APPENDIX A

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

[*] 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.

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 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. § 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[:]

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

> 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 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

[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).

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]

[3] Moreover, in contrast to this case, we recognized in *Grunenthal* that the partial label was the only evidence of inducement

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 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

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and that we could not conclude on those facts that the district court clearly erred.

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." 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

[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.

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?
>
> A. It's correct that FDA said the statement you just had up there. I guess it's gone now, where

[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).

> 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]

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

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

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 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 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

[7] We do not hold that an AB rating in a true section viii carveout (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.

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.

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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.

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, 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 & Nephew induced users to employ the probes

[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.

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 straight-

forward. 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

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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.

immediate market entry for drugs with at least one unpatented FDA-approved use.[3]

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]

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[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 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

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.

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.

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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.

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 brandlabeled 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

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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.

("[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

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[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. 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.

36,683, 36,686, 36,697; *see 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).

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.

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68 Fed. Reg. at 36,683.

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

[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.").

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 '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 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.

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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").

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 digitlalis, to increase survival and, also, to reduce the risk of hospitalization (see CLINICAL TRALS).

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 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 skinnylabel 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," *GlobalTech 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,

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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

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).

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,

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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 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).

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] 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

[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.

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 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)

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 medical guidelines, experience, education, and journals when making their prescribing decisions.

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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.

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

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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.

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]

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

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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.”).

(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 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.

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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.

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.

APPENDIX B

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: October 2, 2020

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

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

Dissenting opinion filed by *Chief Judge* PROST.

NEWMAN, *Circuit Judge*.

GlaxoSmithKline LLC and SmithKline Beecham (Cork) Ltd. (collectively, "GSK") charged Teva Pharmaceuticals USA, Inc. with infringement of GSK's Reissue Patent No. RE40,000 ("the '000 patent"). Trial was held in the United States District Court for the District of Delaware; the jury found the patent valid and infringed, and assessed damages. The jury also found that the infringement was willful. The district

court then granted Teva's motion for judgment of non-infringement as a matter of law.[1] GSK appeals the JMOL, and Teva conditionally cross-appeals the damages verdict. No appeal is taken from the verdict of patent validity.

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

BACKGROUND

The GSK patents

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

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

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

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

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

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

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

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

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

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

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

The label stated that "Carvedilol is indicated to reduce cardiovascular mortality in clinically stable patients who have survived the acute phase of a myocardial infarction and have a left ventricular ejection fraction of ≤ 40% (with or without symptomatic heart failure)." J.A. 5508. Teva's press releases and marketing

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

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

GSK's suit for infringement

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

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

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

include all of the information that the FDA had approved for Coreg®.

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

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

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

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

Jury instruction 4.2.4.

Both sides presented witnesses, documents, and argument. The jury found that Teva induced infringement of claims 1-3 during the period starting January 8, 2008 (the date of the '000 patent's issuance) to April 30, 2011 (the last day before Teva amended its label);

and that Teva induced infringement of claims 1-3 and 6-9 during the amended label period starting May 1, 2011 and ending June 7, 2015 (the date of expiration of the '000 patent). The jury assessed damages based on a combination of lost profits and royalty, and found that the infringement was willful.

Grant of judgment as a matter of law

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

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

as their own experience, in addition to GSK marketing." *Id.*

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

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

DISCUSSION

Standards of review

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

The Third Circuit provides that a "court may grant a judgment as a matter of law contrary to the verdict only if 'the record is critically deficient of the

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

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

A

INDUCED INFRINGEMENT

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

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

GSK argues that the district court erred in law and fact. GSK states that Teva's marketing of carvedilol with knowledge and intent of its infringing use, and promotion of its generic product as the same as

Coreg®, meet the legal requirements of active inducement of infringement. GSK states that there was substantial evidence whereby a reasonable jury could so find.

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

GSK states that the district court erred in law, as shown in long-established and clear precedent that induced infringement may be shown by evidence that the accused inducer promoted the infringing use with knowledge that such use directly infringes the patent claims. GSK cites, *e.g., Toshiba Corp. v. Imation Corp.,* 681 F.3d 1358, 1365 (Fed. Cir. 2012) ("[W]here an alleged infringer designs a product for use in an infringing way and instructs users to use the product in an infringing way, there is sufficient evidence for a jury to find direct infringement."); *Lucent*, 580 F.3d, at 1318 ("Microsoft not only designed the accused products to practice the claimed invention, but also instructed its customers to use the accused products in an infringing way."): *Ericsson,* 773 F.3d, at 1220, 1222 (finding induced infringement where alleged inducer advertised compliance with an infringing standard).

In *Global-Tech Appliances, Inc. v. SEB S.A.,* 563 U.S. 754 (2011), the Supreme Court explained that copying of a patented product is evidence of inducing infringement. *Id.* at 770-71. The Court had applied the principles of induced infringement to copyright issues in *MGM Studios Inc. v. Grokster, Ltd*., 545 U.S. 913 (2005), stating that "active steps … taken to

encourage direct infringement, such as advertising an infringing use or instructing how to engage in an infringing use, show an affirmative intent that the product be used to infringe." *MGM* at 936 (citations omitted, ellipsis in original). The Court held that inducement to infringe is not negated when the direct infringers already knew of the infringing subject matter. *Id.*

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

These principles have been applied to the circumstances of FDA-regulated products; *see, e.g., Eli Lilly & Co. v. Teva Parenteral Meds., Inc.,* 845 F.3d 1357, 1369 (Fed. Cir. 2017) ("[E]vidence that the product labeling that Defendants seek would inevitably lead some physicians to infringe establishes the requisite intent for inducement."); *Sanofi v. Watson Labs. Inc.,* 875 F.3d 636, 645 (Fed. Cir. 2017) (finding induced infringement where the label "directs medical providers

to information identifying the desired benefit for only patients with the patent-claimed risk factors" and "[t]here was considerable testimony that this label encourages … administration of the drug to those patients"); *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010) (finding induced infringement where "despite being aware of the infringement problem presented by the proposed label, Apotex nonetheless proceeded with its plans to distribute its generic drug product"); *Mentor H/S, Inc. v. Med. Device All., Inc.*, 244 F.3d 1365, 1379 (Fed. Cir. 2001) (finding induced infringement where the defendant "sold the [accused] device with the intention that doctors would use it to perform the patented method").

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

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

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

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

Dr. McCullough testified that Teva's Spring 2008 catalog lists Teva's carvedilol tablets next to Coreg® tablets and uses the phrase "AB rating," and that this would lead a doctor to believe that "they're therapeutically interchangeable." Trial Tr., June 14, 2017, at 634-635. He stated that as to Teva's carvedilol "we had lots of information … that indicated that … it was a complete replacement. That in fact the two, the drug was the same, and all the information regarding it was the same." Trial Tr., June 19, 2017, at 1663. Dr. McCullough testified that if he just wrote Coreg on a prescription, the patient would get the generic unless he explicitly wrote "dispense as written" or "DAW." *Id.* at 1162.

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

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

Answer: Yes, unless the doctor feels strongly.

Question: Writes brand only?

Answer: Yes.

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

In response to the question whether "[b]ased on what Teva said in 2004 and 2007, any time after that …, did you ever come to believe that Teva's generic carvedilol had not been approved for the treatment of heart failure?" Dr. McCullough answered: "No, I never knew it." Trial Tr., June 19, 2017, at 1661.

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

Teva argued that the 2004 and 2007 press releases should not be considered as evidence of inducement because the '000 patent was not issued until January 8, 2008. Teva Br. 40, citing *Nat'l Presto Indus., Inc. v. West Bend Co.*, 76 F.3d 1185, 1196 (Fed. Cir. 1996) ("§271(b) does not reach actions taken before issuance of the adverse patent"). However, the evidence before the jury was that the 2007 press release remained on

Teva's website throughout the life of the '000 patent with the caption "Sept. 06, 2007 1:55 PM 'Teva Announces Approval and Shipment of Generic Coreg® Tablets.'" Trial exhibit PTX 1301.0002 bearing the date "4/14/2015,"

The jury was correctly instructed that it could find inducement if Teva "continued to take an action that began before the '000 patent issued, after the '000 patent was issued on January 8, 2008, intending to cause the physicians to directly infringe by administering Teva's carvedilol product." Jury instructions 4.2. The jury properly could consider Teva's continued affirmative promotion of its carvedilol tablet as the AB generic equivalent of Coreg® which could be used as a cardiovascular agent, well after the issuance of the '000 patent. This evidence included the press release on Teva's website after issuance of the '000 patent, and the promotional catalogs circulated by Teva between 2008 and expiration of the '000 patent in 2015. The record includes Dr. McCullough's expert testimony that doctors are "completely reliant" on this type of promotional material from the generic producer. The jury found Teva liable for induced infringement during the period of the '000 patent.

The district court granted Teva's motion for JMOL, stating that "there is not legally sufficient evidence to support a finding that Teva, by listing its carvedilol as AB rated to Coreg® in product catalogs and reference guides, encouraged infringement." Dist. Ct. Op. at 594. The court's reason was that "physicians already knew how to use carvedilol for treating CHF" and thus infringement was not "caused" by Teva. *Id.* The district court applied an incorrect legal standard, for precedent makes clear that when the provider of an

identical product knows of and markets the same product for intended direct infringing activity, the criteria of induced infringement are met. There was ample record evidence of promotional materials, press releases, product catalogs, the FDA labels, and testimony of witnesses from both sides, to support the jury verdict of inducement to infringe the designated claims for the period of the '000 reissue patent.

Precedent has recognized that the content of the product label is evidence of inducement to infringe; *see Vanda Pharm. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1129 (Fed. Cir. 2018) (holding that "[t]he contents of the label itself may permit the inference of specific intent to encourage, recommend, or promote infringement"); *Sanofi,* 875 F.3d at 646 ("The content of the label in this case permits the inference of specific intent to encourage the infringing use."). These rulings comport with precedent on causation in tort liability, as in, *e.g., Tinnus Enter., LLC v. Telebrands Corp.,* 846 F.3d 1190, 1204 (Fed. Cir. 2017) (approving "the use of instruction manuals to demonstrate direct infringement by customers in the context of induced infringement"); *Golden Blount, Inc. v. Robert H. Peterson Co.*, 438 F.3d 1354, 1363 (Fed. Cir. 2006) ("[T]he instructions packaged with each device teach the infringing configuration.").

Applying the standards of law and precedent, there was substantial evidence to support the jury's verdict of inducement to infringe the '000 patent. We remark that our colleague in dissent applies an incorrect standard of review, for this court on appeal of a jury verdict does not find facts afresh, contrary to the substantial evidence standard. For example, the dissent finds that neither "Teva's press releases [nor] its

product catalogs encourage doctors to practice the patented method," Diss. Op. at 22, although Dr. McCullough testified that doctors do read press releases and product catalogs, and even Teva's expert, Dr. Zusman, conceded that "it's possible" that doctors read these materials. Trial Tr., June 16, 2017 at 1238-1241.

Nor is this appeal a policy debate about whether GSK made enough money from carvedilol in past years, and therefore should not be permitted to enforce its patent on its discovery of this novel method of prolonging life for persons with congestive heart failure. The implications of the dissent's position are vast, and if enforcement of patents on new discoveries varies with the extent to which the patentee has profited from past discoveries, this is a policy matter for Congress, not a factor in judicial review of jury verdicts.[4]

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

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

B

DAMAGES

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

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

> 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 nonparties' products, thus, would not exist in the but-for world, which must be constructed to include "likely outcomes with ***infringement factored out of the economic picture.***" *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1350 (Fed. Cir. 1999) (emphasis added).

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

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

Teva also argues that the "prerequisite for lost profits" is "but-for causation," and not the *Panduit* factors on which the jury was instructed. Teva Reply Br. 4. Teva points out that pharmacies are allowed or required to substitute generic products unless explicitly ordered otherwise, and that this would deprive GSK of all profits on its higher priced Coreg®.

