable juror could not have found Teva's post-MI LVD indication "caused or even encouraged direct infringement" of this claimed use. *Id.*

GSK appealed, arguing that substantial evidence supported the jury's finding of induced infringement and that its verdict should be reinstated. We agreed. Teva petitioned for *en banc* rehearing, which we construed as also

requesting panel rehearing. Teva argued our October 2, 2020 decision could be broadly read to impose liability on ANDA filers that carve out patented uses under section viii when seeking approval to market generic drug products, in direct contravention of the Hatch-Waxman Act. *Amici curiae* raised concerns about lack of clarity of our decision when the patented uses are carved out of the FDA-approved label. On February 9, 2021, we granted the petition for panel rehearing, vacated the October 2, 2020 judgment, and withdrew the October 2, 2020 opinions.

Amici were concerned that our prior decision could be read to upset the careful balance struck with section viii carve-outs. The Novartis Brief explained, "Generics *could* be held liable for actively inducing infringement if they marketed a drug with a label describing a patented therapeutic use or if they took active steps to encourage doctors or patients to use the drug in an infringing manner. But generics could *not* be held liable for merely marketing and selling under a 'skinny' label omitting all patented indications, or for merely noting (without mentioning any infringing uses) that FDA had rated a product as therapeutically equivalent to a brand-name drug." Novartis Br. at 1–2. We agree that Novartis accurately stated the law, and we agreed to rehear this case to make clear how the facts of this case place it clearly outside the boundaries of the concerns expressed by *amici*. As this record reflects, in both time periods, substantial evidence supports that Teva actively induced by marketing a drug with a label *encouraging a patented therapeutic use*. They did not "omit[] all patented indications" or "merely note[] (without mentioning any infringing uses) that FDA had rated a product as therapeutically equivalent to a brand-name drug." Novartis Br. at 1–2. This is a case in which substantial evidence supports a jury finding that the patented use was on the generic label at all relevant times and that, therefore, Teva failed to carve out all patented indications. This narrow, case-specific review of substantial evidence does not upset

the careful balance struck by the Hatch-Waxman Act regarding section viii carve-outs.

DISCUSSION

We apply regional circuit law for review of a district court's grant of JMOL. *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1309 (Fed. Cir. 2009). The Third Circuit reviews those grants *de novo*. *Curley v. Klem*, 499 F.3d 199, 205–06 (3d Cir. 2007). Following a jury trial, a 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). "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).

I

INDUCED INFRINGEMENT

"Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). "Infringement is a question of fact, reviewed for substantial evidence when tried to a jury." *Lucent*, 580 F.3d at 1309. A finding of inducement requires establishing "that the defendant possessed specific intent to encourage another's infringement." *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (*en banc* in relevant part) (internal quotation marks omitted). This requires a plaintiff to show "that the alleged infringer's actions induced infringing acts and that he knew or should have known his actions would induce actual infringements." *Id.* (internal quotation

marks omitted). "While proof of intent is necessary, direct evidence is not required; rather, circumstantial evidence may suffice." *Id.* (internal quotation marks omitted). When a plaintiff relies on a drug's label accompanying the marketing of a drug to prove intent, "[t]he label must encourage, recommend, or promote infringement." *Takeda Pharm. USA, Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015) (citations omitted).

GSK argues that substantial evidence supports the jury's verdict of induced infringement. Throughout the trial and on appeal, GSK argued there are two indications on the labels that instruct doctors to prescribe carvedilol for uses that directly infringe the '000 patent claims: the post-MI LVD indication and the congestive heart failure indication. Thus, GSK argues both the partial label and the full label encourage infringement. We first address the partial label period and then turn to the full label period.

THE PARTIAL LABEL PERIOD

A generic producer may exclude a patented use from its label, by way of a "section viii carveout" as provided by 21 U.S.C § 355(j)(2)(A)(viii):

> (2)(A) An abbreviated application for a new drug shall contain—
>
> > (i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");
> >
> > * * *
> >
> > (viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of

> use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The applicant must also submit its proposed label to the FDA omitting or carving out all methods of use claimed in a patent. 21 C.F.R. § 314.94(a)(8)(iv). "FDA acceptance of the carve-out label allows the generic company to place its drug on the market (assuming the ANDA meets other requirements), but only for a subset of approved uses—*i.e.*, those not covered by the brand's patents." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 406 (2012).

GSK argues that, despite Teva's section viii certification purporting to carve out one heart failure indication and its deletion of the indication from its partial label, substantial evidence supports the jury's finding that Teva induced doctors to infringe the method of use claimed in the '000 patent. GSK argues that substantial evidence supports the jury's verdict that Teva's partial label encouraged an infringing use (via the post-MI LVD indication) and that Teva's marketing materials encouraged prescribing carvedilol in a manner that would cause infringement of the '000 patent. We agree.

A

The parties dispute whether Teva effected a section viii carve-out of GSK's patented methods of use, making Teva's label a so-called "skinny label." Since the jury found infringement, we must assume it decided that question in GSK's favor. *Williamson v. Consol. Rail Corp.*, 926 F.2d 1344, 1348 (3d Cir. 1991) ("When reviewing the jury's finding . . . , we give [plaintiff], as verdict winner, the benefit of all logical inferences that could be drawn from the evidence presented, resolve all conflicts in the evidence in his favor and, in general, view the record in the light most favorable to him."). And as a quintessential fact question, we must

uphold the jury's verdict on that point so long as substantial evidence supports it. GSK provided substantial evidence that Teva's partial label instructed the method of use claimed in the '000 patent and thus was not a skinny label.

At the outset, GSK's cardiology expert, Dr. McCullough, explained that doctors, the alleged direct infringers, receive information about generic drug products from a variety of sources, including the drug labels. J.A. 10612:1–9. He then walked through each element of claim 1 of the '000 patent and compared it to Teva's partial label. He relied on the post-MI LVD indication in Teva's partial label, which stated:

> 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) (*see CLINICAL STUDIES [14.1]*).

J.A. 5508 (emphasis and brackets in original). Dr. McCullough testified this description satisfied the "decreasing mortality caused by congestive heart failure in a patient" limitation. *See* J.A. 10623:6–17; *see also* J.A. 10629:19–10630:6, 10630:16–20. He also explained that post-MI LVD "is intertwined with heart failure." J.A. 10673:23–10674:1. Teva's cardiology expert, Dr. Zusman, agreed that a patient who has a left ventricular ejection fraction of less than or equal to 40% with symptomatic heart failure (as recited on Teva's partial label) would be diagnosed as suffering from congestive heart failure under the district court's construction. J.A. 11226:14–19.

GSK presented evidence that Teva's partial label also satisfied the remaining claim limitations. Dr. McCullough testified that the Dosage and Administration section of the partial label disclosed administering particular dosages that satisfied the "administering a therapeutically acceptable amount of carvedilol" and administering "daily

maintenance dosages" limitations. *See* J.A. 10624:12–18, 10624:24–10625:3, 10626:9–19, 10626:23–10627:1. The post-MI LVD indication, the portion of the label Dr. McCullough testified satisfied the CHF limitation, explicitly directs the reader to Clinical Studies § 14.1 of Teva's label. J.A. 5508. The Clinical Studies § 14.1 showed that patients taking carvedilol in the study had background treatment of ACE inhibitors and diuretics. Dr. McCullough explained this satisfied the claim limitation of administering carvedilol in conjunction with one or more other therapeutic agents selected from the group consisting of ACE inhibitors, a diuretic, and digoxin. J.A. 10625:4–19, 10625:24–10626:8; *see also* J.A. 5523 (CAPRICORN study in which 47% of patients receiving carvedilol had symptoms of heart failure, 97% also had background treatment of ACE inhibitors or angiotensin receptor blockers, and 34% had background treatment of diuretics); *Sanofi v. Watson Labs. Inc.*, 875 F.3d 636, 645 (Fed. Cir. 2017) (Indication section referencing clinical study section "expressly direct[ed] the reader to that section for elaboration of the class of patients for whom the drug is indicated to achieve the stated objective"). Finally, Dr. McCullough testified that Figure 1 in Clinical Studies § 14.1 showed treatment for longer than six months, which satisfied the "maintenance period is greater than six months" limitation. J.A. 10627:9–21, 10629:15–18, 10630:21–10631:6, 10631:12–15; *see also* J.A. 5524 (Fig. 1).

Teva characterizes GSK's argument as a "cobbl[ing] together" of disparate portions of the partial label. Teva Principal and Resp. Br. at 48, 50. The dissent appears to adopt Teva's characterization, arguing that a jury would have to "piece[] together" the partial label to arrive at the infringing use. Dis. at 18–20; *see also id.* at 33. All of the claim limitations were contained in the Indication section (which amounted to a single sentence), the Clinical Study section (to which doctors were directly referred by the Indication section), and the Dosage and Administration

section (which immediately follows the Indication section and which says how much and how often to give the carvedilol). The jury was entitled to credit expert testimony regarding the label's instructions on who should take what drug, when, why, and how, and to reject the argument that certain portions of the label were disjointed from others.

Teva relies on our decision in *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316 (Fed. Cir. 2012). In *Bayer Schering*, the patented method of use required achieving three simultaneous effects in the body. *Id.* at 1320. The defendant's drug product label contained an indication for only one of those effects, with no discussion of safety or efficacy for the other two claimed effects. *Id.* at 1322. Thus, we held the label failed to recommend or suggest achieving the claimed combination of effects. *Id.* at 1324. Here, however, as discussed above, Dr. McCullough marched through Teva's label explaining how it met the limitations of claim 1. Unlike the absence of information in the label of *Bayer Schering*, Dr. McCullough provided testimony that Teva's partial label instructed the claimed treatment and use.

Teva never genuinely challenged Dr. McCullough's testimony regarding the contents of Teva's partial label. Teva cites portions of Dr. Zusman's testimony as purporting to contradict that the post-MI LVD indication means treating heart failure. Teva relies on Dr. Zusman's testimony that treating patients to help them survive heart attack is not treating heart failure. Teva Principal and Resp. Br. at 53 (citing J.A. 11183). But Dr. Zusman also agreed the post-MI LVD patients with symptomatic heart failure would be diagnosed as suffering from congestive heart failure under the district court's construction of that term (which has not been appealed). J.A. 11226:14–19. It was within the province of the jury to weigh the testimony presented by both sides and make its finding. *See Dardovitch v. Haltzman*, 190 F.3d 125, 140 (3d Cir. 1999) ("Credibility determinations are the unique province of a fact finder, be it a jury, or a judge sitting without a jury."); *MobileMedia Ideas LLC*

v. Apple Inc., 780 F.3d 1159, 1168 (Fed. Cir. 2015) ("[W]hen there is conflicting testimony at trial, and the evidence overall does not make only one finding on the point reasonable, the jury is permitted to make credibility determinations and believe the witness it considers more trustworthy.").

We also do not agree with Teva's argument that its partial label's recitation of treating patients "with or without symptomatic heart failure" precludes inducement since this may encourage both infringing and noninfringing uses. Teva relies on *HZNP Medicines LLC v. Actavis Laboratories UT, Inc.*, 940 F.3d 680 (Fed. Cir. 2019), and *Grunenthal GmbH v. Alkem Laboratories Ltd.*, 919 F.3d 1333 (Fed. Cir. 2019). According to Teva, when its generic carvedilol is used to treat patients without symptomatic heart failure, there is no infringement, and thus, the label's recommended use on both types of patients somehow obviates infringement. We do not find this argument persuasive, and neither of the cases cited by Teva is analogous to these facts.

In *HZNP*, the claimed method of use required three steps: applying a topical medication, waiting for the treated area to dry, and then applying a second topical product. 940 F.3d at 702. Actavis' generic label, however, only required the first applying step. The district court examined the label and held, at summary judgment, it did not induce the claimed use. *Id.* We agreed given the lack of evidence that the label encouraged, recommended, or promoted users to perform two of the three claimed steps. *Id.* In contrast, substantial evidence in this case supports the jury's determination that Teva's partial label contained information encouraging each claimed step and the preamble. Dr. McCullough's testimony that the partial label met each claim limitation and represented to doctors that the treatment decreased mortality caused by CHF supports the jury's finding. *See* J.A. 10623:6–17, 10629:19–10630:6, 10630:16–20.

In *Grunenthal*, the claimed method of use was treating polyneuropathic pain. 919 F.3d at 1336. The defendants filed section viii statements carving out treatment of diabetic peripheral neuropathy (DPN), a type of polyneuropathic pain. *Id.* at 1339. The generic labels nonetheless maintained an indication to broadly treat severe pain requiring around-the-clock treatment. Yet evidence supported that this severe pain would not necessarily be polyneuropathic, but could also be mononeuropathic or nociceptive. *Id.* In that case, the district court made a factual determination that this label did not instruct the claimed method. We found no *clear error* in the district court's finding of no inducement because the generic labels did not "implicitly or explicitly encourage or instruct users to take action that would inevitably lead to . . . treatment of polyneuropathic pain." *Id.* at 1340.[3] Here, a jury found inducement. The combination of Teva's partial label, Dr. McCullough's element-by-element testimony that the partial label explicitly instructs administering carvedilol for the claimed use of decreasing mortality caused by CHF, and Dr. Zusman's admission that the post-MI LVD indication falls within the definition of congestive heart failure is substantial evidence that supports the jury's finding.

Critically, the district court erred by treating this fact question—whether the post-MI LVD indication instructs a physician to prescribe carvedilol for a claimed use—as though it were a legal one for it to decide *de novo*. In a footnote of the district court's JMOL decision, it decided the post-MI LVD portion of Teva's label was insufficient to find that the label instructed an infringing use. *Dist. Ct. Op.* at 592 n.9. The district court erred at JMOL by making a fact

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[3] Moreover, in contrast to this case, we recognized in *Grunenthal* that the partial label was the only evidence of inducement and that we could not conclude on those facts that the district court clearly erred.

finding, namely, "[w]hile there may be some overlap between populations of patients suffering from CHF – the treatment of which is within the scope of the '000 patent's claims – and those suffering from post-MI LVD – whose treatment is outside the scope of the claims – the two indications are distinct and require different clinical testing and different FDA approvals to treat." *Id.* Whether treating post-MI LVD patients with symptomatic heart failure with carvedilol was within the scope of the claims was a fact question. It was for the jury, not this court or the district court, to resolve. "In determining whether the evidence is sufficient to sustain [the jury's finding of] liability, the court may not weigh the evidence, determine the credibility of witnesses, or substitute its version of the facts for the jury's version." *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1166 (3d Cir. 1993). The district court erred in reweighing the evidence and finding against GSK following the jury's verdict in its favor.

B

To be sure, the record was not devoid of contrary or equivocal evidence. Teva argues that GSK's submissions to the FDA for Orange Book listing associated with the '000 patent is such evidence. If a new drug application (NDA) has already been approved when the applicant obtains a patent, the applicant must notify the FDA of such patent within 30 days of it issuing. 21 C.F.R. § 314.53(c)(2)(ii). Under penalty of perjury, GSK submitted information for the '000 patent, which issued after carvedilol was FDA-approved, declaring it claimed a method of use for carvedilol. J.A. 6880–87 (Form FDA 3542). GSK was required in part 4.2a of its declaration to "identify the use with specific reference to the approved labeling for the drug product." J.A. 6881. It listed: "treatment of mild-to-severe heart failure of ischemic or cardiomyopathic origin, usually in addition to diuretics, ACE inhibitor, and digitalis, to increase survival." *Id.* GSK did not mention the post-MI LVD indication in this submission to the FDA. This,

however, does not appear to be the information listed in the Orange Book.

The FDA further required, in part 4.2b of the Form, that GSK "[s]ubmit the description of the approved indication or method of use that [it] propose[d] FDA include as the '*Use Code*' in the Orange Book." J.A. 6882. GSK answered: "Decreasing Mortality Caused By Congestive Heart Failure." *Id.* The FDA accepted that representation and listed the corresponding use code in the Orange Book as describing what is covered by the '000 patent.

There are two ways in which GSK's failure to identify the post-MI LVD use in its part 4.2a statement could be relevant to inducement in this case. First, that failure is relevant to whether the post-MI LVD use infringes. Second, at least for the partial label period, that failure is relevant to intent to induce infringement.[4] On both points, the jury decided against Teva.

As Teva acknowledged, GSK's submissions to the FDA are "not absolutely dispositive of infringement." *See GlaxoSmithKline LLC v. Teva Pharm. USA, Inc.*, No. 18-1976 (Feb. 23, 2021), Oral Arg. at 55:49–57:07, available at http://oralarguments.cafc.uscourts.gov/default.aspx?fl=18-1976_02232021.mp3. As we have observed, "the FDA is not the arbiter of patent infringement issues." *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1061 (Fed. Cir. 2010). In fact, the FDA has made clear that use codes in the Orange Book "are not meant to substitute for the [ANDA] applicant's review of the patent and the approved labeling."

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[4] It is hard to imagine how GSK's failure to identify that the '000 patent claims the post-MI LVD use has any bearing on the full label period, as during the full label period, Teva's listed all three indications without regard for GSK's assertions in the Orange Book or its FDA declaration.

Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676, 36,683 (June 18, 2003) (to be codified at 21 C.F.R. pt. 314). The FDA further concluded that it has no expertise in patent law and that a court is the appropriate forum for determining the scope of patent rights. *Id.*; *see also* Trial Tr. at 525:12–526:15 (GSK's regulatory expert, Prof. Lietzan, discussing the FDA's statements). Teva's FDA expert, Mr. Karst, agreed that a generic may not rely upon the Orange Book use codes provided by the brand for patent infringement purposes and that ANDA applicants have a separate obligation to analyze the scope of the patents themselves:[5]

> Q. And FDA has also stated that [use codes listed in the Orange Book provided by the patentee] are not meant to substitute for the applicant's review of the patent and the approved labeling. Correct?
>
> A. That is what FDA said, correct.
>
> Q. And that is something that you understand in your line of work; is that correct?
>
> A. Yes, I do.
>
> [. . .]
>
> Q. You believe there's a separate obligation by ANDA applicants to analyze the scope of patents listed in the Orange Book to determine how to prepare their Section viii carve-out label; is that correct?

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[5] In fact, an ANDA filer can omit from its label "an indication or other aspect of labeling protected by patent," whether that patent is contained in the Orange Book or not. *See* 21 C.F.R. § 314.94(a)(8)(iv).

> A. It's correct that FDA said the statement you just had up there. I guess it's gone now, where FDA provides a statement to that effect. That is correct.

Trial Tr. at 1057:13–1058:10. Both FDA experts agreed that the FDA plays no role in determining patent infringement. The jury heard this evidence and the evidence discussed above as to GSK's claim that the post-MI LVD indication infringed the '000 patent. Thus, substantial evidence supports the jury's finding that the post-MI LVD indication infringed the '000 patent.

At oral argument on rehearing, Teva suggested that GSK's FDA submission for the Orange Book listing for the '000 patent, which according to Teva is at odds with GSK's infringement allegations, creates equitable estoppel. *See* Oral Arg. at 53:56–55:28. There are serious consequences for filing false or incomplete information to the FDA. *See id.* at 55:28–56:04 (Teva explaining the consequences including rejection of the NDA); *see also* 18 U.S.C. § 1001 (it is a criminal act to file a false declaration under penalty of perjury). Teva argues one such consequence ought to be equitable estoppel, which should preclude GSK's assertion of the '000 patent against Teva at least as to the post-MI LVD use. GSK's representations regarding the Orange Book listing of the '000 patent, Teva's reliance, and fairness go directly to an equitable estoppel defense, which has not yet been tried to the district court. The district court acknowledged that Teva raised this defense, but decided that it was "reserved to be tried to the Court at a later date." J.A. 29.

There are factual disputes regarding the estoppel issue that the district court has not yet had an opportunity to decide. For example, GSK argued on appeal that the use code that was listed in the Orange Book—"decreasing mortality caused by congestive heart failure"—covers all heart failure patients including post-MI LVD patients and that Teva's assertion that the use code covers only the CHF

indication is wrong. GSK Resp. and Reply Br. at 30. GSK further argues that "the use code is not tied to any particular indication, and the FDA tells generics that the use code 'is not meant to substitute for the applicant's review of the patent and the approved labeling.'" *Id.* (quoting 68 Fed. Reg. at 36,683). And Dr. McCullough testified that the post-MI LVD indication satisfied the first claim limitation, i.e., decreasing mortality caused by congestive heart failure. J.A. 10623:6–10623:23. It is also not clear from this record whether Teva had access to GSK's declaration (which was marked confidential and is not included in the Orange Book). Teva responds that it modified the label exactly as the FDA instructed it to in accordance with the GSK-provided use code. *See* J.A. 6908–10 (FDA mark-up of Teva label). As acknowledged above, Teva's own FDA expert, Mr. Karst, explained that an ANDA filer must perform its own analysis for patent infringement purposes. Trial Tr. at 1057:13–1058:10 (testimony of Mr. Karst). Issues of fact remain as to GSK's representations and Teva's reliance on those representations that have been "reserved to be tried" by the district court. J.A. 29.

The dissent proposes that this court leapfrog that normal process and resolve these questions of law, equity, and fact on appeal without any trial. We decline to do so. The dissent claims it is not focused on estoppel, but rather on whether "the law" permits an inference of intent from a label in light of GSK's representations to the FDA. *See* Dis. at 19. The dissent would hold that GSK's representations to the FDA in its declaration bar a finding of intent by the jury *as a matter of law* regardless of the remainder of the record. But intent is itself a question of fact, and this record contained substantial evidence from which the jury could find Teva intended to infringe despite GSK's representation to the FDA. This rule of law the dissent seeks is exactly the estoppel case made by Teva, which the district court has yet to try.

The issues before us are the issues that were tried to the jury and decided in the district court. We conclude substantial evidence supports the finding that Teva's partial label was evidence Teva instructed physicians to use its carvedilol in an infringing way. Dr. McCullough explained where Teva's partial label met each claim limitation and discussed other materials that would lead physicians to the partial label, culminating with his conclusion that Teva took action that it "intended would encourage or assist actions by another, i.e., the physician." J.A. 10644:15–19. Dr. McCullough did not testify that Teva's actions merely describe infringement; he testified that Teva's actions encouraged infringement.

The dissent's suggestion that there were only three pieces of evidence (the partial label plus the two press releases) on which the jury could have relied to find intent is equally inaccurate. The jury received Teva's partial label, extensive expert testimony, Teva's product catalogs, Teva's advertising and promotional activities, Teva's Monthly Prescribing References for doctors, and testimony from Teva's own company witnesses, all of which the jury could have relied on to find Teva intended to encourage, recommend, or promote infringement.

As the Supreme Court explained in *Grokster*:

> Evidence of 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, and a showing that infringement was encouraged overcomes the law's reluctance to find liability when a defendant merely sells a commercial product suitable for some lawful use.

Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd., 545 U.S. 913, 936 (2005) (citation and alterations omitted). In this case, we must presume the jury found that Teva sold carvedilol with a label that instructed physicians to use it

in an infringing manner. Our precedent has consistently held that, when a product is sold with an infringing label or an infringing instruction manual, such a label is evidence of intent to induce infringement. *See Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1130–31 (Fed. Cir. 2018) (no clear error in the district court's finding that the label instructions constituted a recommendation to infringe the claimed use); *Sanofi v. Watson Labs. Inc.*, 875 F.3d 636, 646 (Fed. Cir. 2017) ("The content of the label in this case permits the inference of specific intent to encourage the infringing use."); *Eli Lilly and Co. v. Teva Parenteral Med., Inc.*, 845 F.3d 1357, 1368 (Fed. Cir. 2017) ("When the alleged inducement relies on a drug label's instructions, '[t]he question is not just whether [those] instructions describ[e] the infringing mode, . . . but whether the instructions teach an infringing use *such that* we are willing to infer from those instructions an affirmative intent to infringe the patent. The label must encourage, recommend, or promote infringement.'") (citation omitted) (quoting *Takeda*, 785 F.3d at 631); *AstraZeneca*, 633 F.3d at 1060 ("The pertinent question is whether the proposed label instructs users to perform the patented method. If so, the proposed label may provide evidence of . . . affirmative intent to induce infringement."); *Arthrocare Corp. v. Smith & Nephew, Inc.*, 406 F.3d 1365, 1377 (Fed. Cir. 2005) (affirming jury's induced infringement determination when defendant distributed marketing material and manuals that instructed how to use the product in an infringing manner).[6]

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[6] Consistent with all of these cases, when a label instructs or teaches an infringing use, it can be considered evidence of intent to encourage that use. The jury was entitled to credit expert testimony regarding the label's instructions on who should take what drug, when, why, and

We assume, as we must, that the jury found the post-MI LVD use infringes the '000 patent, and that Teva's label contained instructions encouraging prescribing carvedilol in a manner that infringes the '000 patent. Throughout, the dissent claims that there was not substantial evidence upon which the jury could conclude that Teva's label would encourage doctors to prescribe Teva's carvedilol for the labeled uses. That is because, according to Teva (and the dissent), there is no evidence that doctors read labels or prescribe according to those labels. But the jury was presented expert testimony from Dr. McCullough (GSK's expert), from Dr. Zusman (Teva's expert), and from Teva's own documents to the contrary. First, Dr. McCullough testified that doctors do read labels. *See* J.A. 10612:7–9 ("Q. Two, that doctors don't read labels? Do you agree that that is the case? A. No, I disagree with that."). Second, Teva's own Monthly Prescribing References, which were "intended solely for use by the medical professional," explained that "[t]he clinician must be familiar with the full product labeling provided by the manufacturer or distributor of the drug, of every product he or she prescribes, as well as the relevant medical literature." J.A. 6196 (Teva's 2012 Monthly Prescribing Reference); *see also* J.A. 10611:19–25 (Dr. McCullough); Trial Tr. at 1253:15–23, 1254:23–1255:9 (Dr. Zusman agreeing that Teva's MPR indicates that the MPR "has been produced to provide an easily accessible reminder of basic information useful to review when prescribing medications" and that physicians should verify any questions against the labelling). In other words, the literature Teva provided to doctors told them to read labels and to prescribe according to them. While Teva's Monthly Prescribing References were published during the full label period, they powerfully refute Teva's claim that doctors do not and need not read labels in

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how, and to reject the dissent's claim that the label describes rather than instructs as to an infringing use.

conjunction with their prescribing practices. Teva's own Monthly Prescribing References merely confirm the quite logical proposition that doctors read labels and that the labels are intended to affect prescribing decisions. We cannot conclude that it would be unreasonable for the jury to think that, in 2007 or 2011, Teva believed doctors did not and need not read labels and only then wisened to the idea in 2012. In fact, Teva's own Director of National Accounts, Mr. Rekenthaler, testified to his belief that doctors would prescribe carvedilol according to the package insert (the label). Trial Tr. at 590:15–17 ("I guess my expectation is, like any drug, that it would be used as detailed in the package insert."); *id.* at 592:5–8 ("I mean my assumption would be, unless something specific was brought up, that it would be used, that the physicians would use it as they should use it, again which is detailed in our insert.").