GSK responds that the district court correctly held that generic carvedilol is not a non-infringing alternative, and that the court correctly stated that "the law is clear that a lost profits analysis must be based on a

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

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

CONCLUSION

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

VACATED AND REMANDED

Each party shall bear its own costs.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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

v.

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

2018-1976, 2018-2023

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

PROST, *Chief Judge*, dissenting.

Through the decades, many, including my colleagues, have spoken on the importance of patents in incentivizing innovation. The calls for robust patent protection have been particularly passionate in the pharmaceutical space. The critical balance of those patent rights, however, is public access to the innovation once patents have expired. Indeed, Congress designed the generic approval system with the express purpose of speeding the introduction of generic drugs to the market as soon as patents allow. Today, the Majority's decision undermines this balance by allowing a drug marketed for unpatented uses to give rise to liability for inducement and by permitting an award of patent damages where causation has not been shown.

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

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

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

The jury returned a verdict in favor of GSK, finding that Teva had induced infringement of the '000 patent by marketing both its skinny and full labels. The district court thereafter applied the law to the evidence presented at trial. In a thoughtful and thorough opinion, the court concluded that there was not legally

sufficient evidence to show that Teva infringed the '000 patent and granted JMOL for Teva. The Majority, with little explanation, reverses that decision by misapplying the law and misconstruing the facts.

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

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

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

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

***

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

I. THE STATUTORY BACKGROUND

Congress contemplated the very circumstances this case presents, and plainly intended for the opposite outcome. It facilitated generic drug approval as soon

as patents would allow and, through 21 U.S.C. § 355(j)(2)(A)(viii), specifically provided generics a pathway to approval that avoids any infringement of a brand's patents.

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

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

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

required to provide information about clinical trials and investigations, but it must demonstrate that its generic version is bioequivalent to the branded drug. *See* 21 U.S.C. § 355(j)(2)(A)(iv).

Related to the approval process, the FDA publishes the Orange Book,[1] which identifies drug products that have been approved as safe and effective. The Orange Book is updated to identify generic versions once an ANDA has been finally approved. It reports a therapeutic equivalence rating that signals whether the generic drug can be expected to have the same clinical effect and safety profile when administered as labeled. *Orange Book Preface*, at § 1.2. Relevant to this case, for example, a therapeutic equivalence rating of "AB" means that the generic version of the brand drug meets necessary bioequivalence requirements. *Orange Book Preface*, at § 1.7.

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

Congress, however, provided the generic manufacturer two pathways to show that its proposed label will not infringe an Orange-Book-listed patent. The

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

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

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

The second pathway, available in circumstances where at least one indication on the brand label is no longer patent protected, allows the generic to "carve out" other still-patented indications from its label. *See* 21 U.S.C. § 355(j)(2)(A)(viii) ("section viii"); 21 C.F.R. § 314.94(a)(8)(iv). The resulting label is commonly called a "skinny label." When the ANDA is finally approved, the generic will be limited to the indications included on its skinny label but will nonetheless be

able to launch its product *without infringing* the remaining method patent.

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

II. THE FACTUAL AND PROCEDURAL BACKGROUND

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

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

Carvedilol is a beta-blocker, which is a class of drugs that have been used since the 1960s to treat certain heart conditions. Carvedilol in particular was developed in the 1980s and was covered by U.S. Patent No. 4,503,067, which issued in 1985 and expired in 2007. The '067 patent claimed the carvedilol compound and a method of using carvedilol to treat hypertension and angina pectoris. *See* '067 patent claims 1-18.

By the early 1990s, research revealed that beta-blockers could also be useful for treating a different

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

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

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

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

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

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

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

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

Both Teva and the FDA announced the approval of generic carvedilol with a press release. Teva's short press release stated that it had been granted "final approval for the company's [ANDA] to market its

Generic version of GlaxoSmithKline's cardiovascular agent Coreg® (Carvedilol) Tablets." J.A. 6342. Teva also announced that it would immediately begin shipping its product but did not suggest that its product should be used to treat CHF. *See id.*

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

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

In marketing its generic carvedilol, Teva *never* stated that it was approved, or could be used, to treat CHF. In fact, the record suggests Teva hardly

marketed its generic at all. Teva publicly acknowledged that it sold generic carvedilol in product catalogs, which were produced for pharmacists and described basic identifying information for all Teva products. In these catalogs, Teva listed carvedilol tablets with the appropriate identifying information and reported that the therapeutic equivalence rating was "AB" and the "Brand" was Coreg® Tablets. J.A. 6214, 6221 (2008 Product Catalog); J.A. 6054, 6056, 6072 (2011 Product Catalog).[2] Teva's product catalogs explained that therapeutic equivalence ratings are codes that "are published in the FDA's Orange Book" for "[d]rug products the FDA considers therapeutically equivalent to other pharmaceutically equivalent products." J.A. 6256. With respect to an "AB" rating, in particular, the catalog stated that an "AB" code identifies "[p]roducts meeting necessary bioequivalence requirements." *Id.* Teva also published prescribing references that were distributed to doctors and included the same basic information. *See* J.A. 6192, 6200. Notably, from the time the generic product was approved, the FDA likewise reported the equivalence rating for Teva's carvedilol product in the Orange Book. J.A. 6865-67.

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

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

greater than six months to decrease a risk of mortality. Claim 1 of the '000 patent recites:

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

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

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

Years later, in 2011, the FDA directed Teva to revise its label to include the CHF indication. Teva complied. Teva did not issue a press release or otherwise notify doctors of the change to its label. Indeed, Teva did not

change anything about how it marketed its generic carvedilol; it continued to sell its product in the same manner that it had done since approved. *See* J.A. 6054. GSK still did not allege that Teva's sales of its generic product infringed the '000 patent.

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

GSK finally sued Teva in the U.S. District Court for the District of Delaware in 2014, more than six years after the FDA's approval of Teva's ANDA and less than one year before the expiration of the '000 patent. GSK did not (and could not) bring an ordinary Hatch-Waxman case relying on Teva's ANDA as an artificial act of infringement, but instead alleged for the first time that Teva had induced infringement of the '000 patent by selling its generic carvedilol under both its skinny and full labels. GSK sought nearly $750 million dollars in damages from Teva.[3]

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

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

Specifically, at trial, GSK failed to produce testimony purporting to show that Teva's label induced infringement of the claimed method by even a single doctor. The parties agreed that when Teva launched, its skinny label did not instruct doctors to prescribe generic carvedilol to treat CHF. *See* J.A. 10584 at ll. 4-6; *see also* J.A. 10542 at ll. 1923. There was no dispute that the only two uses included on Teva's label were hypertension and post-MI LVD—uses that were not patented. *See* J.A. 10545 at ll. 9-14 (GSK's expert, Dr. Lietzan, testifying that in 2008, Teva's carvedilol tablets and Coreg® "were approved for different uses," and "[m]ore precisely, the Teva product was not approved for one of the uses that the Coreg product was approved for").

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

While Teva's label did not seem to influence doctors' prescribing decisions, numerous other industry materials did. Dr. McCullough testified that in prescribing carvedilol to treat CHF, he was informed by

prescribing guidelines established by the American Heart Association and the American College of Cardiology, medical research studying carvedilol, and even GSK's own Coreg® label and the promotional materials advertising it. J.A. 10676 at l. 2 to 10677 at l. 25.

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

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

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

At the conclusion of trial, the jury was instructed that to prove inducement, GSK had to show by a

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

The district court granted JMOL in favor of Teva because "neither sufficient nor substantial evidence supports the jury's finding of inducement." *Id.* at 591. In reaching its decision, the district court carefully considered the evidence that GSK had presented at trial. And it concluded that this evidence failed to show that even a single doctor, much less a class of doctors, was induced to infringe the '000 patent based on Teva's actions. *Id.* at 590-91. It was not disputed that Teva's label, at launch, did not include treating CHF or the method claimed in the '000 patent. The record also showed that Dr. McCullough had not even read Teva's label and that his prescribing behavior, like other doctors, had not changed when generic carvedilol entered the market. *Id.* at 594-95.

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

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

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

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

> [G]iven the dearth of evidence that doctors read and understand and are affected by labels, and given the vast amount of evidence that doctors' decisions to prescribe carvedilol during the relevant periods were influenced by multiple non-Teva factors[, an inference that Teva induced infringement] was an unreasonable one for the jury to have drawn.

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

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

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

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

Contrary to the Majority's suggestion that Teva provided and marketed an "identical product," *see* Maj. 16, Teva did not launch its product with a label that was identical to GSK's.[4] This case is therefore not analogous to either *Vanda* or *Sanofi*, where a brand manufacturer alleged patent infringement based on the generic's ANDA that included a virtually identical label. Unlike those cases, here, Teva's skinny label is insufficient to prove infringement.

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

To hold otherwise, as the Majority does, undermines Congress's provision for skinny labels by substantially nullifying section viii. According to the Majority, a generic company that carves out from its label a patented method of use can nonetheless be found to

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

infringe that patented method based on the content of the FDA-approved label. *See* Maj. 16. By finding inducement based on Teva's skinny label, which was not indicated for—and did not otherwise describe—the patented method, the Majority invites a *claim of inducement* for almost *any generic* that legally enters the market *with a skinny label*. That is directly contrary to Congress's intent. *See, e.g.*, *Caraco Pharm.*, 566 U.S. at 405-06, 415; *Medtronic*, 496 U.S. at 670-71, 676.

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

The same is true in yet another one of our cases. In *Takeda Pharmaceuticals U.S.A. v. West-Ward Pharmaceutical Corp.*, we considered whether a drug's

label induced infringement of a patented method for which it was not indicated. 785 F.3d 625 (Fed. Cir. 2015). Takeda argued that the label induced infringement of the patented method of treating acute gout flares by instructing that "[i]f you have a gout flare while taking [the drug], tell your healthcare provider." *Id*. at 632 (first alteration in original). Takeda argued that this instruction would "inevitably" lead physicians to use the drug for the treatment of acute gout flares. *Id*. We concluded that it did not induce infringement. We explained that "vague label language cannot be combined with speculation about how physicians may act to find inducement," and held that to induce infringement of a patented method, a "label must encourage, recommend, or promote infringement." *Id*. at 631-32.

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

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

Finally, to the extent the Majority finds liability for induced infringement based on Teva's expectation that "off-label" sales of generic carvedilol would occur, *see* Maj. 1315, we have repeatedly rejected the argument that knowledge of off-label infringing uses establishes inducement. *See Takeda*, 785 F.3d at 631 ("The requirement of inducing acts is particularly important in the Hatch-Waxman Act context because the statute was designed to enable the sale of drugs for non-patented uses even though this would result in some off-label infringing uses."); *Warner-Lambert*, 316 F.3d at 1364 ("[M]ere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven."); *see also Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1276 n.6 (Fed. Cir. 2004).

IV. THE MAJORITY MISAPPLIES THE LAW AND MISCONSTRUES THE FACTS

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

GSK failed to prove causation based on either Teva's skinny or full label. I address the skinny and full label periods below.[5] I also discuss uncontroverted evidence

[5] Teva's skinny label period runs from January 8, 2008, when the '000 patent issued, until April 30, 2011. The full label period

that showed that other sources, not Teva, influenced doctors' decisions to prescribe generic carvedilol according to the patented method during both periods.

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

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

During the skinny label period, GSK primarily relied on Teva's label as the basis for its claim that Teva induced doctors to practice the claimed method. *E.g.*, J.A. 10692 at ll. 7-10. Critically, as just discussed, Teva's skinny label did not teach the patented method and could not induce infringement of the '000 patent. *See supra* § III.

Moreover, regardless of what Teva's skinny label encouraged, GSK failed to show that doctors actually relied on Teva's label in deciding to prescribe generic carvedilol. GSK's expert Dr. McCullough expressly testified that he had not read Teva's label before prescribing generic carvedilol, J.A. 11662 at l. 25 to 11663 at l. 3, and also that he had not read any other generic carvedilol label, J.A. 10671 at ll. 3-9. Dr. McCullough

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runs from May 1, 2011, when Teva amended its label at the FDA's direction, until June 7, 2015, when the '000 patent expired.

was also unequivocal that his prescribing behavior did not change once generic carvedilol was launched, *e.g.*, J.A. 10674 at l. 25 to 10675 at l. 9.