This is record evidence that Teva intended its label to affect physician's prescribing practices, and the jury was entitled, as our caselaw has repeatedly held, to rely upon that to determine Teva's intent. But it is not the only evidence.

GSK also presented extensive expert testimony along with Teva's marketing efforts, catalogs, press releases, and testimony from Teva's own witnesses, showing that Teva encouraged carvedilol sales for CHF despite its attempted carve-out. This is evidence supporting the jury's finding that Teva induced infringement.

The jury was presented with evidence of Teva's marketing materials. Teva's Spring 2008 and Spring 2009 Product Catalogs described Teva's carvedilol as an AB rated therapeutic equivalent to Coreg®. J.A. 6221, 6270. Teva and *amici* agree that an AB rating means the generic product is therapeutically equivalent to the brand product under the conditions specified in the generic's label. As explained above, substantial evidence supports the jury's presumed conclusion that the partial label's

indication for post-MI LVD did not effectively carve out the use claimed in the '000 patent. Thus, Teva's AB rated representations under these limited circumstances, when substantial evidence supports the jury's presumed determination regarding the label's contents, are further affirmative evidence supporting the jury's inducement finding.[7]

GSK also presented evidence that, prior to the '000 patent's issuance, Teva issued two relevant press releases: one in 2004 and another in 2007. In its 2004 press release, Teva announced that the FDA granted it "tentative approval" for its carvedilol tablets, with final approval "anticipated upon expiry of patent protection for the brand product on March 5, 2007." J.A. 6347. It noted its "Carvedilol Tablets are the AB rated generic equivalent of GlaxoSmithKline's Coreg® Tablets and are indicated for *treatment of heart failure* and hypertension." *Id.* (emphasis added). The dissent suggests that Teva's "reference to heart failure" is not evidence that supports the jury's finding that Teva intended to encourage infringement of GSK's claimed method. The entire purpose of this press release is to announce its approval as a substitute for GSK's Coreg® Tablets, and it expressly says that the Teva generic "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. The press release's use of "heart failure" does not parse between congestive heart failure or post-MI LVD. This is not an

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[7] We do not hold that an AB rating in a true section viii carve-out (one in which a label was produced that had no infringing indications) would be evidence of inducement. In this case, Teva's representation of AB rating would point physicians to its partial label, which, for the reasons above, the jury was free to credit as evidence of induced infringement.

errant reference to "heart failure"; it is Teva in a press release telling the world that its generic is a substitute for GSK's Coreg® tablets to treat congestive heart failure in the same manner as Coreg® (which is a method that infringed the '000 patent). The dissent criticizes our analysis, claiming that we have weakened intentional encouragement because "simply calling a product a 'generic version' or 'generic equivalent'—is now enough." Dis. at 34–35. That is not our holding or the facts.

Though the dissent seems to think the press release is not evidence of encouragement, it seems self-evident that a jury could conclude that Teva's intent in issuing a press release telling the world it could use Teva's tablets as a substitute for GSK's Coreg® tablets to treat congestive heart failure was to encourage that use. Moreover, Dr. McCullough testified that he saw the 2004 press release and that it indicates physicians should prescribe generic carvedilol for heart failure. J.A. 11656:1–10; J.A. 11657:6–10 (testifying that Teva's press release informed doctors that "it certainly *should* be" prescribed for the treatment of heart failure); J.A. 11659:11–19 (Teva's press release indicates that doctors *should* be able to prescribe generic carvedilol for heart failure). Dr. McCullough also testified that doctors consider press releases so they "know when drugs are going generic." J.A. 11655:9–24.

Teva issued a second press release in 2007 in which it stated that it had received final approval "to market its Generic version of GlaxoSmithKline's cardiovascular agent Coreg® (Carvedilol) Tablets." J.A. 6353. Dr. McCullough testified that the 2007 press release's use of "cardiovascular agent" indicated to doctors they could use Teva's carvedilol "for all indications," including heart failure. J.A. 11660:3–13. Dr. McCullough also testified that he believed that this press release would encourage doctors to prescribe Teva's generic carvedilol for the infringing indications. J.A. 10644:15–19 ("Q. And so this element that Teva took action and failed to take action, what Teva intended

would *encourage* or assist actions by another party, i.e., the physician. In your expert opinion, has that requirement been met? A. Yes." (emphasis added)) (Dr. McCullough discussing the impact of the press releases on doctors). On appeal, we review the jury's verdict for substantial evidence based upon the record; we cannot hunt outside the record to find evidence to try to contradict the verdict. The dissent claims there is no intentional encouragement because the word cardiovascular is "[a] well-understood adjective" that means "relating to the heart," and as such Teva's press release could simply be read to encourage use for non-patented heart related conditions. Dis. at 23. First, the dissent goes outside the record to make up this definition, something the district court explicitly told the jury it could not do. *See* Trial Tr. at 264 ("During the course of the trial, you must not conduct any independent research about the case . . . . In other words, you should not consult dictionaries or reference materials."). Second, there was actual testimony in the record about how the word cardiovascular in this press release would be understood by skilled artisans. *See* J.A. 11660:3–13 (McCullough testifying that a skilled artisan would understand the word cardiovascular in this press release to indicate that the generic could be used for all indications including heart failure). Third, Teva did not merely say its drug is a cardiovascular agent, leaving the world to wonder about its uses. It said its product is a generic equivalent of GSK's cardiovascular agent Coreg®. It was reasonable for the jury to conclude, especially in light of the prior press release that expressly mentioned heart failure, that Teva was again encouraging the substitution of its product for all of Coreg's® cardiovascular indications, including as claimed in the '000 patent.

We have acknowledged that, as a matter of law, affirmative acts taken before a patent issues cannot violate § 271(b). *Nat'l Presto Indus., Inc. v. W. Bend Co.*, 76 F.3d 1185, 1196 (Fed. Cir. 1996). Consistent with this rule, the

jury was instructed GSK needed to prove by a preponderance of the evidence:

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

J.A. 168. In this case, the jury was presented with evidence from which it could infer that Teva's press releases remained on Teva's website until at least 2015. J.A. 6353 (2007 press release date stamped "4/14/2015"). Teva's Director of Marketing testified that Teva added carvedilol product information to the Teva website as part of its 2007 launch. J.A. 10991:13–22 (Suzanne Collier, Teva's Director of Marketing Communications and Trade Dress). The 2007 press release given to the jury contains a directory path showing it was stored on the Teva website as follows: "Home page>Media>Latest News." And GSK demonstrated the 2007 Teva press release was available on the Teva website as late as 2015. The press releases were extensively and repeatedly presented before the jury, with at least five witnesses discussing them. *See* J.A. 10643:2–10644:14, 11656:4–11657:5, 11659:11–11660:17 (discussed with Dr. McCullough); J.A. 11238:10–11241:14, Trial Tr. at 1241:15–1243:5 (discussed with Dr. Zusman); J.A. 10533:16–23, 10542:1–25 (discussed with Prof. Lietzan); Trial Tr. at 445:9–447:10, J.A. 10973:15–10974:23, Trial Tr. at 974:24–975:4 (discussed with Teva's Senior Director of Regulatory Affairs, Jill Pastore); Trial Tr. at 1619:9–18 (discussed with Teva's damages expert, Dr. Sumanth Addanki). Teva neither provided contrary evidence nor argued to the jury that the press releases, at least one of which could be found on the Teva website even at the time of trial, were not available on Teva's website throughout the alleged infringement period. Under these circumstances, the jury could infer, from Teva's placement of

information on its website and from its press releases, that Teva intended its website to be a source of information for prescribing doctors and that its website promoted the infringing use throughout the period of infringement.[8] Teva had encouraged in its labels, press releases, product catalogs, and marketing materials. Substantial evidence supports the jury's verdict that Teva induced infringement.

C

GSK presented evidence that Teva's partial label did not successfully carve out the patented use, and thus, Teva was selling its generic with a label which infringed the method claim. GSK presented evidence that doctors read and consider labels, that Teva's marketing materials guided doctors to the label and to its website promoting the patented use, that Teva issued press releases encouraging doctors to prescribe carvedilol for the patented use, that Teva's own employees expected doctors to prescribe carvedilol during the partial label period for the patented uses, and expert testimony that Teva's actions encouraged doctors to do so. This is substantial evidence from which a reasonable jury could conclude that Teva intentionally encouraged the practice of the claimed method. Accordingly,

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[8] The jury was even presented evidence that Teva encouraged doctors to visit its website for information about its generic drugs when prescribing them. Trial Tr. at 1245:16–19 (Teva's expert, Dr. Zusman, acknowledging that Teva advised doctors to "visit its website" to obtain product information); Trial Tr. at 1249:12–15 (same); Trial Tr. at 1251:8–11 (same); Trial Tr. at 1258:12–20 (same). Though the evidence comes from Teva's 2012 and 2013 Monthly Prescribing References for doctors (during the full label period), it was reasonable for the jury to conclude that Teva intended for doctors to visit its website for prescribing information about the Teva's products.

substantial evidence supports the jury's finding of induced infringement for the partial label period.

THE FULL LABEL PERIOD

Beginning on May 1, 2011, Teva's carvedilol label contained all three indications present in the Coreg® label. That is, in addition to the post-MI LVD and hypertension indications, Teva's label contained the "Heart Failure" indication. Specifically, it added the following indication:

> 1.1 Heart Failure. Carvedilol tablets are indicated for the treatment of mild-to-severe chronic heart failure of ischemic or cardiomyopathic origin, usually in addition to diuretics, ACE inhibitors, and digitalis, to increase survival and, also, to reduce the risk of hospitalization [see Drug Interactions (7.4) and Clinical Studies (14.1)].

J.A. 5532 (brackets in original, italics omitted). Dr. McCullough testified that the addition of the heart failure indication also met all the claim limitations of the '000 patent. J.A. 10623:24–10625:3, 10625:20–10626:11, 10626:20–10627:8, 10628:15–10629:20, 10630:7–23, 10631:7–21. Substantial evidence supports the jury's presumed finding that Teva's full label contains all of the claim limitations, which Teva does not dispute.

In addition to the information Teva placed in its press releases and on its websites, Teva sent marketing materials and catalogs to healthcare providers during the full label period. For example, Teva's 2012 Monthly Prescribing Reference, which explained a "clinician must be familiar with the full product labeling . . . of every product he or she prescribes, as well as the relevant medical literature," contained a listing for carvedilol with the heart failure indication. J.A. 6196, 6200. Dr. McCullough testified that the 2012 MPR was intended for prescribing doctors and that he and doctors across the country receive the MPR "on a regular basis." J.A. 10607:9–10608:1, 10609:19–22. He

also testified that the 2012 MPR was telling doctors to "verify any questions against the labeling or contact the company marketing the drug," that the label "provides the base information that flows to doctors," and that Teva is "clearly telling doctors they should read the labels." J.A. 10610:3–21.

Teva's 2013 MPR contained the same information, same instructions to doctors, and same carvedilol listing with the heart failure indication. J.A. 6205, 6208. Dr. Zusman agreed that one could interpret the 2013 MPR as being a part of the educational materials Teva provided to doctors and that Teva wanted the MPR to be a part of a treating doctor's toolbox. Trial Tr. at 1250:18–23, 1252:5–1253:9. He also agreed that the 2013 MPR was instructing doctors to verify the information in the MPR by referring to the product labeling or contacting the company marketing the drug, here Teva. Trial Tr. at 1254:24–1255:9, 1256:1–10. He also acknowledged that the 2013 MPR instructed doctors to visit Teva's website for more information. Trial Tr. at 1258:8–20.