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

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

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

Teva published two releases before the '000 patent issued. The first was published in 2004 and announced the *tentative* approval of Teva's generic product. J.A. 6347. The second was published in 2007 and

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

The Majority nonetheless exhumes Teva's press releases to establish infringement because they remained on Teva's website after the '000 patent's issuance. Maj. 1516. The continued presence of the press releases, however, is not probative evidence of inducement. Our caselaw is clear that inducement requires "an affirmative act to encourage infringement." *E.g.*, *Takeda*, 785 F.3d at 632 n.4; *Microsoft Corp. v. DataTern, Inc.*, 755 F.3d 899, 904 (Fed. Cir. 2014); *see also Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 918 (2005); *see also* J.A. 11797 at ll. 7-8, 13-18 (jury instructions). In this case, passive maintenance of the pre-issuance press releases is not an affirmative act of inducement.[6]

[6] To the extent the Majority means to argue that the press releases are probative evidence of continued inducement because they were maintained on Teva's website, that argument also fails. Not only is passive maintenance not an affirmative act, but further, the "continued infringement" argument was not made to the jury. It therefore could not have provided substantial evidence for its verdict. At most, the jury saw a copy of the press releases taken from Teva's website with a footer indicating that they had been printed from the website in 2015. J.A. 6346-47, 6352-53.

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

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

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

Teva's press releases and product catalogs, like its skinny label, do not promote treating CHF at all. For example, the 2007 press release said nothing of CHF. J.A. 6373; *see also* J.A. 10671 at ll. 11-14 (GSK's expert Dr. McCullough testifying that the release "said nothing about what indications were or weren't on the label"). The product catalogs likewise said nothing about the product's indications. Instead, the catalogs merely included carvedilol in a table that reported basic product information, like physical description, units of sale, and therapeutic equivalence. *See* J.A. 6221. The Majority, purportedly "[a]pplying the

standards of law and precedent," focuses on whether doctors read these materials. Maj. 17. But the question is not just whether these materials were read (though there is scant evidence even of that, *see infra* § IV.A.3); the question is whether these materials can reasonably be viewed as having *encouraged infringement*. And they simply cannot.

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

Without a disclosure of the claimed method, the Majority seems to rely on references to Teva's "AB rating" or therapeutic equivalence as evidence of inducement. *See* Maj. 12-16. These statements, however, cannot be legally sufficient to prove inducement. As recognized by the Majority, *see* Maj. 6 n.3, and clarified in Teva's publications, *see* J.A. 6256, therapeutic equivalence is

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

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

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

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

equivalence with respect to the off-label uses." J.A. 10583 at ll. 1-4; *see also* J.A. 10542 at ll. 13-14 ("AB rating means that [the drug is] therapeutically equivalent as labeled ….."). Thus, Teva's reporting of equivalence information cannot be evidence of inducing infringement for a method that the generic is not indicated to treat.[9]

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

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

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

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

evidence that Teva caused infringement. *Power Integrations*, 843 F.3d at 1330-31.

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

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

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

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

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

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

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

induced infringement in part because before the generic's alleged inducement, the FDA had previously informed healthcare providers to prescribe the drug according to the claimed method).

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

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

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

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

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

As previously described, GSK's evidence showed that doctors, including the very doctor it chose to put on the stand, did not rely on generic labels in making prescribing decisions. *See* J.A. 10671 at ll. 3-9. Though GSK was given multiple opportunities to prove causation, *e.g.*, J.A. 10962 at ll. 7-10; J.A. 10959 at ll. 9-20, GSK's expert Dr. McCullough testified that he did not read Teva's label before prescribing generic carvedilol, J.A. 11662 at l. 25 to 11663 at l. 3, and he testified that his decision to prescribe carvedilol never changed, J.A. 10674 at l. 25 to 10675 at l. 9. Indeed, when Dr. McCullough was asked about Teva's amendment from a skinny to a full label, he specifically testified that the change had no effect on his prescribing habits:

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

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

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

While the evidence failed to show that doctors relied on Teva's full label (or any other communication by Teva during the full label period), the record was consistent with the skinny label period demonstrating other sources, not Teva, influenced doctors' decision to prescribe generic carvedilol according to the patented method. *See supra* § IV(A)(4). Specifically, the record confirmed that information from the American Heart Association and American College of Cardiology, as well as medical research, and even GSK's own marketing, encouraged doctors to prescribe carvedilol according to the '000 patent. *E.g.*, J.A. 10676 at l. 2 to 10677 at l. 25; J.A. 11151 at l. 3 to 11153 at l. 22; J.A. 11164 at l. 11 to 11172 at l. 12; J.A. 11296 at l. 17 to 11297 at l. 3.

The record also demonstrated that many generic carvedilol sales occurred without the doctors'

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

knowledge at all. *See supra* § IV(A)(4). That is, even after Teva amended its label, doctors merely prescribed carvedilol, and it was pharmacies that dispensed generic carvedilol. *See* J.A. 10674 at l. 25 to 10675 at l. l. 9; J.A. 10678 at l. 2 to 10679 at l. 7.

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

V. CONCLUSION

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

Indeed, far from "speed[ing] the introduction of low cost generic drugs," this result discourages generics from entering the market in the first instance. Teva did everything right—using a skinny label, taking care not to encourage infringing uses—and yet, given today's result, it was ultimately more costly for Teva to sell an unpatented drug for unpatented uses than

it would have been to stay out of the market altogether: Teva only sold $74 million worth of carvedilol during the allegedly infringing period (mostly for unpatented uses) but now owes $234 million in damages for sales made for a single indication. This irony reflects the fact that Teva's product was dramatically less expensive—costing less than 4 cents per pill as compared with Coreg®'s price of at least $1.50 per pill.

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

For these reasons, I respectfully dissent.

APPENDIX C

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

GLAXOSMITHKLINE LLC and SMITHKLINE BEECHAM (CORK) LIMITED,	:	
Plaintiffs,	:	C.A. No. 14-878-LPS-CJB
v.	:	
TEVA PHARMACEUTICALS USA, INC.,	:	
Defendant.	:	

ORDER

At Wilmington, this **28th** day of **March, 2018**:

For the reasons set forth in the Memorandum Opinion issued this date,

IT IS HEREBY ORDERED that:

1. Teva's motion for judgment as a matter of law, or in the alternative for a new trial (D.I. 464), is GRANTED IN PART and DENIED IN PART.

2. GSK's motion for enhanced damages, attorney fees, and interest (D.I. 466) is DENIED AS MOOT.

3. Teva's motion to strike (D.I. 474) is DENIED AS MOOT.

IT IS FURTHER ORDERED that the parties shall meet and confer and shall submit a joint status report, no later than April 2, 2018, advising the Court of any remaining order(s) it should enter in this case and how the case should now proceed.

Leonard P. Stark
UNITED STATES DISTRICT COURT

APPENDIX D

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

GLAXOSMITHKLINE LLC and SMITHKLINE BEECHAM (CORK) LIMITED, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	: : : : : : :	C.A. No. 14-878-LPS-CJB

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MEMORANDUM OPINION

March 28, 2018
Wilmington, DE

[signature]

STARK, U.S. District Judge:

Beginning on June 12, 2017, the Court held a seven-day jury trial in this patent infringement action (D.I. 457, 458, 459, 460, 461, 462, 463 (hereinafter, "Tr.")), resulting in a verdict of: (1) willful induced infringement of claims 1, 2, and 3 of U.S. Patent No. RE40,000 ("the '000 patent") by Defendant Teva Pharmaceuticals USA, Inc. ("Teva") during the "skinny label" (also referred to as "partial label" or "carve-out") period; (2) no induced infringement of claims 6, 7, 8, and 9 of the '000 patent by Teva during the skinny/partial label period; (3) willful induced infringement of all asserted claims (claims 1-3 and claims 6-9) of the '000 patent by Teva during the "full label" (also referred to as "amended label") period; (4) no invalidity of the '000 patent; and (5) an award to Plaintiffs GlaxoSmithKline and SmithKline Beecham (Cork) Ltd. ("GSK") of $234,110,000 in lost profits and $1,400,000 in reasonable royalty damages. (D.I. 448)

Pending before the Court are the parties' post-trial motions. Teva filed a renewed motion for judgment as a matter of law ("JMOL"), or in the alternative for a new trial, on five grounds: (1) no inducement of

infringement of any claims at any time—that is, during either the skinny label or full label periods—and no lost profits; (2) no inducement of any claims during the skinny label period; (3) no inducement of claims 6 and 7 during the full label period; (4) no willful infringement; and (5) invalidity. (D.I. 464)[1] GSK filed a motion for enhanced damages, attorney fees, and pre- and post-judgment interest. (D.I. 466) Finally, Teva has moved to strike multiple exhibits GSK submitted in support of its post-trial motion that Teva contends were not part of the trial record. (D.I. 474)

The Court heard oral argument on October 26, 2017. Having considered the parties' briefing (D.I. 465, 467, 471, 472, 475, 476, 477, 478, 479) and letters regarding supplemental authority (D.I. 483, 485, 486, 487), and for the reasons discussed below, the Court will grant in part and deny in part Teva's JMOL motion (D.I. 464), and deny as moot both GSK's motion (D.I. 466) and Teva's motion to strike (D.I. 474).[2]

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[1] During oral argument on the pending motions, Teva also argued that if the Court found liability, the proper remedy was a remittitur of damages to a figure not to exceed $1.4 million for a reasonable royalty, rather than a new trial on damages which would, in Teva's view, be futile. (D.I. 484 (hereinafter, "Hr'g Tr.") at 27-28)

[2] On July 27, 2017, the Court advised the parties of its inclinations (D.I. 456) concerning the issues the parties indicated they intended to raise (D.I. 455) in their post-trial motions. The Court's ruling today in favor of Teva on the key issue of GSK's liability for induced infringement is different than the previously-announced inclinations. (*See* D.I. 456 at 2 ("I am inclined to disagree with Teva that no reasonable juror could have concluded that Teva's actions induced even a single physician to administer Teva's carvedilol to a patient for use in an infringing manner."); *but see also generally id.* at 3 ("I conclude by

I. BACKGROUND

Congestive heart failure ("CHF") is a chronic condition that occurs when a diseased heart is unable to deliver sufficient oxygenated blood to the rest of the body. (*See generally* '000 patent; Lukas Tr. at 359-60[3]) CHF affects over five million people in the United States, and half of those who develop CFIF will die within five years of diagnosis. Prior to 1997, CHF treatment included limitation of physical activity, restriction of salt intake, and the use of a diuretic—a drug that decreases excess fluid—and digoxin—a drug that stabilizes heart rhythm. (*See* '000 patent; Lukas Tr. at 361) Angiotensin converting enzyme ("ACE") inhibitors were also prescribed in conjunction with a diuretic, digoxin, or both. (*See* '000 patent) While ACE inhibitors caused an improvement in CHF mortality rates, doctors were still looking for other solutions. (Lukas Tr. at 362)

In the late 1980s, GSK and its research partner, Boehringer Mannheim GmbH, began researching the possibility of using carvedilol to treat CHF. (Ruffalo Tr. at 1271-72) Carvedilol belongs to a class of chemical compounds known as beta-blockers, which are drugs used to treat high blood pressure or hypertension. In the early 1990s, beta-blockers, which slow the

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emphasizing that the views expressed in this letter do not constitute an order but are merely my present inclinations, based principally on my recollection of the trial and the parties' limited post-trial submissions. I will only be able to make final decisions after receiving the forthcoming briefing and conducting oral argument."))

[3] Citations to the trial transcript are in the format: "[Witness name] Tr. at [page number]."

heart rate and depress the heart's contractility—that is, its ability to pump—were clinically contraindicated for CHF, as CHF patients are critically dependent on how well their heart pumps. (*See* Lukas Tr. at 357-58) Treating high blood pressure with beta-blockers worsened a patient's heart failure due to the beta-blocker's depressive effect on the heart's pumping function. (*See id.*)

GSK's research led to unexpected results showing that "the patients who were receiving carvedilol were staying alive whereas the patients on placebo were the ones who were dying." (*Id.* at 364-67, 370-72; PTX-879) These results prompted GSK to file New Drug Application ("NDA") No. 20-297 with the U.S. Food and Drug Administration ("FDA"), seeking approval of carvedilol in combination with ACE inhibitors, diuretics, or digoxin to reduce the risk of mortality caused by heart failure, as well as an application for a patent on a method of using carvedilol to decrease the risk of mortality caused by CHF. (Lukas Tr. at 373, 379-81; PTX-229) In May 1997, the FDA approved carvedilol as the first beta-blocker for the treatment of CHF, leading to GSK's launch of Coreg®, the brand name of its carvedilol tablets. (Lukas Tr. at 377) The patent issued in June 1998 as U.S. Patent No. 5,760,069 (the "'069 patent"), entitled "Method of Treatment for Decreasing Mortality Resulting from Congestive Heart Failure."

GSK ultimately received approval from the FDA to market Coreg® for three indications: (1) hypertension; (2) mild-to-severe CHF; and (3) left ventricular dysfunction ("LVD") following myocardial infarction (heart attack) in clinically stable patients ("Post-MI LVD"). (*See* Lukas Tr. at 382-83) Despite receiving

FDA approval for three indications, GSK only marketed Coreg® in the United States for the CHF indication. The FDA published the '069 patent in the Orange Book[4] with use code U-233, "decreasing mortality caused by congestive heart failure." (*See* Pastore Tr. at 889)

GSK undertook further patent prosecution efforts, including to correct certain errors in the '069 patent. Consequently, on January 8, 2008, the '069 patent reissued as the '000 patent. (*See* Lukas Tr. at 373-74, 405, 409-10) Claim 1 of the '000 patent, the only independent claim, recites:

> 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.*

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[4] The Orange Book is the name commonly used to refer to the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations.* It includes a listing of approved drug products and, among other things, information about the patents that cover each drug product. *See Intendis GmbH v. Glenmark Pharm. Inc., USA,* 822 F.3d 1355, 1359 (Fed. Cir. 2016); *see also* 21 U.S.C. § 355(b)(1); 21 C.F.R. §§314.3,314.53.

(emphasis in original) After issuance of the '000 patent, the '069 patent was de-listed from the Orange Book, and the '000 patent was listed with the same use code, i.e., U-233, "decreasing mortality caused by congestive heart failure." (Karst Tr. at 1042)

Meanwhile, back in March 2002, Teva had filed with the FDA Abbreviated New Drug Application ("ANDA") No. 76-373, seeking permission to market generic carvedilol tablets. (*See* Pastore Tr. at 442-43) Teva initially submitted a paragraph IV certification asserting that the '069 patent was invalid and requesting that its ANDA not be given final approval until a second Orange Book listed patent (one which covered the carvedilol compound) expired in March 2007.[5] Then, however, in August 2007, Teva sought FDA approval of its ANDA pursuant to 21 U.S.C. § 355(j)(2)(A)(viii)—a "section viii carve out"—so that it could label its generic carvedilol tablets as indicated only for uses not covered by GSK's '000 patent: that is, for treatment of hypertension and post-MI LVD. (*See* Pastore Tr. at 456-57; Lietzan Tr. at 534-37) At this point, since the '000 patent only claimed a method of using carvedilol for treatment of mild to severe CHF, Teva's position was that its "skinny label" generic product would not run afoul of the '000 patent because Teva's product would not be approved—or labeled as being approved—for the infringing use of treatment of CHF.

In 2007, with the expiration of the '067 patent, GSK's period of exclusivity with respect to carvedilol ended and generic carvedilol entered the market.

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[5] U.S. Patent No. 4,503,067 (the "'067 patent"), not at issue here, covers the carvedilol compound.

Fourteen companies marketed generic carvedilol, including Teva. (*See* Zusman Tr. at 1164; *see also* Pastore Tr. at 897-98; Hofmann Tr. at 1533) Specifically, on September 5, 2007, Teva received FDA approval of its generic tablets and launched its drug product with the carved out/skinny label—that is, excluding the CHF indication. (*See* Pastore Tr. at 461)

In April 2011, the FDA sent Teva a letter in response to the de-listing of certain GSK patents from the Orange Book, instructing Teva to "revise [its] labeling to include the information associated with [the de-listed] patent." (*Id.* at 461-63; PTX-15) One of the patents that had been de-listed was GSK's '069 patent, which had been reissued in 2008 as the '000 patent. (*See* PTX-15; Lukas Tr. at 352-53) Teva, therefore, amended its label in 2011 to be essentially a copy of GSK's full label, thereby covering all three indications: hypertension, CHF, and post-MI LVD. (Pastore Tr. at 461-65) The '000 patent expired on June 7, 2015, the date the '069 patent was originally set to expire.

The following table is helpful for understanding the principal issues that were in dispute at trial and are again presented by the pending motions.

Indications Implicated at Various Points

Indication	GSK's '000 patent	GSK's FDA Approval	GSK's Marketing of Coreg®	GSK's Orange Book Listing	Teva's Skinny a.k.a. Partial a.k.a. Carve-Out Label (Jan. 2008 - April 2011)	Teva's Full a.k.a. Amended Label (May 2011 - June 2015)
hypertension	No	Yes	No	No	Yes	Yes
mild/severe CHF	Yes	Yes	Yes	Yes (U-233)	No	Yes
post-MI LVD	No	Yes	No	No	Yes	Yes

As shown, GSK's patent-in-suit only claims a method of using carvedilol for the treatment of mild to severe CHF. (PTX-1; *see* Lukas Tr. at 352-54) Although GSK obtained FDA approval to market carvedilol as safe and effective also for the treatment of hypertension and post-MI LVD, it did not have patent protection on such uses, and it has never marketed its branded drug, Coreg®, to be used to treat anything other than CHF. (*See* Lukas Tr. at 350-52) The Orange Book listing for the '000 patent refers only to CHF, and not also to hypertension or post-MI LVD. (*See* Karst Tr. at 1040-44; Pastore Tr. at 888-90; Lietzan Tr. at 527-29, 566-67) When Teva initially launched and sold its generic carvedilol, during the skinny label period of January 2008 through April 2011, its label identified as approved indications only hypertension and post-MI LVD. (*See* Karst Tr. at

1027-28) It was not until the full label period, May 2011 through the expiration of the '000 patent in June 2015, that Teva's label also included the previously-patented method of use—treatment of CHF—as an approved indication for Teva's generic product. (*See* Pastore Tr. at 461-62; Zusman Tr. at 1229)

II. LEGAL STANDARDS

A. Judgment as a Matter of Law

Judgment as a matter of law is appropriate if "the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for [a] party" on an issue. Fed. R. Civ. P. 50(a)(1). "Entry of judgment as a matter of law is a sparingly invoked remedy," one "granted 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) (internal quotation marks omitted).

To prevail on a renewed motion for judgment as a matter of law following a jury trial, the moving party "must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusions implied [by] the jury's verdict cannot in law be supported by those findings." *Pannu* v. *Iolab Corp.,* 155 F.3d 1344, 1348 (Fed. Cir. 1998) (internal quotation marks omitted). "'Substantial' evidence is such relevant evidence from the record taken as a whole as might be accepted by a reasonable mind as adequate to support the finding under review." *Perkin-Elmer Corp.* v. *Computervision Corp.,* 732 F.2d 888, 893 (Fed. Cir. 1984).

In assessing the sufficiency of the evidence, the Court must give the non-moving party, "as [the] 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." *Williamson v. Consol. Rail Corp.,* 926 F.2d 1344, 1348 (3d Cir. 1991); *see also Perkin-Elmer Corp.,* 732 F.2d at 893. The Court may not assess the credibility of witnesses nor "substitute its choice for that of the jury between conflicting elements of the evidence." *Perkin-Elmer Corp.,* 732 F.2d at 893. Rather, the Court must determine whether the evidence reasonably supports the jury's verdict. *See Dawn Equip. Co. v. Ky. Farms Inc.,* 140 F.3d 1009, 1014 (Fed. Cir. 1998); *Gomez v. Allegheny Health Servs. Inc.,* 71 F.3d 1079, 1083 (3d Cir. 1995) (describing standard as "whether there is evidence upon which a reasonable jury could properly have found its verdict"); 9B Charles Alan Wright, Arthur R. Miller & Edward H. Cooper, Federal Practice & Procedure § 2524 (3d ed. 2008) ("The question is not whether there is literally no evidence supporting the party against whom the motion is directed but whether there is evidence upon which the jury properly could find a verdict for that party.").

B. New Trial

Federal Rule of Civil Procedure 59(a) provides in pertinent part, "[t]he court may, on motion, grant a new trial on all or some of the issues—and to any party—as follows: … after a jury trial, for any reason for which a new trial has heretofore been granted in an action at law in federal court." New trials are commonly granted where "the jury's verdict is against the

clear weight of the evidence, and a new trial must be granted to prevent a miscarriage of justice," where "newly-discovered evidence exists that would likely alter the outcome of the trial," where "improper conduct by an attorney or the court unfairly influenced the verdict," or where the jury's verdict was "facially inconsistent." *Zarow-Smith v. N.J. Transit Rail Operations,* 953 F. Supp. 581, 584-85 (D. N.J. 1997) (internal citations omitted).

The decision to grant or deny a new trial is committed to the sound discretion of the district court. *See Allied Chem. Corp.* v. *Daiflon, Inc.,* 449 U.S. 33, 36 (1980); *Olefins Trading, Inc. v. Han Yang Chem Corp.,* 9 F.3d 282, 289 (3d Cir. 1993) (reviewing "district court's grant or denial of a new trial motion" under "abuse of discretion" standard). Although the standard for granting a new trial is less rigorous than the standard for granting judgment as a matter of law, in that the Court need not view the evidence in the light most favorable to the verdict winner, ordinarily a new trial should only be granted "where a miscarriage of justice would result if the verdict were to stand," the verdict "cries out to be overturned," or the verdict "shocks [the] conscience." *Williamson,* 926 F.2d at 1352-53.

III. DISCUSSION

A. The Jury Could Not Reasonably Find that Teva Caused Doctors to Infringe

The jury found that Teva induced infringement of claims 1, 2, and 3 of the '000 patent during the skinny label period and of claims 1-3 and 6-9 during the full label period. (D.I. 448 at 2-3) Teva moves for JMOL of no inducement or no lost profits damages on the basis

that the jury could not reasonably have found that Teva caused doctors to infringe these claims of GSK's patent during the respective periods.[6] (D.I. 465 at 4) Having reviewed the record under the appropriate standard, including by drawing all reasonable inferences in favor of GSK as the verdict winner, the Court concludes that substantial evidence does not support the jury's findings on inducement in either the skinny or full label period. Therefore, the Court will grant this portion of Teva's JMOL motion.

To prove inducement, GSK was required to prove by a preponderance of the evidence that, among other things, "Teva's alleged inducement, ***as opposed to other factors,*** actually ***caused*** the physicians to directly infringe." (D.I. 440 at 26) (emphasis added) The jury was instructed that "Teva cannot be liable for induced infringement where GSK does not show that Teva successfully communicated with and induced a third-party direct infringer ***and that the communication was the cause of the direct infringement by the third-party infringer.***" (*Id.* at 31) (emphasis added) Thus, the Court must now evaluate whether substantial evidence supports the jury's finding that Teva did cause the alleged infringement.[7]

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[6] Teva requested a new trial as an alternative to JMOL, but explained that if the Court agreed there is a lack of evidence of inducement, a new trial would be futile. (*See* D.I. 465 at 10 n.3 ("[W]hile Teva requests a new trial under Rule 59 as an alternative remedy, that trial would inevitably result in a similar failure of proof."); *see also* Hr'g Tr. at 28) The Court agrees with Teva that, given the conclusions announced here, a new trial would be futile.