Substantial evidence supports the finding that Teva encouraged physicians to use its carvedilol for an infringing purpose during the full label period. The jury was entitled to credit the full label itself containing the infringing use, Dr. McCullough's testimony that the full label contained each claim limitation, and Teva's marketing materials as demonstrating Teva specifically intended to encourage, recommend, or promote the use of carvedilol in an infringing manner. The dissent confronts none of this evidence. To be clear, the dissent would overturn a jury verdict, finding Teva's full label encouraged doctors to prescribe an infringing manner, as not supported by substantial evidence where the label undisputedly encourages an infringing uses (CHF) and when Teva tells doctors to read its label for prescribing information. To do so would be a major change in our precedent.

CAUSATION

To establish inducement, a patent owner must show that the accused inducer's actions actually induced the infringing acts of another and knew or should have known that its actions would induce actual infringement. *DSU Med.*, 471 F.3d at 1304. The jury was instructed "GSK must prove that Teva's alleged inducement, as opposed to other factors, actually caused physicians to directly infringe the '000 patent." J.A. 173. Teva could only be found liable for induced infringement if GSK showed "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." *Id.* The jury was also instructed "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." *Id.*

Teva argues that it did not cause doctors to actually prescribe generic carvedilol. Teva argues that, at all relevant times, doctors were prescribing carvedilol for CHF based on information they had received for GSK's Coreg®. Teva points to guidelines from the American College of Cardiology (ACC), the American Heart Association (AHA), medical textbooks, and treatises to argue doctors already knew to treat CHF using carvedilol long before Teva launched its generic. Teva argues that this information, not its actions, made physicians aware of all the benefits of carvedilol for heart failure patients. The district court accepted Teva's argument as sufficient to overcome the jury's verdict in GSK's favor. *Dist. Ct. Op.* at 594. We do not agree.

The jury had before it Teva's partial label, full label, various marketing materials, and press releases. It heard from the expert witnesses that doctors read labels and that Teva's labels satisfied all of the claim limitations. *See* J.A. 10612:7–9 (testimony of Dr. McCullough: "Q. Two, that

doctors don't read labels? Do you agree that that is the case? A. No, I disagree with that."). It also heard that doctors received marketing materials from Teva, that these materials directed doctors to prescribe according to the labels, and that these materials told doctors to visit Teva's website for more information regarding its products. Teva tried to convince the jury that doctors do not read labels even after its own marketing material, which was sent directly to doctors, explicitly instructed them to read the labels.

Despite all of this evidence, Teva asks us to supplant the role of the jury and reweigh evidence in its favor. But it was for the jury to decide—not us, the district court, or the dissent—whether Teva's efforts actually induced infringement. It was fair for the jury to infer that when Teva distributed and marketed a product with labels encouraging an infringing use, it actually induced doctors to infringe.[9] "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." *Power Integrations*, 843 F.3d at 1335; *see also Arthrocare*, 406 F.3d at 1377 ("There was also strong circumstantial evidence that Smith & Nephew's probes were used in an infringing manner, and that Smith &

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[9] The dissent acknowledges that an example of when a jury might reasonably infer causation is when a product's user manual encourages an infringing use. Dis. at 32–33 (collecting cases). But the dissent would hold, nonetheless, that a jury cannot infer causation from the full label, which undisputedly contains all of the claim limitations, despite the evidence showing the full label instructs doctors to infringe, just as a user manual.

Nephew induced users to employ the probes in that way."). Given Teva distributed other materials in addition to its labels, we do not have to decide in this case whether the labels alone are enough to establish causation. The dissent criticizes the presence of circumstantial evidence, but as the jury was correctly instructed, "[i]t is your job to decide how much weight to give the direct and circumstantial evidence. The law makes no distinction between the weight that you should give to either one, nor does it say that one is any better evidence than the other." J.A. 147 (Jury Instruction 1.4). The jury had sufficient circumstantial evidence, in the form of labels, marketing materials, catalogs, press releases, and expert testimony, for it to conclude that Teva succeeded in influencing doctors to prescribe carvedilol for the infringing use. We thus vacate the district court's grant of JMOL of no induced infringement and reinstate the jury verdict, which was supported by substantial evidence.

II

DAMAGES

The Patent Act provides: "the court shall award [the patent owner] damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use of the invention by the infringer." 35 U.S.C. § 284. To recover lost profit damages, "the patent owner must show 'causation in fact,' establishing that 'but for' the infringement, he would have made additional profits." *Grain Processing Corp. v. Am. Maize-Prod. Co.*, 185 F.3d 1341, 1349 (Fed. Cir. 1999).

GSK's damages expert testified that 17.1% of Teva's 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 a reasonable royalty payment of $1,400,000. The verdict amount is about half of that presented by GSK's damages expert. Teva

argues that, if the jury had been properly instructed, it would have assessed no damages or at most only a reasonable royalty.

Teva argues the jury should have been instructed that GSK must prove that, for every infringing sale Teva made, the direct infringer would have purchased Coreg® rather than another generic producer's carvedilol. The district court declined to present that instruction, explaining:

> 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).

J.A. 222 (Memorandum Order (June 9, 2017) (emphasis in original)). The district court recognized that "[i]t 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," J.A. 222 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." J.A. 223 (emphasis in original).

Teva argues that it was incorrect to instruct the jury that "[t]he 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." J.A. 195

(Jury Instruction 6.3.3). Teva argues that this instruction ignores the reality of the marketplace because other carvedilol producers who had not been sued for infringement would have made the sales Teva made, in part because pharmacies would automatically substitute generic carvedilol for Coreg® prescriptions. Teva's argument is in conflict with long-standing precedent that the presence of noninfringing alternatives precludes an award of lost profits, but the presence of other infringers does not.

The district court correctly instructed the jury that the availability of carvedilol from other generic producers is not a "non-infringing substitute." GSK's expert's analysis accounted for Teva's sales for the infringing use, amounting to 17.1% of Teva's total carvedilol sales. Had another generic producer made those sales, those uses too would have been infringing. The other generic carvedilol producers were, therefore, not noninfringing alternatives. *See Grain Processing*, 185 F.3d at 1350 ("The 'but for' inquiry therefore requires a reconstruction of the market, as it would have developed absent the infringing product, to determine what the patentee would have made.") (internal quotations and alterations omitted); *Micro Motion, Inc. v. Kane Steel Co., Inc.*, 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."). Accordingly, the damages verdict, which is not otherwise challenged, is sustained.

CONCLUSION

Because substantial evidence supports the jury's verdict of induced infringement, we vacate the district court's grant of JMOL. Because the district court did not err in its jury instructions on damages, we affirm on the cross-appeal. We remand for appropriate further proceedings.

VACATED-IN-PART, AFFIRMED-IN-PART, AND REMANDED

COSTS

Costs are awarded to GSK.

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, Judge Leonard P. Stark.

PROST, *Circuit Judge*, dissenting.

GSK's patent on carvedilol expired in 2007. At the time, however, it still had a patent on one of carvedilol's three FDA-approved uses. Because the FDA cannot authorize a generic version of a drug that would infringe a patent, this one remaining patented use could have prevented a less-expensive, generic carvedilol from coming to market altogether—even though the drug *itself* and other uses of it were unpatented. Congress saw this problem coming. It wanted to make sure that one patented use wouldn't prevent public access to a generic version of a drug that also has unpatented uses. *See Caraco Pharm.*

Labs. Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 415 (2012). So it created rules for just this situation.

These rules, embodied in the so-called skinny-label provisions of the Hatch-Waxman Act, are straightforward. If a brand drug company (here, GSK) has a patent on one of a drug's uses, it tells the FDA which use is patented. In fact, it tells the FDA exactly what language from its label is covered by its patents. The FDA will then permit a generic version of that drug to come to market if the manufacturer "carves out" such use from its drug label by omitting the language that the brand drug company identified. That's what happened here. GSK's sworn FDA filings identified just one use as patented. So Teva carved out that use and came to market with its "skinny" label. It played by the rules, exactly as Congress intended. It sold its generic for years without controversy.

And then, in the seventh year, GSK finally sued. It alleged that, even though Teva's skinny label carved out the very use—indeed, the *only* use—that GSK said was patented, the label showed that Teva intended to encourage an infringing use. GSK also supported its inducement case by pointing to two cursory, pre-patent press releases that announced Teva's drug's approval (or "tentative" approval) and called it the generic equivalent of GSK's brand drug Coreg. The evidence of inducement—i.e., that Teva had culpable intent to encourage infringement and that its skinny label or press releases caused doctors' prescribing practices—was thin to nonexistent. But a jury found Teva liable all the same. This sometimes happens. And when it does, there is a remedy: a court will reverse a jury's verdict if there is insufficient evidence to support it. The experienced trial judge sensibly did just that.

The majority, now on its second try, again reinstates the verdict nonetheless. Its first try prompted widespread criticism concerning the troubling implications for skinny labels. This effort is no better. With reasoning sometimes

labored, sometimes opaque, the majority strains to prop up a jury verdict that is unsupportable. For example, based on language that remained on the skinny label after Teva's carve-out, the majority finds it reasonable to infer that Teva *intentionally encouraged* infringement. It finds this reasonable even though Teva, by carving out everything that GSK said would infringe, was trying to *avoid* having its label encourage infringement. The majority then indulges the inference that doctors, as a class, *relied* on Teva's skinny label to infringe, even though every expert cardiologist at trial said he *didn't even read* the label to make prescribing decisions. And, most troubling, the majority is willing to see culpable intent behind a generic's describing its product as the "equivalent" of a brand drug—in a system that *requires* generic drugs to be equivalent, and in which everyone understands that generic drugs are equivalent.

I write in this case because far from being a disagreement among reasonable minds about the individual facts, this case signals that our law on this issue has gone awry. I am particularly concerned with three aspects of the majority's analysis. First, even setting aside the majority's willingness to glean intentional encouragement from a label specifically designed to avoid encouragement, the majority further weakens the intentional-encouragement prong of inducement by effectively eliminating the demarcation between describing an infringing use and encouraging that use in a label. Second, the majority defies basic tort law by eviscerating the causation prong of inducement. The upshot of these two moves is that a plaintiff now has to show very little for a jury to speculate as to the rest. Third, the majority creates confusion for generics, leaving them in the dark about what might expose them to liability. These missteps throw a wrench into Congress's design for enabling quick public access to generic versions of unpatented drugs with unpatented uses.

I. BACKGROUND

A. *Hatch-Waxman: Congress's Compromise*

With the Hatch-Waxman Act, Congress contemplated this case. Indeed, Congressman Waxman himself agrees.[1] When Congress passed the Act, it enacted a complex statutory framework to balance generic and brand interests. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.[2] One effect was to bolster patent terms for brand companies. *Eli Lilly & Co. v. Medtronic Inc.*, 496 U.S. 661, 669 (1990). Another was to "speed the introduction of low-cost generic drugs to the market," *Caraco*, 566 U.S. at 405, in part by permitting immediate market entry for drugs with at least one unpatented FDA-approved use.[3]

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[1] *See* Brief of Amicus Curiae Former Congressman Henry A. Waxman in Support of Petition for Rehearing En Banc 3–8, ECF No. 170 ("Waxman Br.").

[2] *See generally* Brief of Amici Curiae Fifty-Seven Law, Economics, Business, Health, and Medicine Professors in Support of Cross-Appellant's Petition for Rehearing En Banc, ECF No. 171 ("57 Law Professors Br."); Waxman Br.; Brief of Amicus Curiae Association for Accessible Medicines in Support of Defendant-Cross-Appellant in Support of Affirmance 1–9, ECF No. 69; Brief for the Association for Accessible Medicines as Amicus Curiae in Support of Rehearing En Banc 5–7, ECF No. 164.

[3] *See also Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003); H.R. Rep. No. 98–857, pt. 1, at 14–15 (1984) ("The purpose . . . is to make available more low cost generic drugs by establishing a generic drug approval procedure . . . ."); *id.* at 22 (explaining that a "listed drug may be approved for two indications. If the [generic] applicant is seeking approval only for Indication No. 1, and not Indication No. 2 because it is protected

Under Congress's design, the FDA regulates the manufacture, sale, and labeling of prescription drugs. *See Caraco*, 566 U.S. at 404–05. The process begins when a brand manufacturer submits a new drug application ("NDA"). The NDA must include a proposed label describing the specific uses—called indications—for the drug. *Id.* at 404; *see* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.50(a)(1), (e)(2)(ii). *See generally* 21 C.F.R. pt. 201.