[7] As an alternative basis for JMOL of no inducement, Teva contends that GSK failed to "offer any evidence that any doctor—

Teva contends that the substantial uncontroverted evidence presented at trial showed that alternative factors caused doctors to infringe GSK's patent. Teva thus asserts that a reasonable jury could not conclude that even a single doctor—let alone the entire class of infringing doctors—was induced to infringe based on ***Teva's*** actions. Moreover, because GSK only asserted a "class" theory of liability—that is, that Teva induced doctors as a class to infringe—and failed to prove that theory, Teva's view is that GSK cannot now have the verdict upheld on an alternative theory of liability (i.e., the theory' that "at least one" doctor was induced to infringe by Teva's actions). (*See* D.I. 465 at 1-2)

GSK responds that the jury's verdict should be sustained because GSK presented "ample evidence," including Teva's label and marketing materials, "from which [the jury] could infer Teva actually caused physicians to directly infringe." (D.I. 472 at 6) (internal quotation marks omitted) GSK argues that "JMOL of no inducement is only appropriate where the plaintiff fails to present sufficient evidence of even one act of direct infringement." (*Id.* at 9; *see also* Hr'g Tr. at 52 ("[T]he law doesn't require us to prove [inducement of the entire class]. What the law requires us to prove is just one of the class."); *id.* at 57 ("All we needed was circumstantial evidence of one doctor …."); *see generally* D.I. 440 at 4.2.1 (instructing jury: "Proof of direct

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let alone ***all*** doctors—administer carvedilol with the specific intent to decrease mortality instead of to treat symptoms or for other purposes." (D.I. 465 at 9) Without proving such intent, Teva argues, there can be no direct infringement, and accordingly, no inducement. (*Id.* at 8-9) Because the Court finds GSK failed to prove the causation element, it need not address this argument.

infringement may be based on circumstantial evidence.")) GSK contends that it provided substantial evidence through the testimony of its expert, Dr. Peter McCullough, permitting a reasonable factfinder to find that at least one doctor was induced to prescribe generic carvedilol by Teva's actions. (*Id.* at 71-72)

The Court agrees with Teva that neither sufficient nor substantial evidence supports the jury's finding of inducement. GSK failed to prove by a preponderance of the evidence that "***Teva's*** alleged inducement, as opposed to other factors, actually ***caused*** the physicians [i.e., as a class or even at least one of them] to directly infringe," by prescribing generic carvedilol and to do so for the treatment of mild to severe CHF. (D.I. 440 at 26, 31) (jury instruction; emphasis added) Without proof of causation, which is an essential element of GSK's action, a finding of inducement cannot stand.[8]

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[8] The parties dispute whether the "class" theory and the "at least one" theory are really two separate theories and, if so, which theory GSK was required to prove. (Hr'g Tr. at 14-15, 24-26, 52) While Teva argues that the Federal Circuit clearly outlined two separate theories for proving induced infringement, *see Dynacore Holdings Corp. v. U.S. Philips Corp.,* 363 F.3d 1263, 1274 (Fed. Cir. 2004); *see also* Hr'g Tr. at 14-15, GSK maintains that the two theories "are actually one and the same" (Hr'g Tr. at 78, 52). The Court agrees with Teva that the two theories are distinct from one another. *See Dynacore,* 363 F.3d at 1274-75 ("Plaintiffs who identify ***individual*** acts of direct infringement must restrict their theories of vicarious liability—and tie their claims for damages or injunctive relief—to the ***identified*** act. Plaintiffs who identify an entire category of infringers (e.g., the defendant's customers) may cast their theories of vicarious liability more broadly, and may consequently seek damages or injunctions across the entire category.") (internal citations omitted); *see also Pharmastem Therapeutics, Inc. v. Viacell, Inc.,* 2004

GSK insists that Dr. McCullough identified himself as at least one doctor who was induced to prescribe generic carvedilol to a patient for the treatment of mild to severe CHF due to Teva's actions (or inactions), including Teva's label. (*See* Hr'g. Tr. at 52-53 (discussing GSK slide 4); *id.* at 69-72 (discussing GSK slides 32-33)) But the portion of Dr. McCullough's testimony to which GSK points (*see* McCullough Tr. at 631, 1659-63) does not show Dr. McCullough stating what GSK seems to think he said. Dr. McCullough merely said, in a conclusory manner, that Teva's labels (partial and full) "'meet each and every limitation of claim 1" and a doctor performing the method of the claim would be the direct infringer. (*See id.* at 631) But even if the label were enough in a post-launch world, Dr. McCullough specifically stated that he did not read Teva's label prior to administering generic carvedilol, but "just assume[d] they were the same" based on the information the generic company provided. (*See id.* at 1659-63) As Dr. McCullough concedes that he did not read Teva's label, he cannot state, for instance, that he noticed or otherwise knew what (if anything) that label said about using carvedilol to treat CHF. Moreover, Dr. McCullough testified that he relied on various other sources, none of which are attributable to Teva, in deciding to prescribe carvedilol, both before and after generics entered the

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WL 2898061, at *3 (D. Del. Dec. 14, 2004) (requiring plaintiffs to "adduce evidence that 100% of the defendants' ... units [infringed]" after plaintiffs' position at trial was that "all" of defendants' units infringed). The Court need not decide which theory GSK was required to prove as, under either theory, GSK failed to prove causation.

market. (*See* McCullough Tr. at 666-69, 676-78) GSK, therefore, has not met its burden to show inducement.

Below, the Court describes with more particularity its conclusion with respect to first the skinny label period and then the full label period.

1. The Skinny Label Period

The skinny label period, January 8, 2008 through April 30, 2011, is the period during which Teva's label carved out the CHF indication pursuant to 21 U.S.C. § 355(j)(2)(A)(viii) ("section viii"). The Court agrees with Teva that the record lacks substantial evidence that Teva's skinny label, in combination with other acts Teva took (or refrained from taking) during this period, caused of any physician's direct infringement. (*See* D.I. 465 at 13-25) Instead, as Teva argues, the record conclusively demonstrated—and a reasonable jury could only have found—that any infringing use by any physician during the skinny label period was caused by factors unrelated to Teva.

The unrebutted evidence presented at trial showed that Teva's skinny label omitted from its label the language contained on GSK's Coreg® label concerning the use of carvedilol to treat CHF. (*See* Lietzan Tr. at 539, 541; Zusman Tr. at 1190-91) It is further undisputed that Teva's generic carvedilol, during the skinny label period, was not approved for treatment of CHF, making such use an "off-label" use. Moreover, GSK's expert, Dr. McCullough, conceded that he would not prescribe generic carvedilol for CHF if it was not an approved use on the label. (*See* McCullough Tr. at 1660-61) The Court may, indeed must, consider unrebutted evidence presented at trial that supports the moving party on JMOL, in

evaluating whether the jury had substantial evidence to support a reasonable finding against the moving party. *See Integra Lifesciences I, Ltd. v. Merck KGaA*, 496 F.3d 1334, 1345 (Fed. Cir. 2007) ("The rule that a jury verdict is reviewed for support by 'substantial evidence' does not mean that the reviewing court must ignore the evidence that does not support the verdict…. [T]he court should give credence to the evidence favoring the nonmovant as well as that evidence supporting the moving party that is uncontradicted and unimpeached.") (internal quotation marks omitted).

Teva's skinny label did not instruct doctors to prescribe generic carvedilol for an off-label use, i.e., treatment of CHF. *See Warner-Lambert* v. *Apotex Corp.,* 316 F.3d 1348, 1364-65 (Fed. Cir. 2003) ("[T]he request to make and sell a drug labeled with a permissible (non-infringing) use cannot reasonably be interpreted as an act of infringement (induced or otherwise) with respect to a patent on an unapproved use, as the ANDA does not induce anyone to perform the unapproved acts required to infringe."). Similarly, Teva's skinny label identified the approved indications as being hypertension and post-MI LVD, which were not covered by GSK's patent, and which cannot be considered infringing uses. *See id.*[9]

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[9] GSK contends that certain post-MI LVD language in Teva's skinny label provides instructions for "treating heart failure patients" and that "patients with post-MI LVD … suffer from an early stage of heart failure." (D.I. 472 at 14; *see also* PTX-1080.0003 (Teva skinny label: "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

While GSK's evidence of inducement during the skinny label period consisted principally of Teva's label (and testimony about it), GSK did present other evidence. In seeking to prove inducement, GSK relied on Teva's "AB rating" as well as Teva's 2008 and 2009 product catalogs and Teva's October 2009 Generic Product Reference Guide. (PTX-1208; PTX-1212; PTX-1226) These marketing materials trumpeted Teva's AB rating, without expressly stating that Teva's generic carvedilol was not approved for treatment of CHF. In the Court's view, even the totality of this evidence, taken in the light most favorable to GSK, and drawing all reasonable inferences in favor

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symptomatic heart failure)….")) To GSK, this language on Teva's label "encourages doctors to use carvedilol to reduce the risk of death from symptomatic congestive heart failure, as required by the claims." (D.I. 472 at 14) The Court disagrees. While 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. (*See* Zusman Tr. at 1183-84 (explaining difference between post-Mi LVD patients and CHF patients); *see also* Shusterman Tr. at 1522-23 (explaining that studies for each indication involved "[f]undamentally different patient group[s]" and "[f]undamentally different physiology going on in those two periods of time"); McCullough Tr. at 605-06 (differentiating post-MI LVD patients from CHF patients); *id.* at 682 (admitting that post-MI LVD is broader than CHF, as not all post-MI LVD patients suffer from CHF)) To infringe the '000 patent, carvedilol must have been prescribed to treat the risk of mortality ***caused by CHF***. Accordingly, a reasonable juror could not have found that Teva's inclusion of post-MI LVD language in its skinny label caused or even encouraged direct infringement of the '000 patent's claimed method of use of treating CHF.

of GSK, cannot support a reasonable finding that Teva caused any infringement of GSK's '000 patent.

The jury was instructed that "[t]he fact that Teva obtained an AB rating for its generic product is not by itself a sufficient basis to find that Teva had an intent to infringe." (D.I. 440 at 29) GSK argues that Teva did something more than "obtain[] an AB rating;" Teva also listed and marketed Teva's generic carvedilol as AB rated ***to Coreg®***, without specifying that Teva's generic carvedilol—unlike GSK's Coreg®—was ***not*** approved for the CHF indication. (*See* D.I. 472 at 5, 15) But this fact does not support a reasonable finding that Teva caused infringement. As both parties showed at trial, being AB rated signifies that a generic drug is therapeutically equivalent to a branded drug. (*See* Lietzan Tr. at 542; Karst Tr. at 1031-32) The undisputed evidence demonstrates that a generic drug cannot be listed as "AB rated" generally, as "AB rated" is a relative term; it necessarily requires a comparison between the generic drug and some branded reference drug. (*See* Lietzan Tr. at 534; *see also* Karst Tr. at 1031-32)

In addition, as GSK conceded, there is no FDA requirement that a generic drug company specify for which uses it is (or is not) AB rated. (*See* Lietzan at 577-78) Nor had either party's experts ever seen such a clarifying statement in any press release or product catalog. (*See* Lietzan Tr. at 548-49, 577-78; Karst Tr. at 1030).[10] The Orange Book states that therapeutic

[10] Teva contends that "GSK seeks to impose on Teva (and the entire industry) an affirmative duty to correct the incorrect ***assumption*** that doctors purportedly make by misunderstanding the FDA's AB-rating designation, or risk being held liable for ***all***

equivalent determinations are not made for unapproved off-label indications. (*See* DTX-2171; Karst Tr. at 1035) GSK's expert, Professor Erika Lietzan, acknowledged that "the meaning of therapeutically equivalent of AB rating is if the generic drug is used ***in accordance with its label,*** you would expect it to have the same clinical effect in a person as if that person had taken the brand drug." (Lietzan Tr. at 534 (emphasis added); *see also id.* at 542 ("AB rating means ... if a patient took the generic carvedilol for one of the uses in its label, you would expect it to have the same clinical effect as if the patient is taking Coreg.")) Teva's skinny label, as addressed above, omitted substantial information regarding the CHF indication and, instead, stated that the product was approved for hypertension and post-MI LVD indications. Accordingly, there is not legally sufficient evidence to support a finding that Teva, by listing its carvedilol as AB rated to Coreg® in product catalogs and reference guides, encouraged infringement.