Once the FDA has approved a brand drug, another company may seek permission to market a generic version by filing an abbreviated new drug application ("ANDA"). Because the Act is designed to minimize the barriers to entry for generic drugs, the generic doesn't have to rehash the brand's safety-and-efficacy trials. It must, however, show that what it manufactures is bioequivalent to the brand drug. 21 U.S.C. § 355(j)(2)(A)(iv), (j)(4)(F); 21 C.F.R. § 314.94(a)(7)(i).[4] And the generic's proposed labeling must essentially copy the brand drug's label. *See* 21 U.S.C. § 355(j)(2)(A)(i), (v), (j)(4)(G); *Caraco*, 566 U.S. at 406. Thus, by congressional design, generic approval is a comparison of equivalence between the generic and a specific brand drug.

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by a use patent, then the applicant must make the appropriate certification and a statement explaining that it is not seeking approval for Indication No. 2").

[4] "Bioequivalence is the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed [bioequivalence] study." 21 C.F.R. § 314.3(b). That is, two drugs are "bioequivalent" if they would be expected for all practical purposes to be the same.

Often a generic wants to launch while patents remain on a drug or its uses. Anticipating this, Congress provided two pathways for generics to show that a proposed label will not infringe.

The first pathway is to file a certification explaining why the generic label will not infringe any patent that a brand has identified to the FDA as covering the drug. The commonly used "paragraph IV" certification states that a generic label will not infringe because the patent "is invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Paragraph IV often prompts litigation. If a generic, armed with a good-faith paragraph IV argument, files an ANDA with a brand's full label, the Hatch-Waxman Act allows the brand to sue and entitles it to an automatic 30-month stay of final FDA approval of the generic drug while the underlying patent issues are worked out in court. *See* 35 U.S.C. § 271(e)(2)(A); 21 U.S.C. § 355(j)(5)(B)(iii); *Eli Lilly*, 496 U.S. at 670–71, 676. This first pathway, then, has parties sort things out up front if infringement or validity are in legitimate dispute.

The second pathway—and the one relevant here—is available if at least one brand-labeled use is unpatented. If that's so, the generic can just "carve out" the patented uses from its label. *See* 21 U.S.C. § 355(j)(2)(A)(viii) ("section viii"); 21 C.F.R. § 314.94(a)(8)(iv); *Caraco*, 566 U.S. at 404–07; *Takeda*, 785 F.3d at 630 ("Congress intended that a single drug could have more than one indication and yet that an ANDA applicant could seek approval for less than all of those indications." (cleaned up)). The result, an exception to "the usual rule that a generic drug must bear the same label" as the brand, *Caraco*, 566 U.S. at 406, is commonly called a "skinny" or "partial" or "carve-out" label.

Because the skinny-label pathway's availability depends on at least one brand-labeled use being unpatented, the FDA needs to know whether any labeled uses are

unpatented—and which. More pragmatically, because the FDA "cannot authorize a generic drug that would infringe a patent," *Caraco*, 566 U.S. at 405, it needs assurance that a generic's skinny label has carved out the patented brand-labeled uses, leaving behind only unpatented ones. But because the FDA is not an arbiter of patent issues,[5] how can it know whether the skinny-label pathway is available and whether it can approve a given label?

The solution that worked—before today, at least—was for the FDA and generics to rely on what brands say their patents cover. *See Caraco*, 566 U.S. at 407 ("[W]hether section viii is available to a generic manufacturer depends on how the brand describes its patent."); *see also* 21 U.S.C. § 355(b), (c) (requiring submission of patent information with NDA). In particular, a brand submits under penalty of perjury a declaration identifying "each pending method of use or related indication and related patent claim" and "the specific section of the proposed labeling for the drug product that corresponds to the method of use claimed by the patent submitted." 21 C.F.R. § 314.53(c)(2)(O) (2008).[6] This declaration also contains a brand-crafted, 240-character "use code."[7] 68 Fed. Reg. at 36,683, 36,686, 36,697; *see*

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[5] Indeed, it routinely disclaims expertise on that front. *See, e.g.*, 68 Fed. Reg. 36,676, 36,683 (2003) ("[W]e have long observed that we lack expertise in patent matters."); *Caraco*, 566 U.S. at 406–07.

[6] Subsequent amendments to the FDA's regulations now require even *more* detail, underscoring the critical public-notice function of patent declarations. *See, e.g.*, 21 C.F.R. § 314.53(c)(2)(O) (2020).

[7] The majority quotes a portion of the Federal Register saying that use codes "are not meant to substitute for the [ANDA] applicant's review of the patent and the approved labeling" and relies on testimony concerning the same. Maj. 20–21 (alteration in original) (quoting 68 Fed.

also 21 C.F.R. § 314.53(c). This "use code" appears in the Orange Book,[8] a reference in which brands list the patents on their drugs and the covered uses to provide notice to generics and the FDA. The FDA relies on what the brand says: "In determining whether an ANDA applicant can 'carve out' the method of use, . . . we will rely on the description of the approved use provided by the NDA holder or patent owner in the patent declaration and listed in the Orange Book." 68 Fed. Reg. at 36,682; *see also Caraco*, 566 U.S. at 406 (in assessing a proposed skinny label, the FDA looks to what the brand says, takes it "as a given," and approves the label only if there is no perceived overlap).

Reg. at 36,683); *see also id.* at 21–23. It bears emphasizing that this statement refers specifically to the 240-character use code (given its length limitations and particular notice role), as distinct from other parts of the declaration (e.g., part 4.2a) identifying the label language corresponding to the claimed method. The full context of the passage makes this clear:

> Use codes are intended to alert ANDA applicants to the existence of a patent that claims an approved use. They are not meant to substitute for the applicant's review of the patent and the approved labeling. We understand that in some cases 240 characters may not fully describe the use as claimed in the patent. The declaration, which includes the complete description of the method-of-use claim and the corresponding language in the labeling of the approved drug, will be publicly available after NDA approval.

68 Fed. Reg. at 36,683.

[8] U.S. Food & Drug Admin., *Approved Drug Products with Therapeutic Equivalence Evaluations* (40th ed. 2020).

The point is clarity. Hatch-Waxman is designed to resolve patent disputes as early as possible.[9] And to know whether there *is* a dispute, the FDA and generic manufacturers rely on a brand's representations of which labeled indications are patented. *See, e.g.*, 68 Fed. Reg. at 36,682.

B. *Carvedilol*

Carvedilol, the drug here, is well studied and well understood. By 2007, the compound itself was no longer patented, nor were most uses of it.

Carvedilol is a beta blocker, a class of drugs used since the 1960s to treat 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 claimed the compound itself.

By the early 1990s, research from various groups revealed that beta blockers could be useful for treating a condition called congestive heart failure ("CHF"), which prevents the heart from being able to deliver enough oxygenated blood to the body. By 1995, GSK had already received approval for an NDA under the brand name Coreg for hypertension. A supplement to that NDA added the CHF indication to the label in 1997. After the approval of the CHF labeling, GSK received U.S. Patent No. 5,760,069, relating to a particular manner of using carvedilol with other drugs to treat CHF. GSK listed the '069 and

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[9] *See* Brief of Amici Curiae Novartis Pharmaceuticals Corporation and Sandoz Inc. in Support of Rehearing En Banc 7, ECF No. 168 ("Novartis & Sandoz Br.") ("Both branded and generic pharmaceutical companies require stable, predictable legal environments to operate effectively. Patent litigation inherently entails some uncertainty, but the governing legal framework should be as predictable as possible and consistent with Congress's intent.").

'067 patents in the Orange Book. Eventually, and well before any generic launched, carvedilol became the standard of care for CHF. This standard was incorporated into the official guidelines of the American College of Cardiology and American Heart Association (as well as numerous medical textbooks and journals) and taught to medical students around the country.

As the 2007 expiration of GSK's carvedilol compound patent approached, interest grew among generics. Upon this expiration, generics would be able to market carvedilol in one of two ways: either with an all-indications label (by challenging GSK's method patent under a paragraph IV certification) or by simply omitting any patented uses from the label (with a section viii statement). Teva first chose the former, reasoning—correctly, as it turned out—that GSK's '069 method patent was invalid. And so in mid-2002 Teva filed its ANDA with a proposed full label directed to hypertension and CHF, certifying that it would wait for GSK's compound patent to expire but that GSK's '069 method patent was invalid. J.A. 3003–19, 5463. GSK did not sue or seek to block Teva's approval. Instead it sought reissue of its '069 patent, admitting invalidity of the original and adding narrowing limitations to overcome validity challenges.

In 2003, GSK got approval to add another indication to its label: post-MI LVD.[10] This entailed a discrete new set of label text, with new underlying clinical studies and new instructions. Teva likewise updated the label accompanying its pending ANDA to include all three indications. In 2004, the FDA determined that Teva had shown its product

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[10] This condition concerns patients who have recently suffered a heart attack (a "myocardial infarction," or "MI") and whose hearts have trouble pumping blood ("left ventricular dysfunction," or "LVD").

to be bioequivalent to GSK's and granted it tentative approval pending resolution of any exclusivity issues.

But by 2007—the year GSK's compound patent was set to expire—it was apparent that other generic manufacturers had opted for skinny labels instead. So Teva did too, informing the FDA that it now intended to carve out from GSK's label the uses GSK said were patented.

Again, GSK's label contained three sets of instructions for three distinct indications: CHF, post-MI LVD, and hypertension:

INDICATIONS AND USAGE

Congestive Heart Failure: COREG is indicated for the treatment of mild to severe heart failure of ischemic or cardiomyopathic origin, usually in addition to diuretics, ACE inhibitor, and digitalis, to increase survival and, also, to reduce the risk of hospitalization (see CLINICAL TRIALS).

Left Ventricular Dysfunction Following Myocardial Infarction: COREG is indicated to reduce cardiovascular mortality in clinically stable patients who have survived the acute phase of a myocardial infarction and have a left ventricular ejection fraction of ≤40% (with or without symptomatic heart failure) (see CLINICAL TRIALS).

Hypertension: COREG is also indicated for the management of essential hypertension. It can be used alone or in combination with other antihypertensive agents, especially thiazide-type diuretics (see PRECAUTIONS, Drug Interactions).

J.A. 7992. And according to GSK's sworn declaration to the FDA (which appropriately tracked the label's language), only one of these three was patented—CHF:

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

J.A. 6895. Faithful to GSK's declaration, the FDA forwarded Teva a redlined label for use that omitted everything GSK had said the '069 method patent covered:

1 INDICATIONS AND USAGE

~~**1.1 Heart Failure**~~

~~COREG is indicated for the treatment of mild-to-severe heart failure of ischemic or cardiomyopathic origin, usually in addition to diuretics, ACE inhibitors, and digitalis, to increase survival and, also, to reduce the risk of hospitalization *(see CLINICAL STUDIES [14.1]).*~~

1.1 Left Ventricular Dysfunction following Myocardial Infarction

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) *(see CLINICAL STUDIES [14.1]).*

1.2 Hypertension

Carvedilol is indicated for the management of essential hypertension. It can be used alone or in combination with other antihypertensive agents, especially thiazide-type diuretics *(see DRUG INTERACTIONS [7.2]).*

J.A. 6913. It instructed Teva to use that label, which Teva did—with the same carve-out as the other seven generic manufacturers that launched at that time.

After the generics launched, GSK's '069 method patent reissued as U.S. Patent No. RE40,000, the patent relevant here. GSK added several narrowing limitations to the '000 patent to save it from invalidity. With the reissue process now completed, GSK delisted its '069 method patent from the Orange Book and listed the '000 patent in its stead—again submitting a sworn declaration identifying *only* the CHF indication as covered. J.A. 6880–87. Consistent with this representation, GSK did not sue the generics, whose skinny labels included everything but CHF.

Years later in 2011, the FDA directed Teva to revise its label to include the CHF indication. Teva complied. The skinny-label period thus ended and the full-label period began. 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 since approved. And, to little surprise, nothing changed in the market: Teva and GSK maintained their respective market shares, and no doctor's prescribing habits changed.

C. *This Litigation*

GSK did not sue in 2004 when Teva made its full-label paragraph IV certification. Nor in 2007 when Teva launched its skinny-label generic. Nor in 2008 when GSK's '000 patent emerged from reissue. Nor even in 2011 when Teva transitioned to the full label. It sued instead in 2014, just before the '000 patent expired.

The lawsuit ultimately led to a seven-day jury trial in 2018. The jury was asked to determine whether Teva induced infringement of the '000 patent based on the skinny-label period and the full-label period separately. It found that Teva induced infringement of the '000 patent based on both labels. It also found that GSK was entitled to $234.1 million in lost profits and $1.4 million in reasonable-royalty damages.

After the verdict, Teva filed a renewed motion for JMOL, 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 Pharms. USA, Inc.*, 313 F. Supp. 3d 582 (D. Del. 2018). GSK appealed, and Teva cross-appealed as to damages.

The case was argued to us in September 2019. In October 2020, the majority issued a first opinion reversing the district court's JMOL. That opinion prompted widespread consternation and confusion, as described in Teva's petition for rehearing and the eight amicus briefs in support. Among these amici: both generics *and* brands, fifty-seven law professors, and Congressman Waxman. *See* Novartis & Sandoz Br.; 57 Law Professors Br.; Waxman Br.