Additionally, a reasonable juror would had to have found, based on the record presented at trial, that in

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conduct of the doctors." (D.I. 465 at 2-3) This is not the only unprecedented "duty" GSK seeks to impose. GSK also asks that this case make clear that when a generic adds an indication to its label by eliminating a previous carve-out it must send the branded company a new paragraph IV notice (*see* Hr g Tr. at 120; Tr. at 1840-41 (GSK closing argument)), and provide "disclaimers clarifying its product was not approved for heart failure" (*see, e.g.,* D.I. 472 at 15). GSK points to no authority to support the obligations it would have the Court create, duties which appear to be inconsistent with governing law. *See generally Warner-Lambert,* 316 F.3d at 1365 ("[I]ntent to induce infringement cannot be inferred even when the defendant has actual knowledge that some users of its product may be infringing the patent.").

July 2007, prior to the launch of generic carvedilol (including by Teva), doctors deciding to write a prescription for carvedilol relied on various sources ***other than Teva's label and marketing materials***. In addition to the knowledge and experience that ordinarily skilled cardiologists had acquired by July 2007 about the benefits of treatment with carvedilol, such doctors had access to American Heart Association and American College of Cardiology guidelines, carvedilol research studies published in the *New England Journal of Medicine, The Lancet,* and the *British Heart Journal,* GSK's own Coreg® label and product insert, and GSK's extensive promotional activity—totaling nearly $1 billion (*See* Vojir Tr. at 508-09)—which included sending doctors to hospitals, giving seminars, and detailing, marketing, and advertising Coreg®. (*See* D.I. 465 at 7-8; Vojir Tr. at 497-511; McCullough Tr. at 666-69, 676-77; Zusman Tr. at 1151, 1164-65; PTX-78; DTX-2655.4; PTX-534)

Further, Teva showed that once generic carvedilol entered the market in September 2007, and continuing beyond 2007, doctors continued prescribing carvedilol (be it Coreg® or a generic) in the same manner as they had prior to the generics' entrance, as they based their prescription decisions on the various factors addressed above without relying on Teva's—or any other generic manufacturers'—label. (*See* McCullough Tr. at 677-78) GSK's expert, Dr. McCullough, testified that he had not read Teva's generic label before he started writing prescriptions for carvedilol. (*See id.* at 1662-63).[11] As GSK concedes,

[11] The specific testimony was as follows:

prior to the generics' entrance into the market in 2007, physicians already knew how to use carvedilol for treating CHF. (Hr'g Tr. at 85-86) Three cardiologists testified at trial—GSK's expert, Dr. McCullough, and Teva's experts, Drs. Zusman and Rosendorff—and all three agreed that even in September 2007, when generic companies (including Teva) began selling carvedilol, doctors relied on guidelines and research, as well as their own experience, in addition to GSK marketing. (*See* McCullough Tr. at 676-79; Zusman Tr. at 1164-72, 1176-77; Rosendorff Tr. at 1296-97) None viewed generic labeling, including Teva's label, as impacting prescribing behavior. (*See id.*).[12] In

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Q. Now, before you started administering generic carvedilol to your patients, whether you wrote it as Coreg or not, did you read Teva's generic label?

A. No, I didn't.

Q. Why not?

A. I just assume they were the same.

The Court also agrees with Teva that Dr. McCullough failed to acknowledge the causation requirement of an inducement claim. (*See, e.g.,* D.I. 477 at 3) (citing, e.g., McCullough Tr. at 614-17)

[12] The only "exception" to this is Dr. Randall Zusman's testimony regarding the hypothetical scenario of what might be called an "unfrozen caveman cardiologist" (*see also Saturday Night Live: Unfrozen Caveman Lawyer* (NBC television broadcast 1991-96))—that is, "someone who is inexperienced, somehow has missed all of this education during the course of the their training, now they are going to treat a patient with heart failure, and they somehow came upon Teva's skinny label." (Zusman Tr. at 1153-54) Even such a doctor (who would not have been a person of ordinary skill in the art at any pertinent date) "would immediately see that the [CHF] indication is not included" on Teva's skinny label and would then have turned to various non-

this context, there was no reasonable basis for the jury to have found that anything Teva did—including selling generic carvedilol, giving it a "skinny label," and all aspects of how Teva marketed its carvedilol—caused even a single doctor to prescribe carvedilol for the treatment of CHF.

Teva's uncontroverted evidence of alternative factors that caused physicians to prescribe carvedilol in an infringing manner cannot be ignored. *See Integra,* 496 F.3d at 1345 ("The rule that a jury verdict is reviewed for support by 'substantial evidence' does not mean that the reviewing court must ignore the evidence that does not support the verdict…. [T]he court should give credence to the evidence favoring the nonmovant as well as that evidence supporting the moving party that is uncontradicted and unimpeached.") (internal quotation marks omitted).

As Teva correctly notes, no direct evidence was presented at trial that any doctor was ever induced to infringe the '000 patent by Teva's label (either skinny or full). There was no direct evidence that Teva's label caused even a single doctor to prescribe generic carvedilol to a patient to treat mild to severe CHF. Hence, in order to uphold the verdict, the Court must find in the record substantial evidence to render it reasonable for the jury to have inferred that at least one doctor was so induced. GSK, as the verdict winner, is entitled to the benefit of all reasonable inferences that may be drawn from the evidence presented to the jury. The Court's determination, however, is that—given the dearth of evidence that doctors read and

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Teva guidelines, textbooks, and research to gather information necessary to making a prescribing decision. (*See id.*)

understand and are affected by labels, and given the vast amount of evidence that doctors' decisions to prescribe carvedilol during the relevant periods were influenced by multiple non-Teva factors—such an inference was an unreasonable one for the jury to have drawn. *See McAnally* v. *Gildersleeve,* 16 F.3d 1394, 1500 (8th Cir. 1994) ("[Courts] cannot accord the jury with the benefit of unreasonable inferences, or those at war with the undisputed facts.") (internal quotation marks omitted).[13]

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[13] In reaching this conclusion, the Court is applying the same legal standards on which it instructed the jury, including its instructions on "Induced Infringement" and "Inducement Must Cause Direct Infringement." (D.I. 440 at 4.2 (listing each element GSK must prove to show inducement, including "that Teva's alleged inducement, as opposed to other factors, actually caused the physicians to directly infringe"); *id.* at 4.2.4 ("Teva cannot be liable for induced infringement where GSK does not show that Teva successfully communicated with and induced a third-party direct infringer and that the communication was the cause of the direct infringement by the third-party infringer…. GSK is not required to present hard proof of any direct infringer physician stating, for example, that she read Teva's labels or other Teva materials and that these labels or other Teva materials caused her to prescribe Teva's generic carvedilol in an infringing manner. GSK must prove that Teva's actions led physicians to directly infringe a claim of the '000 patent, but GSK may do so with circumstantial—as opposed to direct—evidence."))

The Court recognizes that these are not the instructions GSK proposed. (*See generally* D.I. 431 at 27-29) GSK, while not waiving any objections, has not renewed its objections nor raised any argument that the Court should, in evaluating Teva's JMOL motion, apply a standard different than the one on which it instructed the jury. (*See generally* Tr. at 1414-15, 1430-32) Teva contends that the jury instructions were correct and emphasizes that GSK has not contended the Court should not apply them to the motion. (*See* Hr'g Tr. at 6 ("The jury instructions correctly set

GSK suggests that the Court cannot (or at least should not) grant Teva's JMOL because it denied Teva's motion for summary judgment. (*See, e.g.,* D.I. 472 at 2) ("Teva's JMOL request should be denied because it repeats the same arguments the Court has rejected before trial, wrongly argues that GSK's evidence is insufficient even though the Court already concluded it could support a jury verdict, asks the Court to substitute its judgment for the jury's on disputed facts, and ignores the jury charge.") The Court disagrees. In connection with adopting Magistrate Judge Burke's recommendation to deny Teva's motion for summary judgment of noninfringement, the Court wrote:

> Defendants may prevail at trial based on their view that GSK's "long chain of inferences" does not establish causation. But that is a matter for the jury to decide after hearing the conflicting

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out the law…. And we, we think, to be clear, that the instructions are correct. But we think that GSK hadn't argued specifically that you should apply a different standard."))

Therefore, the Court perceives no basis to conclude that its instructions were incorrect and, for purposes of Teva's JMOL motion, the Court has applied the standards it provided in its jury instructions. (*See also* D.I. 411 at 3-5 (holding that in post-launch context, patentee must prove actual inducement); Tr. at 1414 (GSK counsel conceding, in context of post-launch inducement, "the law is and … the [C]ourt's rulings have shown there [are] causation requirements"); *see generally Markman v. Westview Instruments, Inc.,* 52 F.3d 967, 975 (Fed. Cir. 1995) ("While the jury's factual findings receive substantial deference on motion for JMOL, the legal standards that the jury applies, expressly or implicitly, in reaching its verdict are considered by the district court and by the appellate court de novo to determine whether those standards are correct as a matter of law."))

> evidence (e.g., what the label instructs versus whether anyone read it, how Teva marketed its generic product versus whether cardiologists already knew to use carvedilol before GSK even obtained its patent, etc.) to be presented by both sides. The Court does not find, on the record before it, that "GSK's proposed inferences [are] unreasonable."

(D.I. 411 at 5) (internal citations omitted) After reviewing the entirety of the record GSK actually created at trial, as well as the unrebutted trial evidence presented by Teva, the Court now concludes (as it is free to do, notwithstanding the assessment it made prior to trial), that the inference of causation that GSK asks be drawn is not reasonable, as it is not supported by substantial evidence in the trial record.

Considering the record as a whole, substantial evidence does not support a finding by a reasonable fact-finder that even at least one doctor was induced to prescribe generic carvedilol to be used in an infringing manner due to ***Teva's*** actions, as opposed to the various other factors supported in the record, during the skinny label period.[14] Therefore, the Court cannot

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[14] Following oral argument, the parties notified the Court on several occasions of subsequent authority they believe is pertinent to the issues pending before the Court. (*See* D.I. 483, 485, 486, 487) The Court has considered these new cases, and they do not alter the outcome announced in this opinion.

For instance, GSK directs the Court to *Sanofi* v. *Watson Laboratories Inc.,* 875 F.3d 636, 646 (Fed. Cir. 2017), for the proposition that the marketing of a generic drug with labeling that encourages infringement can be viewed as causing infringement despite the fact that the innovator company published the results of clinical studies and promoted the patented use. (*See* D.I. 485

uphold the verdict of infringement with respect to the skinny label period.

2. The Full Label Period

The full label period, May 1,2011 through June 7, 2015, runs from when Teva amended its label to include the CHF indication until the '000 patent expired. In attempting to prove inducement during the full label period, GSK presented evidence of Teva's full label along with various other materials, including Teva's 2004 and 2007 press releases, Teva's 2011 product catalog, the 2012 and 2013 editions of Teva's Monthly Prescribing Reference ("MPR"), and Teva's AB rating (including as it was listed on Teva's

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at 2) That case does not persuade the Court to reach a different conclusion than described above. *Sanofi* involved the ordinary Hatch-Waxman framework, "where a claim of induced infringement is filed ***before*** the generic has launched its product, and necessarily, before the generic has even attempted to communicate with any direct infringer." (D.I. 411 at 3) (emphasis added) In those cases, as this Court held during earlier portions of this case, "the focus must be on intent, rather than actual inducement." (*Id.*) Here, by contrast, "GSK filed its case almost seven years after Defendants launched their generic carvedilol products into the market. Hence, GSK's inducement claims are not premised on a hypothetical, but instead must be supported by sufficient evidence as to what actually happened during the relevant time period." (*Id.* at 3-4) (internal citations and quotation marks omitted) This Court has decided that reliance on a label and speculation about what may occur in the future cannot substitute for actual evidence about what has actually occurred in the past when, as in this case, there has been a period of actual, past conduct that is pertinent to infringement. Additionally, unlike the label involved in *Sanofi,* Teva's skinny label expressly carved out the patented use from its label. Therefore, the skinny label here does not support the same sort of inducement inferences the court found present in *Sanofi.*

website). (*See* PTX-1297; PTX-1301; PTX-1165; PTX-1203; PTX-1205; PTX-0860; McCullough Tr. at 635-36)

As addressed above, however, Teva presented substantial, unrebutted evidence of multiple factors unrelated to Teva that actually caused doctors to infringe the '000 patent. A reasonable factfinder could only have found that these alternative, non-Teva factors were what caused the doctors to prescribe generic carvedilol for an infringing use. Regardless of Teva's actions after it amended its label in May of 2011, including its elimination of the carve-out from its label, physicians were already prescribing generic carvedilol to treat CHF at that time. No substantial evidence was presented at trial to support a finding that anything about doctors' behavior—either as a class, or even a single doctor—was induced to change by Teva's label, or by anything else Teva did (or failed to do).[15] GSK conceded that physicians' reasons for and methods of prescribing carvedilol did not change when generics entered the market. (*See* McCullough Tr. at 677-78) For all these reasons, a reasonable jury could not find that Teva caused any direct infringement and, therefore, Teva cannot be held liable for inducement of infringement.

In sum, substantial evidence does not support the jury's finding on causation, and therefore does not

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[15] In coming to this conclusion, the Court is not holding that a full label will never be sufficient to prove causation, only that, in the context of this specific case, confronting Teva's specific motion, Teva's full label (along with the other evidence presented at trial) is insufficient. (*See* Hr'g Tr. at 87) (GSK's counsel acknowledging that "this is such a fact specific case")

support its verdict that Teva is liable for induced infringement, during both the skinny and full label periods. The Court will grant Teva's JMOL. Without a finding of infringement, there is no liability, so Teva cannot be found to be a willful infringer and cannot be ordered to pay GSK any damages. Accordingly, the Court will grant Teva's JMOL motion on each of these grounds.[16]

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[16] Both sides of this case identify important policy questions they see as being implicated by their disputes. GSK contends that a finding in favor of Teva, absolving the generic from liability for a method of treatment claim, will cause "the entire Hatch-Waxman framework [to] come[] crashing down" because it will result in "every generic dragging their feet so as not to go to trial during the 30-month stay in the Hatch-Waxman cases and then launch at risk and they're home free," because the innovator branded company will necessarily already have educated the market to use the drug. (Hr'g Tr. at 86-87) This reality, it is argued, combined with the Court's determination that the branded company cannot rely exclusively on the generic's label when the generic has already begun marketing its product, create a formula for generics to insulate themselves from any possible liability for induced infringement. (*See id.; see also* D.I. 472 at 11 (warning that acceptance of Teva's view "creates an incentive for generic manufacturers to launch at risk, destroy the innovator's market, and then argue it was not liable because its label was not the 'sole cause' of the direct infringement"))

For its part, Teva asserts that "GSK is fundamentally trying to use this case to put the [Hatch-Waxman] system on trial." (Hr'g Tr. at 30) In particular, in Teva's view, upholding the jury's verdict and allowing GSK to collect enormous damages (well beyond Teva's carvedilol revenues, and orders of magnitude above its profits on the product (*see id.* at 47-48, 117)) would eviscerate the section viii carve-out, as there would be no way a generic could avoid inducing infringement even if all the infringement is based on an off-label use. (*See id.* at 31 (arguing carve-outs are "part of the statute," which was "designed to enable the sale of drugs for non-patented uses [that are addressed on the skinny

B. Substantial Evidence Supports the Jury's Finding of No Invalidity

Teva additionally seeks JMOL of invalidity, or a new trial, on two grounds: (1) the Kelly reference anticipates the asserted claims; and (2) the asserted claims are obvious in light of Kelly and Garg. (*See* D.I. 465 at 27-29) The Court is not persuaded by Teva and will deny this aspect of Teva's JMOL motion.

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label] even though this would result in some off-label infringing uses"); *see also* D.I. 477 at 10-11 ("The implications of GSK's position cannot be understated: GSK seeks to place an affirmative obligation on generic pharmaceutical companies to police and affirmatively correct doctors' misunderstanding of AB-ratings. This is not the law."); D.I. 465 at 23 n.11 ("By endorsing [GSK's] legal theory, the Court would create a new rule that would dramatically upset the delicate balance struck by the Hatch-Waxman Act."). Since section viii is in the statute, it would be wrong and problematic, in Teva's view, to effectively read it out of the Hatch-Waxman Act. *See Caraco Pharma. Labs., Ltd.* v. *Novo Nordisk A/S,* 566 U.S. 399, 415 (2012) ("[S]ection viii provides the mechanism for a generic company to identify those [unpatented] uses, so that a product with a label matching them can quickly come to market."); *Takeda Pharms. U.S.A., Inc.* v. *West-Ward Pharm. Corp.,* 785 F.3d 625, 630 (Fed. Cir. 2015) ("[A] generic manufacturer may avoid infringement by proposing a label that does not claim a patented method of use, ensuring that one patented use will not foreclose marketing a generic drug for other unpatented ones.") (internal quotation marks omitted); *id.* at 631 ("[Hatch-Waxman] was designed to enable the sale of drugs for non-patented uses even though this would result in some off-label infringing uses.").

The Court notes the parties' concerns and hopes neither side is correct in its predictions as to the dire consequences of the Court's ruling. Beyond prompting these observations, however, the parties' policy arguments have not impacted the Court's ruling on the pending motions.

Regarding anticipation, before trial, the Court identified three genuine disputes of material fact: (1) whether Kelly disclosed a maintenance period greater than six months; (2) whether Kelly's patient population was the same as that covered by the claims; and (3) whether Kelly was "too theoretical" to be considered enabling. (*See* D.I. 380 at 2-3, 5-6; D.I. 417 at 1-2 & n.1) On each of these factual questions, Teva contends that the jury's findings for GSK were unreasonable. (*See* D.I. 465 at 27-29) The Court disagrees.

GSK presented sufficient evidence to support a reasonable inference that the Kelly reference only taught treatment follow-up ***after*** six months, rather than ***continuing*** treatment for six months (*see, e.g.,* McCullough Tr. at 1673, 1677-78, 1731-32) and that the study may have dealt with a different patient population, as more than one type of heart failure exists and Kelly did not specify which type of heart failure patients it was treating (*see, e.g., id.* at 1672-73, 1681-82). GSK also presented sufficient evidence to support the inference that Kelly was too theoretical, as the study had not yet begun and could require undue experimentation. (*See, e.g., id.* at 1678-79) Each of these factual disputes was for the jury to resolve, and its finding that Teva did not prove the contrary by clear and convincing evidence was reasonable based on the record.

Regarding obviousness, Teva contends that the questions left open by Kelly (as addressed above) were all answered by Garg. (*See* D.I. 465 at 29) Thus, Teva asserts that the claims are obvious and the jury's conclusion, even in light of GSK's evidence of secondary considerations of non-obviousness, was unreasonable. (*See id.* at 29-30) However, as GSK notes (and as the

Court finds above), the jury's finding that Kelly did not disclose the three disputed claim elements was reasonable based on the record. Moreover, contrary to Teva's contention, GSK provided evidence through Dr. McCullough that Garg does not supply the duration element lacking in Kelly. (*See* McCullough Tr. at 1682) This evidence, in addition to GSK's evidence that the prior art taught away from and discouraged beta-blockers in heart failure, was sufficient to render the jury's finding that the patent was non-obvious reasonable. Therefore, the Court will deny Teva's motion for JMOL or a new trial on invalidity.

IV. CONCLUSION

For the reasons stated above, the Court will grant in part and deny in part Teva's motion for judgment as a matter of law. (D.I. 464) Because substantial evidence does not support a finding of induced infringement, there is no basis for enhanced damages, attorney fees, and interest. Accordingly, GSK's motion (D.I. 466) and Teva's motion to strike multiple exhibits GSK submitted in support of its motion (D.I. 474) will be denied as moot. An appropriate Order follows.

APPENDIX E

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.

ON PETITION FOR REHEARING EN BANC

JUANITA ROSE BROOKS, Fish & Richardson, P.C., San Diego, CA, filed a response to the petition for plaintiffs-appellants. Also represented by MICHAEL ARI AMON, CRAIG E. COUNTRYMAN, JONATHAN ELLIOT SINGER; ELIZABETH M. FLANAGAN, MICHAEL J. KANE, Minneapolis, MN; NITIKA GUPTA FIORELLA, DOUGLAS E. MCCANN, Wilmington, DE.

WILLIAM M. JAY, Goodwin Procter LLP, Washington, DC, filed a petition for rehearing en banc for defendant-cross-appellant. Also represented by JAIME SANTOS;

ELAINE BLAIS, ROBERT FREDERICKSON, III, CHRISTOPHER T. HOLDING, ALEXANDRA LU, LANA S. SHIFERMAN, DARYL L. WIESEN, Boston, MA.

MATTHEW S. HELLMAN, Jenner & Block LLP, Washington, DC, for amicus curiae Association for Accessible Medicines. Also represented by ASHWINI BHARATKUMAR; JEFFREY FRANCER, The Association for Accessible Medicines, Washington, DC.

ANDREW M. ALUL, Taft, Stettinius & Hollister, LLP, Chicago, IL, for amicus curiae Apotex Inc.

STEFFEN NATHANAEL JOHNSON, Wilson Sonsini Goodrich & Rosati, Washington, DC, for amicus curiae Mylan Pharmaceuticals Inc. Also represented by JOHN BERNARD KENNEY, GEORGE E. POWELL, III; WENDY L. DEVINE, TUNG ON KONG, San Francisco, CA; ADAM WILLIAM BURROWBRIDGE, McDermott Will & Emery, Washington, DC.

WILLIAM BARNETT SCHULTZ, Zuckerman Spaeder LLP, Washington, DC, for amicus curiae Henry A. Waxman. Also represented by MARGARET DOTZEL, CASSANDRA TROMBLEY-SHAPIRO JONAS.

CHARLES DUAN, Washington, DC, for amici curiae Michael Carrier, Michael Carroll, Bernard Chao, Samuel F. Ernst, Yaniv Heled, Amy Kapczynski, Mark A. Lemley, Lee Ann Wheelis Lockridge, Christopher Morten, Tyler T. Ochoa, Luigi Palombi, Ana Santos Rutschman, Joshua David Sarnoff, Jason Michael Schultz.

Before MOORE, *Chief Judge*, NEWMAN, DYK, PROST, O'MALLEY, REYNA, TARANTO, CHEN, HUGHES, and STOLL, *Circuit Judges*.*

MOORE, *Chief Judge*, with whom NEWMAN, O'MALLEY, TARANTO, CHEN, and STOLL, *Circuit Judges*, join, concurs in the denial of the petition for rehearing en banc.

PROST, *Circuit Judge*, with whom DYK and REYNA, *Circuit Judges*, join, dissents from the denial of the petition for rehearing en banc.

DYK, *Circuit Judge*, dissents from the denial of the petition for rehearing en banc.

REYNA, *Circuit Judge*, dissents from the denial of the petition for rehearing en banc.

PER CURIAM.

ORDER

Teva Pharmaceuticals USA, Inc. filed a petition for rehearing en banc. A response to the petition was invited by the court and filed by GlaxoSmithKline LLC and SmithKline Beecham (Cork) Limited. The court also accepted amicus briefs filed by Apotex, Inc.; the Association for Accessible Medicines; Mylan Pharmaceuticals Inc.; Henry A. Waxman; and 14 Professors of Law. The petition was first referred to the panel that heard the appeal, which denied panel rehearing. Thereafter, the petition was referred to the circuit judges who are in regular active service. The court conducted a poll on request, and the poll failed.