Following these submissions, the majority vacated its first opinion and ordered another round of oral argument. Order, ECF No. 181. The majority now issues a second opinion reaching the same result as before, but with new reasoning. In particular, it now declares that this is not a "true" skinny-label case. *E.g.*, Maj. 10–11, 28 n.7. But this remains a skinny-label case, the record remains the record, and inducement liability remains unsupportable.

II. DISCUSSION

Although the JMOL standard is well settled, two points bear emphasizing. First, while we give the verdict winner the benefit of "every favorable and reasonable inference," *Dun & Bradstreet Software Servs., Inc. v. Grace Consulting, Inc.*, 307 F.3d 197, 205 (3d Cir. 2002), the operative word here is "reasonable." Indeed, "only all *reasonable*" inferences need be drawn in GSK's favor, not "*all* possible inferences." *See Villiarimo v. Aloha Island Air, Inc.*, 281 F.3d 1054, 1065 n.10 (9th Cir. 2002). Second, if too many inferences must be strung together to support the verdict, the verdict is likely unsupportable. *See Roebuck v. Drexel Univ.*, 852 F.2d 715, 736 (3d Cir. 1988) ("Although we believe that each of the inferences that we have discussed [is] individually logically sound, we recognize that at some point too many inferences become[s] mere speculation . . . ."); *cf. United States v. Weber*, 923 F.2d 1338, 1345 (9th Cir. 1990) ("Each of these inferences standing alone may be reasonable. But with each succeeding inference, the last reached is less and less likely to be true.").

As to induced infringement under 35 U.S.C. § 271(b), GSK bore the burden at trial to prove two things relevant here. First, GSK had to prove that, more likely than not, Teva engaged in "culpable conduct, directed to encouraging another's infringement." *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc in relevant part); *see Metro-Goldwyn-Mayer Studios Inc. v. Grokster*, 545 U.S. 913, 937 (2005) ("The inducement rule . . .

premises liability on purposeful, culpable expression and conduct . . . ."). In other words, not only must Teva have "possessed specific intent to encourage another's infringement," *DSU*, 471 F.3d at 1306, it must have taken "affirmative steps to bring about [that] desired result," *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 760 (2011).

Second, GSK had to prove that, more likely than not, Teva's affirmative steps actually *caused* the infringement it wanted to bring about. *DSU*, 471 F.3d at 1304 (plaintiff must show that "the alleged infringer's actions induced infringing acts"); *see Grokster*, 545 U.S. at 936–37 (when defendant takes "affirmative steps" to "foster infringement, [it] is liable for the *resulting* acts of infringement by third parties" (emphasis added)); *Sanofi v. Watson Labs. Inc.*, 875 F.3d 636, 644 (Fed. Cir. 2017) (noting the "purposeful-causation connotation" of the Supreme Court's characterization of inducement).

The discussion that follows has three parts. Part A addresses the lack of inducement during the skinny-label period, as well as the flaws in the majority's analysis. Part B does the same for the full-label period. Part C addresses more broadly why the majority's analysis has troubling implications for skinny labels and inducement law generally.

A. *The Skinny-Label Period*

For the skinny-label period—that is, from Teva's skinny-label launch in 2007 to its full-label amendment in 2011—the majority relies on three key pieces of evidence to conclude that substantial evidence supports the verdict: the skinny label itself (in particular, the post-MI LVD indication on that label) and two press releases distributed before the '000 patent issued—one from 2007, another from 2004. I discuss each in turn, followed by the majority's supposedly substantial other evidence of intent. From them, alone or combined, no reasonable jury could have found (1) culpable intent to encourage infringement or (2) causation, much less both.

1. The Skinny Label Itself

Before discussing what the skinny label said, recall what it didn't say—and why. The label omitted the CHF indication (and only the CHF indication) because GSK's sworn FDA filings asserted patent coverage of the CHF indication (and only the CHF indication). Analogizing to a typical patent case, it's as though Teva had drafted a potentially infringing user manual and then, abiding by the patentee's clear guidance, deleted all the pages that might be viewed as encouraging infringement of a patented method. Ironically, everything about this process signals that, far from intending to encourage infringement, Teva very much intended *not* to encourage infringement with its skinny label.

Of course, this will likely be true of most generics that get approved via the Hatch-Waxman section viii skinny-label pathway. Indeed, inferring intentional encouragement to infringe a method—from a label that has intentionally omitted everything that the brand said covers that method—is a lot to ask of a reasonable factfinder. Only once has this court upheld an inducement finding involving a putative skinny label, and that case had a crucial, additional fact: the generic knew it had an infringement problem. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010); *see Grunenthal GmbH v. Alkem Labs. Ltd.*, 919 F.3d 1333, 1340 (Fed. Cir. 2019) ("[*AstraZeneca*] held that specific intent could be inferred because the defendant proceeded with a plan to distribute the generic drug knowing that its label posed infringement problems."). By contrast, GSK put on no similar evidence here. Indeed, the facts surrounding Teva's skinny label are simple and undisputed.

The majority nonetheless manufactures a factual dispute, all on its own. It surmises that: maybe, just maybe, GSK's declarations were confidential, hidden from Teva's view—the implication being that Teva *couldn't* have relied

on them.[11] Maj. 23. Of course, GSK itself has never made this argument, despite having every incentive to do so (given how Teva featured the declarations and their significance to the jury, the district court, and this court). It's easy to guess why: the FDA confirms that the declarations are available to the public. 68 Fed. Reg. at 36,683.

At any rate, the majority's confidentiality conjecture is a red herring. Even if it were true that Teva never laid eyes on GSK's exact documents, it wouldn't matter. As no one disputes, Teva asked to carve out GSK's patented uses, and the FDA in return used GSK's representations to provide Teva with a carved-out label. The FDA itself took no non-infringement position; GSK did. And so by accepting the FDA-provided skinny label, which hewed to GSK's patent declarations, Teva relied on GSK's representations of patent scope.[12] *See, e.g.*, Cross-Appellant's Br. 12–13, 51–52; J.A. 12475 (Teva's JMOL motion).

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[11] The suggestion appears to be based on the word "confidential" at the bottom of the declarations' pages in our appendix. *See* Maj. 23. The majority's reliance on this branding seems misplaced. Among documents similarly branded "confidential": (1) the American College of Cardiology/American Heart Association Guidelines, published in the Journal of American College of Cardiology, J.A. 3245; and (2) Teva's 2012 Monthly Prescribing Reference, J.A. 6192, a circulation that the majority says doctors received "on a regular basis," Maj. 33 (quoting J.A. 10607–08).

[12] To that end, the declarations also belie GSK's insistence that the 240-character use code was "not tied to any particular indication." *See* Appellant's Reply Br. 30. GSK submitted a patent declaration identifying only one indication. *E.g.*, J.A. 6895. From that declaration came the use code. GSK's use-code argument is therefore wrong as a matter of law here. And regardless, GSK's problem

Everything that follows must be assessed against the carve-out backdrop. With that in mind, I turn to what remained of the label *after* it was carved out. For a drug label to induce, it must "encourage, recommend, or promote infringement." *Takeda*, 785 F.3d at 631. "Merely describing an infringing use" in a label "will not suffice." *HZNP Meds. LLC v. Actavis Labs. UT, Inc.*, 940 F.3d 680, 702 (Fed. Cir. 2019); *Takeda*, 785 F.3d at 631.

The majority supports the verdict with GSK's expert testimony concerning the post-MI LVD indication. Again, this indication remained on the label because GSK's sworn declarations never said it was patented. Dr. McCullough did walk through claim 1 of the '000 patent and compare each limitation to somewhere on the skinny label. Maj. 14–16 (citing testimony at J.A. 10623–31). But he never testified that the skinny label encouraged, recommended, or promoted practicing the claimed method.[13]

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remains part 4.2a of the declarations, which required GSK to "[s]ubmit indication or method of use information *as identified specifically in the approved labeling*." *E.g.*, J.A. 6895 (emphasis added).

[13] The majority suggests otherwise, via a misleading cite to a snippet of testimony. *See* Maj. 24 (citing J.A. 10644). While Dr. McCullough did testify that Teva "took action" intended to encourage, none of the evidence he was referencing included the skinny label itself. His earlier skinny-label testimony concerned underlying direct infringement. *E.g.*, J.A. 10631. But after moving to the *intent* element of inducement, where the majority finds this testimony, the label did not come up again—neither directly nor indirectly. J.A. 10634–44. This may explain why GSK never cited this testimony to show that the skinny label encouraged. Had GSK done so, Teva would have had an opportunity to contest the characterization the majority now adopts.

Rather, in response to a series of questions about whether certain portions of the label "met" the claim limitations, he testified that some limitations were met (or "mentioned") in the Indications and Usage section, others in the Dosage and Administration section, and still others in the Clinical Studies section. J.A. 10623–31. At most, a reasonable jury could have found that the skinny label *described* the infringing use (if pieced together just right), in the context of post-MI LVD patients. Describing is not enough.

This failure of proof alone should end the intentional-encouragement inquiry as to the skinny label here. But when we also consider the backdrop as to how the skinny label arose—i.e., that Teva took out the only indication GSK said was patented—the lack of inducement based on this label is beyond dispute. *See Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1329 n.2 (Fed. Cir. 2009) ("[The question] is whether [defendant's] instructions teach an infringing use . . . *such that we are willing to infer* from those instructions an affirmative intent to infringe the patent." (emphasis added)); *see also Grokster*, 545 U.S. at 937 ("The classic instance of inducement is by advertisement . . . that broadcasts a message *designed to* stimulate others to commit violations." (emphasis added)). The law simply does not permit an inference of culpable, intentional encouragement from the label on this record.[14]

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[14] Despite the majority's characterization, this is not a contention that estoppel arose from GSK's FDA filings. Maj. 23. Rather, the issue concerns what *intent* could be reasonably gleaned from the skinny label, given the way that label came about and the absence of other evidence of intent. Intent is a required element of inducement—and, as the majority itself acknowledges, GSK's failure to list the post-MI LVD indication in its FDA filings "is relevant to intent to induce infringement." *Id.* at 20. Estoppel is a separate issue based on a different legal standard that the

All of that is just the intentional-encouragement prong though; GSK also had to show causation. At a minimum, it had to prove that doctors would have read the skinny label, then pieced together the disparate portions just like Dr. McCullough did at trial, then viewed that pieced-together description as an encouragement to prescribe carvedilol for CHF according to the specific limitations of the claimed method, and *then relied* on that pieced-together message to make that prescribing decision.

Dr. McCullough certainly didn't connect these dots. Indeed, he would have been a poor choice for that task. A question arose at trial as to whether he had even *read* the label before making his prescribing decisions. To survive a pre-verdict JMOL motion on causation, GSK's counsel promised the trial judge that if given another chance, Dr. McCullough would "absolutely" testify that he did so. J.A. 10959; *see also* J.A. 10959 (counsel insisting that "obviously, he always reads the label"). But when given the chance, he testified that no, he *didn't* read the label before making his prescribing decisions. J.A. 11662–63. Not that Dr. McCullough was alone in this regard; the other two expert cardiologists at trial testified that they didn't do so either. J.A. 11151 (Dr. Zusman); J.A. 11296–97 (Dr. Rosendorff).

Nothing else connected these dots. In fact, evidence from both sides showed that doctors relied primarily on

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district court may resolve in the first instance. The majority's charge that I seek to "leapfrog" and resolve estoppel here on appeal is therefore disturbingly off-base. *Id.* at 23. I am instead addressing what a reasonable jury could find Teva's intent to be. I do not understand the majority to be suggesting that the potential availability of a different type of relief (i.e., estoppel) forecloses the court from considering the main issue in this appeal (i.e., inducement) if resolution of the two issues might involve some of the same facts.

medical guidelines, experience, education, and journals when making their prescribing decisions. *E.g.*, J.A. 10668, 10676–77 (Dr. McCullough), 11151–52, 11164–68 (Dr. Zusman), 11296–97 (Dr. Rosendorff). Evidence from both sides also showed that pharmacies substituted generics for the brand version automatically, as all fifty states allow or even require. *See, e.g.*, J.A. 10678–79 (Dr. McCullough), 10750–51 (Dr. Reisetter), 11038 (Mr. Karst), 11076–77 (Ms. Kinsey). The majority, however, disregards this uncontroverted, direct evidence of causation in favor of letting unsupported inferences bridge GSK's evidentiary gap. It starts with the label's contents and that they were perhaps "read"—then ends up at causation. Maj. 35–36. I disagree with the majority that this inferential leap is "fair," *id.* at 36, particularly here, where direct evidence across the board points to medical texts and expertise as being the main influence. In my view, "fair" would be ensuring that causation means something. *See infra* Part II.C.2.

Before turning to the press releases, one last, critical point bears mentioning. The majority confines its reliance on the skinny label to the post-MI LVD indication. In particular, its skinny-label inducement path starts with "encouragement" from the post-MI LVD indication, and ends in direct infringement when a doctor prescribes carvedilol for any post-MI LVD patient who *also* happens to have CHF (assuming that the rest of the claim limitations are met when so prescribing). *See* Maj. 13–16, 18–19. Notably, however, as both sides acknowledge, the damages award in this case was *not* confined to just the appropriate subset of infringing prescriptions to post-MI LVD patients who also had CHF—it encompassed CHF patients more broadly. Cross-Appellant's Br. 54; *see* Appellant's Reply Br. 31–32. GSK's damages testimony was not predicated on, nor did it quantify, the subset of uses that would infringe under the majority's skinny-label-based inducement theory.

Recognizing the problem, GSK leans on the press releases to save the full damages award; it says they

"encouraged the infringing use for all . . . symptomatic heart failure patients." Appellant's Reply Br. 31. But, as I explain below, that's far too much weight for these press releases to bear. Accordingly, even if the majority's upholding the verdict on the basis of the skinny label were appropriate, we would have to remand this case for a proper damages calculation. But Teva's argument on this important issue goes unacknowledged in the majority's opinion.

2. The 2007 Press Release

Beyond the skinny label itself, the majority also supports the verdict with a 2007 Teva press release that announced final FDA approval for Teva to market its "[g]eneric version of [GSK's] cardiovascular agent Coreg® (Carvedilol) Tablets." Maj. 29 (citing J.A. 6353). From this press release—which was distributed before the '000 patent issued but apparently appeared on Teva's website during the patent's term—the majority permits inferences of intentional encouragement and causation. Neither is reasonable.

As to intentional encouragement, the majority interprets Teva's 2007 press release as saying that its product is a "generic equivalent of GSK's cardiovascular agent Coreg®," *id.* at 30—and, from this, permits the inference that Teva intended to encourage substitution of its product for *all* of Coreg's indications, including CHF, *id.* at 29–30. In other words, the majority holds that a generic can be deemed liable for inducement for saying that its product is a "generic version" or "generic equivalent" of a brand drug. This is a drastic holding. And it makes little sense. Essentially *all* ANDA generics are the "generic version" or "generic equivalent" of a brand drug; the law *requires* them to be. To come to market, such a generic must demonstrate that its product is bioequivalent to a brand drug. 21 U.S.C. § 355(j)(2)(A)(iv), (j)(4)(F); 21 C.F.R. § 314.94(a)(7)(i); *see also* 21 C.F.R. § 314.92(a) (noting that, with limited

exceptions not relevant here, ANDAs are suitable only for "[d]rug products that are the same as a listed drug," and that "the same as" includes drugs with label modifications made for patent carve-outs). *See generally supra* Part I.A. The system is inherently comparative. I therefore find it highly unlikely that Congress intended to make generics liable for simply stating what the law requires.

The majority also sees culpable intent in Teva's describing its product as a "cardiovascular" agent. *See* Maj. 29–30. A well-understood adjective, "cardiovascular" means relating to the heart. Carvedilol is a heart-related drug; it's used to treat CHF, post-MI LVD, and hypertension—all heart-related conditions. I cannot see how using the word "cardiovascular" to describe a heart-related drug could *reasonably* be viewed as evidencing culpable intent to encourage practicing the specific claimed CHF method in particular here—or how this adjective does anything beyond what "generic version" or "generic equivalent" do in terms of intent.

And still there remains causation. The majority never explains how a reasonable jury could have found that this press release (as it later appeared on Teva's website) affected doctors' prescribing practices so as to cause their infringement. Indeed, outside of testimony that doctors "get" press releases, J.A. 11655, and that it's "possible" doctors read them, J.A. 11239, GSK supplied no evidence that any doctor read *this* one before the litigation—much less accessed it from Teva's website, and was then so moved by it that it caused him or her to prescribe carvedilol in an infringing manner, trumping every medical text along the way.

We simply have a press release that describes a generic version of a cardiovascular brand drug as a "*generic version*" of a "*cardiovascular*" brand drug. From that alone, the majority permits inferences of culpable intent to

encourage and causation. I fail to see how those inferences are reasonable.

3. The 2004 Press Release

The majority's final key piece of evidence is the 2004 press release, which announced Teva's "tentative [FDA] approval" to market its product, described as "the AB-rated generic equivalent of [GSK's] Coreg® . . . indicated for treatment of heart failure and hypertension." J.A. 6347.

Before turning to whether these statements could show intentional encouragement to infringe, some undisputed facts must be acknowledged. First, this press release was distributed several years before the '000 patent issued, at a time when Teva was pursuing a different pathway to regulatory approval. At that time, Teva's product *was* indicated for treatment of CHF. But Teva ultimately pursued the section viii pathway. Second, the press release announced the product's "*tentative* approval," which has a specific, legal meaning—namely, that a patent or regulatory exclusivity stands in the way of final approval. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(A); 21 C.F.R. § 314.3(b); *see* J.A. 10533. In other words, this "approval" had conditions.

With that in mind, the question remains: what is there in this press release to suggest intent to encourage infringement of the (future-issued) '000 patent? Like the 2007 press release, the majority sees culpable intent in Teva's describing its product as the "AB-rated generic equivalent" of Coreg. Maj. 28. But, for the reasons described above, this cannot plausibly support liability within Congress's framework in this area. And although the press release does reference "heart failure," given the circumstances here—i.e., that the press release was distributed years before the patent issued (under materially different regulatory circumstances) and announced "tentative" approval—inferring culpable intent from this press release exceeds the bounds of reasonableness.

And again: causation. To prove it, GSK first had to show that Teva made this years-old press release available on its website during the patent's term. This should have been a crucial showing—after all, this press release is one of the three key pieces of evidence the majority relies on. Once again, though, direct evidence is missing. And once again, the majority is untroubled. It simply calls up some inferences to bridge the gap. In particular, the majority suggests the inference that, because the 2007 press release was on Teva's website, and because Teva had a website with some information about carvedilol, the 2004 press release must have been there too. Maj. 30–31. GSK, for its part, never argued any of these inferences to the jury. And while the majority faults Teva for not showing that the 2004 press release was *not* there, *id.* at 31, this is GSK's case and its burden—and besides, it's hard to blame Teva for not rebutting a fact that GSK never even tried establishing.

But, for argument's sake, let's assume the jury could have reasonably found that GSK carried its burden on this point. A further question remains: what is there to suggest that any doctor saw it—years later on the website—then relied on *that* as the basis for his or her infringing prescribing decisions? The answer: nothing. At least, that's the answer the majority gives. *See id.* at 35–37. Nothing in the record suggested that doctors were in the habit of searching a generic's website for old press releases to help them make life-or-death prescribing decisions. The most we have is that Dr. McCullough saw the 2004 press release (timing unspecified) and that it said what it said. The rest is left to sheer possibility.

And indeed, it's possible that things panned out this way. Maybe a doctor *did* search Teva's website for old press releases, found this one (assuming it was there), and then relied on that press release to make his or her prescribing decision (at least three years after the date of this press release), trumping every medical text along the way.

Maybe every relevant doctor did. Many things are possible. But "'[m]ere speculation' is not substantial evidence." *OSI Pharms., LLC v. Apotex Inc.*, 939 F.3d 1375, 1382 (Fed. Cir. 2019) (quoting *Intell. Ventures I LLC v. Motorola Mobility LLC*, 870 F.3d 1320, 1331 (Fed. Cir. 2017)).

In sum, the 2004 press release's description of Teva's product as the "AB-rated generic equivalent" of Coreg, along with its reference to "heart failure," would be a slender enough reed upon which to rest culpable intent, given that this communique was distributed years before the patent issued (under materially different regulatory circumstances) and announced an approval that was only "tentative." But it's the causation that truly vexes me. It's the notion that, instead of the various medical texts (and experience, and education), all along it was really the 2004 press release, found years later on the website, that caused doctors' CHF prescribing decisions. In the face of uncontroverted evidence of the former, *some* evidence of the latter should be necessary. But there's none.

4. The Supposedly Substantial Other Evidence of Intent

The majority calls it "inaccurate" to observe that it relies on only three key pieces of evidence as to culpable intent during the skinny-label period. Maj. 24. It says there's additional evidence too.[15] But while the majority discusses the three pieces above in some detail, it only gestures to the rest without much meaningful discussion. Such references can hardly be enough to sustain a verdict, and they return us to the uncertainty concerns plaguing the first, vacated version of the majority's opinion. At

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[15] Much of this evidence comes in the form of trial testimony that was not included in the record on appeal—which means it's testimony that GSK didn't rely on, and to which Teva therefore had no occasion to respond. Anything the majority cites as "Trial Tr." references such testimony.

bottom, however, this other evidence just relates back to the three key pieces.

There was "extensive expert testimony," the majority first insists without elaboration. Maj. 24. As best I can tell, the majority is referring to Dr. McCullough and Dr. Zusman, *see id.* at 26—Dr. McCullough saying that doctors read labels, and Dr. Zusman agreeing that Teva's circulations suggested reading labels if doctors have questions. So, we're back to the skinny label—the first of the three key pieces of evidence. And if the skinny label doesn't show intent, then neither does suggesting that doctors should read it.[16]

Teva's "Monthly Prescribing References" get some attention elsewhere. *See id.* at 26–27. But, like the "extensive" expert testimony discussed above, that's just for the proposition that Teva intended doctors to read its labels. Again, back to the skinny label.

The majority adds to the list Teva's "product catalogs" and "advertising and promotional activities." *Id.* at 24. I presume it means Teva's catalogs discussed shortly afterward. But the only thing for which *that* evidence was relied on was to show that Teva described its drug as the "AB rated" equivalent to Coreg. *See id.* at 27 (discussing 2008 and 2009 catalogs at J.A. 6221 and J.A. 6270). Statements of equivalence were discussed with respect to the two press releases—the other two key pieces of evidence. So it's unclear what this adds to the intent calculus. And as before, if this is evidence of intent, we should be disturbed.

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[16] Of course, because causation is an element, what matters in the end is whether doctors *did* in fact not only read but also *rely* on this label. *See supra* pp. 20–21. Recall too that every relevant witness testified that he *hadn't* read this label before prescribing.

Finally, the majority notes "testimony from Teva's own company witnesses." *Id.* at 24. Maybe this means Teva's marketing director (who the majority says "added carvedilol product information to the Teva website" in 2007) and regulatory-affairs director (who the majority says "discussed" the press releases with the jury). *See id.* at 31. Whatever the case, this discussion just concerns the press releases—well-trodden ground. Or maybe instead the majority means Mr. Rekenthaler, who it quotes as having "expected" or "assum[ed]" that doctors would use drugs as labeled. *Id.* at 27. But this just brings us back to the skinny label.

The bottom line is that, to the extent that this evidence is relevant, its relevance depends on finding culpability from the three key pieces of evidence—i.e., the skinny label or the two press releases, particularly their statements of equivalence.

B. *The Full-Label Period*

As with the skinny-label period, JMOL of no inducement was necessary for the full-label period. The reason is simple: nothing about doctors' prescribing practices changed when Teva amended its label to the full version. Both GSK and its experts confirmed as much. Appellant's Br. 21 ("Doctors continued to administer Teva's accused product for infringing use during [the full-label] period (*without change from the partial label period*) . . . ." (emphasis added)); J.A. 12204–05 (GSK's counsel conceding that any market impact as a result of the amendment was "minimal"); J.A. 10699 (Dr. McCullough agreeing that, in his practice, there was "no difference in [his] prescribing habits from when Teva had its skinny label to after Teva amended to have its full label"); J.A. 10754 (different GSK expert testifying that his survey of 200 doctors indicated no change in prescription patterns from pre- to post-amendment).

The majority, for its part, identifies nothing about doctors' prescribing practices that changed after Teva amended its label. Maj. 33–37. If nothing about this changed, then nothing Teva did during the full-label period could have caused anything beyond whatever caused direct infringement during the skinny-label period. And because the record lacks evidence that Teva caused direct infringement during the skinny-label period, Teva cannot have caused direct infringement during the full-label period—and therefore cannot have induced.

C. *Why the Majority's Flawed Analysis Matters*

In reinstating the jury's unsupportable verdict, the majority commits several errors—some legal, some practical, and all spelling trouble for skinny labels specifically and inducement law generally. Below are three main concerns with the majority's approach.

1. The Majority Weakens the Intentional-Encouragement Requirement as to Labels

Direct infringement is strict liability; induced infringement is not. And when it comes to inducement's intentional-encouragement requirement, the law draws a line between encouraging, recommending, or promoting an infringing use and merely describing that use. *E.g.*, *Takeda*, 785 F.3d at 631. This line is important because while the former provides evidence of intent, the latter does not. *See id.* (collecting cases); *HZNP*, 940 F.3d at 702 ("Merely describing an infringing use . . . will not suffice . . . ."). The majority blurs this line beyond recognition.[17]

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[17] GSK would have us ignore this line entirely. Appellant's Reply Br. 28 ("It is doubtful whether such a distinction actually exists . . . ."); *see id.* at 16 ("Teva's partial label encouraged doctors to infringe GSK's patent because it described every limitation of the claimed method.").

Take the skinny label here. GSK's expert Dr. McCullough, despite having *never read* the label himself before making prescribing decisions, walked through it and found piecemeal language that he could say "met" or "mentioned" each claim limitation in isolation. *Supra* pp. 18–19. That was the extent of it. There was no testimony or other evidence that this label language encouraged practicing the patented method, or that it even came with a wink or nudge. At most, then, a reasonable jury could have found that the skinny label *described* the infringing use.

The majority somehow ends up at encouragement but fails to justify how it got there. In particular, it never meaningfully engages with the legal distinction between encouraging, recommending, or promoting an infringing use and describing it. Nor does it explain how a reasonable jury could have found the former from the latter on this record. If a jury can simply infer culpable intent to encourage from a mere description, the legal distinction is meaningless. Description would *always* suffice to infer inducement.

That's a problem. "[S]howing that infringement was encouraged" is necessary to "overcome[] the law's reluctance to find liability when a defendant merely sells" a product with legitimate non-infringing uses, like carvedilol. *Grokster*, 545 U.S. at 936; *see id.* at 937 (acknowledging "the need to keep from trenching on regular commerce or discouraging the development of technologies with lawful and unlawful potential"). "This 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." *Takeda*, 785 F.3d at 631 (citing *Caraco*, 566 U.S. at 414–15).

On that note, I emphasize that this criticism is all about how the majority treats what was left of the skinny

label *after* the carve-out. That Teva first carved out exactly what GSK said would infringe should settle the question of what intent could be reasonably inferred from the label itself on these facts. It's also a circumstance that distinguishes every case the majority relies on to support its holding.

2. The Majority Eviscerates the Causation Requirement

Patent infringement is a tort. *E.g.*, *Wordtech Sys., Inc. v. Integrated Networks Sols., Inc.*, 609 F.3d 1308, 1313 (Fed. Cir. 2010); *see Carbice Corp. of Am. v. Am. Pats. Dev. Corp.*, 283 U.S. 27, 33 (1931). Accordingly, liability attaches only to one who causes the injury—here, practice of the patented method. Legal cause, not simply but-for cause, is required. Restatement (Second) of Torts § 9 cmt. a.

Traditional tort principles inform how a plaintiff proves, or fails to prove, causation:

> As on other issues in civil cases, the plaintiff is required to produce evidence that the conduct of the defendant has been a *substantial factor* in bringing about the harm he has suffered, and to sustain his burden of proof by a preponderance of the evidence. . . . *A mere possibility of such causation is not enough; and when the matter remains one of pure speculation and conjecture, or the probabilities are at best evenly balanced, it becomes the duty of the court to direct a verdict for the defendant*.

Id. § 433B cmt. a (emphasis added); *see also id.* § 876 cmt. d (noting that if "encouragement or assistance is a substantial factor in causing [a] resulting tort, the one giving it is himself a tortfeasor"). Therefore, to prove causation, GSK had to show that Teva's conduct (apart from simply being on the market) was a substantial factor in causing doctors to prescribe its carvedilol in an infringing way. A mere

possibility wouldn't do; rather, a reasonable jury must have been able to find that it was more likely than not. Here it could not.

To start, the majority identifies no direct evidence of causation by Teva. And it casts aside the direct evidence from both sides pointing to the same things—things other than Teva—as the cause. *Supra* pp. 20–21, 23–26. Instead, it says that it was "fair" for the jury to "infer" causation from the existence of the skinny label itself and the two press releases. Maj. 36. This conclusion relies on a passing observation in one case saying: "[W]e 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." *Id.* (quoting *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1335 (Fed. Cir. 2016)). But this observation is not a license to substitute speculation for proof. The evidence-to-conclusion link must always make sense.

In some inducement cases, a jury might reasonably infer causation based solely on circumstantial evidence. One example might be where a product's user manual encourages an infringing use, and where the user had no familiarity with the product *other than* the manual. A reasonable jury might infer that the manual caused the user, otherwise unfamiliar with the product's intricacies, to use the product that way, and we have upheld inducement verdicts on this basis. *E.g.*, *Golden Blount, Inc. v. Robert H. Peterson Co.*, 438 F.3d 1354, 1362–63 (Fed. Cir. 2006) (causation evidence included an instruction sheet teaching infringement and packaged with each product); *ArthroCare Corp. v. Smith & Nephew, Inc.*, 406 F.3d 1365, 1377 (Fed. Cir. 2005) (causation evidence included "sales literature accompanying one of the accused devices" and other instruction manuals recommending an infringing use); *Moleculon*

Rsch. Corp. v. CBS, Inc., 793 F.2d 1261, 1272 (Fed. Cir. 1986) (causation evidence included "dissemination of an instruction sheet teaching" the infringing method). Although purely circumstantial, the inferential hops are few and short. In those cases, what else but the user manual might have caused the user to use the product in an infringing way? *Cf. Golden Blount*, 438 F.3d at 1363 ("[N]othing in the record suggests that either [defendant] or any end-user ignored the instructions . . . .").

In other inducement cases, inferential leaps are too many and too great, and evidence of a different cause too strong, for the circumstantial evidence that is offered to carry the day. Take this case. To accept that Teva's skinny label was a substantial factor in causing doctors to infringe, one would have to infer doctors read it to make prescribing decisions (even though all three testifying expert cardiologists said they didn't); infer those doctors pieced together the portions of the label to uncover a description of the infringing use (maybe); infer those doctors interpreted that description as an encouragement (no evidence); and then infer those doctors relied on that description to make their prescribing decisions (no evidence). *Supra* pp. 20–21. As to the press releases, one would have to infer Teva made them available during the relevant time period (maybe); infer doctors read them during that time (no evidence); and then infer doctors relied on some inducing message therein to make prescribing decisions affecting their patients' health (no evidence).[18] *Supra* pp. 23–26.

Unlike the prototypical user-manual case, in which we might permit the inference that a user relied on the manual without requiring testimony to that effect, the

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[18] This is to say nothing of the causal implications of pharmacies' ubiquitous automatic-substitution practices—where, for example, a doctor might write "Coreg," but a generic is dispensed nonetheless. *See* J.A. 10750–51.

inference might not hold up as well in this context—with highly educated users and well-studied products. And whatever strength the inference has in a context such as this, it crumbles when, as here, we *have* users who testified, and they either (1) failed to say they relied or (2) affirmatively said they *didn't* rely on the allegedly inducing materials.

Moreover, unlike the prototypical user-manual case, it's not as though the record here was wanting for another cause. Both sides' expert cardiologists said under oath and without contradiction that medical texts, education, and experience caused their prescribing decisions. *Supra* pp. 20–21. Under these circumstances, would accepting the Teva-caused version of events amount to anything more than speculation, given the chain of inferences required—not all of them reasonably grounded in the record evidence?

The most troubling part of all this is that the majority never explains how a reasonable jury could have come out this way on this record. Given the size of the infringing doctor class here, it should have been easy to present testimony of causation if that theory had a basis in fact. *Cf. TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2212 (2021) (pointing to evidence that could have been sought and citing *Interstate Circuit, Inc. v. United States*, 306 U.S. 208, 226 (1939), for the proposition that "[t]he production of weak evidence when strong is available can lead only to the conclusion that the strong would have been adverse"). But not a single doctor testified as to causation by Teva, and in fact, the most on-point testimony shows the *absence* of causation.

As a doctrinal matter, the majority's opinion suggests that there is no independent causation element for inducement; intentional encouragement might always suffice to infer causation too. Add that to the majority's weakening of intentional encouragement (where describing an

infringing use piecemeal—or simply calling a product a "generic version" or "generic equivalent"—is now enough), and finding inducement becomes possible based largely on speculation. The law requires more from a plaintiff.

3. The Majority Creates Confusion About Skinny Labels

The majority's opinion will create confusion for everyone. Under its analysis, the difference is indiscernible between this case and one in which the generic is safe. Indeed, it's unclear what Teva even did wrong—or, put another way, what another generic in its shoes should do differently.

Initially, the majority suggests that this is not a skinny-label case. Nothing to see here, the majority reassures concerned amici: the Act remains intact. *See* Maj. 10–11. But it's hard to see how. As a matter of law, this is a skinny-label case about the skinny-label provisions. The Act's text makes that much clear: section viii by its own terms references the brand-submitted patent "information" (i.e., patent declaration). 21 U.S.C. § 355(j)(2)(A)(viii); *see* 21 C.F.R. § 314.53(c)(2)(O) (patent "information" includes portions of label covered by method patent). This patent information dictates whether a generic label is a section viii label. If a generic omits the uses the brand has said are patented, the label is skinny. The FDA understands that. *See supra* Part I.A (discussing brand-dependent regulatory framework). So does the Supreme Court. *Caraco*, 566 U.S. at 404–07. So should we.

What's more, the background facts here will seemingly persist in most skinny-label cases. Under the Act, "[g]eneric copies" are essentially "the same as the original drug." *See* H.R. Rep. No. 98–857, pt. 1, at 14–15; *accord* 21 U.S.C. § 355(j)(2)(iv); 21 C.F.R. § 314.92(a)(1). Thus, bioequivalence; comparison to a brand drug; duplication of a brand's label (at least in part); reliance on a brand's clinical-trial data; references to a drug's therapeutic class;

cursory press releases announcing a generic's regulatory approval; doctors' assumptions about what going generic means; pharmacies' generic substitution; a generic's knowledge that some sales may occur from off-label, infringing uses—all of that will generally be there whether there is inducement or not. *See, e.g.*, *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1380 (Fed. Cir. 2012) (discussing "market realities" of substitution that do not implicate infringement). Those facts cannot sort inducement from non-inducement.

So where did Teva go wrong in this case? Should it not have followed the brand's sworn representations as to what was patented? The majority offers no principled division between this and what it suggests would be a true skinny label. For decades, everyone has assumed they could rely on what brands said about what their patents covered. The FDA's skinny-label approval pathway and regulations are expressly predicated on that. As far as adherence to Congress's framework, this was about as faithful as it gets.

Or is the takeaway, instead, that Congress meant to expose ANDA generics to liability for simply describing themselves as the "generic version" or "generic equivalent" of a brand drug? Given that the Hatch-Waxman Act's framework requires ANDA generics to be the same as a brand drug, and that doctors understand what being a generic means, this seems a dubious proposition.

One of amici's key criticisms of the first version of the majority's opinion was that it was unclear what among the muddled mass of evidence actually formed the basis of liability. So too here. It's unclear whether the skinny label was enough—or whether the press releases were, or some of the other ancillary evidence in the record, "all of which" the majority suggests the jury "could have relied on." Maj. 24.

The lack of clarity extends to the majority's characterization of its holding as "case-specific." *See id.* at 10–11.

For example, the majority's new opinion relies on the post-MI LVD indication remaining on the skinny label as a potentially "case-specific" circumstance. *See id.* Not only is this reliance problematic (for the reasons described above), it's a mirage. If the majority were truly relying on this circumstance to distinguish this case, it would accept Teva's argument that the damages should be confined to the appropriate subset of infringing prescriptions to post-MI LVD patients who also had CHF. *See supra* pp. 21–22. But, given that this argument goes unacknowledged in the majority's opinion, the implication is that the press releases alone—with their references to "generic version" or "generic equivalent"—suffice to support the *entire* verdict, encompassing CHF patients more broadly. And if that's so, then it's unclear why the majority's analysis of the skinny label itself is relevant. Under the majority's holding, a brand can just rely on statements of equivalence to capture even that portion of the market that was specifically carved out.

The only clear thing now is that no generic can know until hit with the bill whether it's staying within the confines of the law. Being unable to predictably rely on use codes and patent declarations "throws a wrench" into Congress's skinny-label design. *See Caraco*, 566 U.S. at 419.

III. CONCLUSION

Before today, there was an equilibrium to the skinny-label system—one that allowed companies to make informed, responsible decisions in this area. If a generic wanted to avoid patented uses, it had the simple expedient of omitting from its label the uses the brand identified. And if a brand wanted to block a skinny label containing a use it thought was patented, it had the simple expedient of including that use in its FDA patent declaration. That equilibrium is no more.

So, what's next? We are now on the majority's second opinion in this case. The first was vacated in light of Teva's

petition for rehearing and the eight amicus briefs in support. This new opinion does little to assuage, and even exacerbates, concerns raised by the original.

I respectfully dissent.

CERTIFICATE OF SERVICE

I hereby certify that on October 7, 2021, 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 3,900 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 for Microsoft 365.

/s/ *William M. Jay*
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