* Circuit Judge Lourie and Circuit Judge Cunningham did not participate.

Upon consideration thereof,

IT IS ORDERED THAT:

(1) The petition for panel rehearing is denied.

(2) The petition for rehearing en banc is denied.

FOR THE COURT

February 11, 2022
Date

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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MOORE, *Chief Judge*, with whom NEWMAN, O'MALLEY, TARANTO, CHEN, and STOLL, *Circuit Judges*, join, concurring in the denial of the petition for rehearing en banc.

The dissents advance, as bases for en banc review, legal positions that Teva has not asserted or developed. Teva never objected to the admission of the partial label as evidence, and in this court, it never challenged the jury's finding on the separately instructed requirement that it knew that the uses it was encouraging would infringe. Besides challenging causation (not raised by the dissents), Teva challenged, as to the partial label period, the jury's verdict that Teva actively encouraged certain patent-covered uses, including one (for post-MI LVD) it retained as an indication on its partial label. But Teva did not argue to the panel, and has not argued on rehearing, that GSK's

representations to the FDA constituted a bar to admission of the partial label or to satisfaction of the inducement liability standard during the partial label period. But that is the legal position advanced in the dissents, whether under a theory that those communications preclude meeting the encouragement element or under a preemption theory. Prost Dis. 2-4; *accord* Dyk Dis. 2-3; Reyna Dis. 2.

What the parties presented to the panel was the question whether, considering all the facts, substantial evidence supports the jury's verdict that Teva actively encouraged infringement. To be sure, Teva cited and discussed the FDA's regulatory framework. *See* Prost Dis. 7. But it did so only as background and support for its cobbling together argument. Teva never argued that there was a conflict between the FDA regulatory framework and patent law (as the dissents now claim); nor did it argue that the partial label was not evidence relevant to or otherwise impermissible for deciding inducement (as the dissents now suggest). Teva cited GSK's representations to the FDA to try to refute GSK's contention that one of the indications Teva retained on its partial label (use for post-MI LVD) was an infringing use, not to present the broader legal positions the dissents advance.

The majority reinstated the jury's verdict as supported by substantial evidence. Specifically, it answered the encouragement question (the subject of the dissents) based on all the evidence presented below—including the labels, press releases, testimony, marketing materials, and the GSK representations.[1] The

[1] GSK "presented extensive expert testimony along with Teva's marketing efforts, catalogs, press releases, and testimony

majority discussed how Teva's compliance with GSK's representations to the FDA was "contrary … evidence" to GSK's argument that Teva's partial label "instructed physicians to prescribe carvedilol for an infringing use." *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1330-33 (Fed. Cir. 2021). As district courts have already recognized, the majority's decision is narrow and fact dependent. *See* Memorandum Opinion at 5, *Amarin Pharma, Inc. v. Hikma Pharma. USA Inc.*, No. 1:20-cv-1630 (D. Del. Jan. 4, 2022).

Teva's petition for rehearing is no broader. The petition focuses on a single argument (causation aside): that the majority "eviscerate[d] this Court's construction of § 271(b)'s active encouragement element." Pet. 2. It faults the majority for looking to "testimony that disparate portions of the label mention or meet individual claim limitations." Pet. 13. Rephrased, Teva presents the "cobbling together" argument from Judge Prost's panel dissent for full court review. *See GlaxoSmithKline*, 7 F.4th at 1349-53 (Prost, J., dissenting). Teva's focus—cobbling together—is clear:

> As to rehearing, Teva's petition set forth the statutory carve-out provision and presented its first question for review as: Where a product has substantial noninfringing uses and the defendant has deleted

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from Teva's own witnesses, showing that Teva encouraged carvedilol sales for CHF despite its attempted carve-out." *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1333 (Fed. Cir. 2021). Teva's press releases on its website expressly encouraged doctors to prescribe carvedilol *for the treatment of congestive heart failure*. *Id.* at 1335-37. And there was testimony that doctors read and rely upon press releases and that Teva told doctors to look to its website for prescribing information.

> 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*?

Id. (quoting Pet. viii); *see also* Pet. 11-15. The dissents abandon this cobbling together argument in favor of seeking en banc adoption of different legal positions.[2]

Ultimately, it is a sense of fairness that drives the dissents to advance these positions. They believe Teva's partial label cannot be evidence of the intent required for active encouragement when Teva "play[ed] by the skinnylabel rules." Prost Dis. 4; *accord* Prost Dis. 5; *see also* Dyk Dis. 2-3. And they cannot see how it would be fair for Teva to be "liab[le] for using a label required by the FDA." Dyk Dis. 1; *accord* Prost Dis. 4. On the other hand, they view Teva's conduct as blameless. Prost Dis. 4 ("Ultimately, if playing by the skinny-label rules doesn't give generics some security from label-based liability, generics simply

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[2] And for good reason: the cobbling together argument is a nonstarter. We regularly allow claim elements to be found in different portions of a label. *See, e.g.*, *Sanofi v. Watson Lab'ys Inc.*, 875 F.3d 636, 646 (Fed. Cir. 2017). FDA regulations and guidance even instruct applicants to break out drug indications, dosages, and clinical studies into *separate* sections. *See, e.g.*, 21 C.F.R. § 201.57(c) (listing requirements for different subsections for indications, dosage, and clinical studies); *Prescription Drug Labeling Resources*, U.S. Food & Drug Admin. (last accessed January 30, 2021), https://www.fda.gov/drugs/laws-acts-and-rules/prescription-drug-labeling-resources.

won't play. And who could blame them?"); *accord* Dyk Dis. 2 ("Teva was obligated to use the label at issue.").

I too am concerned that GSK's representations to the FDA are at odds with its enforcement efforts in this case. It would be troubling to hold Teva liable for relying on GSK's representations to the FDA. But that concern does not readily fit the standards governing inducement, given the sufficient evidence of active encouragement and that Teva never disputed in this court the jury's finding that it knew that the uses it encouraged, through the partial label and otherwise, infringed. On the other hand, it fits squarely within the affirmative defense of equitable estoppel that Teva pleaded and that the district court must still decide on remand. Teva alleged, "GSK's failure to communicate to Teva or FDA that the Post-MI LVD was an alleged infringing use of the '000 patent led Teva to reasonably infer that GSK did not intend *to enforce* its patent against Teva for the use of carvedilol for Post-MI LVD." Answer ¶ 100, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, No. 1:14-cv-0087 (Feb. 9, 2016) (pleading equitable estoppel).

Equitable estoppel, a doctrine designed to avoid injustice, has three elements: misleading conduct, reliance, and prejudice. *Radio Sys. Corp. v. Lalor*, 709 F.3d 1124, 1130 (Fed. Cir. 2013). The patentee's conduct must "lead[] the alleged infringer to reasonably infer *that the patentee does not intend to enforce its patent against the alleged infringer*" in circumstances presented in the patentee's later enforcement suit. *Id.* (emphasis added). And the alleged infringer must rely on that belief to its detriment, altering its conduct because the patentee removed any threat of litigation. *See id.* Estoppel focuses on the patentee's conduct in

communicating a relied-on message of non-enforcement, rather than the accused infringer's intent to encourage others to engage in infringing conduct or even the accused infringer's own knowledge or beliefs about infringement.

The dissents' fairness concerns—which are limited to the partial label period—track this three-element framework precisely. First, the dissents claim GSK misrepresented its patent rights, "provid[ing] a sworn declaration to the FDA that identified *only* the CHF use as still patent-covered." Prost Dis. 2. Second, they note how Teva "faithfully followed" that representation. Prost Dis. 3; *accord* Dyk Dis. 2. And third, the dissents blame GSK for suing Teva despite its representations to the FDA. Prost Dis. 2 ("GSK sued nonetheless…. Never mind that GSK hadn't said this language was patent-covered."); *accord* Dyk Dis. 2. This theory fits the textbook structure of an equitable estoppel argument. And as Teva pleaded the defense, consistent with case law, the theory is not dependent on the "hallmark of inducement"—Teva's culpable intent defined by the inducement elements of active encouragement of acts known to be infringing. *See* Prost Dis. 3. Teva's allegation does not demand proof of how the FDA process affected Teva's knowledge or intent required for the inducement elements. It focuses on GSK's conduct in communicating a message of non-enforcement and Teva's reliance on that message.

Judge Prost "ha[s] doubts that an equitable-estoppel theory applies here," Prost Dis. 9, but that hesitancy does not match Teva's allegation of equitable estoppel and its supporting case law. She claims "the panel majority already undercut [equitable estoppel]" by saying "a generic may not rely upon the Orange

Book use codes provided by the brand *for patent infringement purposes*." Prost Dis. 9 (quoting *GlaxoSmithKline*, 7 F.4th at 1332). But this statement is directed at infringement, not estoppel. *See also, e.g.*, *GlaxoSmithKline*, 7 F.4th at 1332 ("GSK's submissions to the FDA are not absolutely dispositive *of infringement*."). Equitable estoppel applies when the alleged infringer has a reasonable belief, based on the patentee's representations, that the patentee *will not sue*—which is precisely what Teva alleged in its answer here, consistent with what our case law deems sufficient, *e.g., Radio Sys. Corp.*, 709 F.3d at 1130. An infringer can both know its label infringes (as Teva did here) and reasonably believe the patentee will not sue (as Teva alleges here). Estoppel here is about Teva's belief about whether GSK will enforce, not Teva's infringement or even its beliefs about what constitutes infringement. That, in a nutshell, makes equitable estoppel the natural vehicle to address the concerns the dissents express over GSK's representations to the FDA.

In fact, the dissents' arguments parallel our treatment of patentees' representations to standards setting organizations, a context in which we have relied on equitable estoppel to resolve nearly identical concerns. "A member of a[] standard setting organization may be equitably estopped" from "assert[ing] infringement claims against standard-compliant products" based on the patentee's conduct in the standard setting organization that, under the organization's rules, would reasonably be understood as a representation of nonenforcement against products following a particular standard. *Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1347-48 (Fed. Cir. 2011).

Essentially, the dissents (and Teva) claim GSK engaged in the same type of nonenforcement-communicating conduct in the FDA.

Importantly, equitable estoppel could remedy the dissents' concerns completely. In most cases, "[e]quitable estoppel serves as an absolute bar to a patentee's infringement action." *John Bean Techs. Corp. v. Morris & Assocs., Inc.*, 887 F.3d 1322, 1327 (Fed. Cir. 2018). And it is well established that "[e]quitable remedies must be flexible." *Freeman v. Pitts*, 503 U.S. 467, 487 (1992). At a minimum, a finding of equitable estoppel by the district court would result in the exclusion of the label as evidence of inducement during the partial-label period. Excluding the partial label as evidence (a remedy never requested by Teva) would require a new trial. If the district court finds GSK's representations trigger estoppel, it has the discretion to craft a just remedy—which could even eliminate the need for a new trial. But we should leave the equitable question to the district court in the first instance.[3]

We should not grant Teva's en banc petition to consider altering our settled inducement law standards based on fairness concerns that are central to the equitable estoppel defense not yet addressed. Let us allow the district court to address these fairness concerns by adjudicating that defense on remand. If the result is unsatisfying, we will surely have a chance to review it. I concur in the denial of rehearing en banc.

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[3] And in future cases, if equitable estoppel applies in circumstances like those presented by the partial label period here, the issue could be decided early, entirely obviating the need for a trial on inducement for the period covered by the estoppel.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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2018-1976, 2018-2023

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PROST, *Circuit Judge*, with whom DYK and REYNA, *Circuit Judges*, join, dissenting from the denial of the petition for rehearing en banc.

The court's decision not to rehear this case en banc is disappointing. The issues in this case, at the intersection of patent law and pharmaceutical regulation, are unquestionably important—affecting millions of Americans. The panel majority's treatment of these issues has raised enough alarm to warrant the full court's attention. As the circuit court vested with exclusive jurisdiction to review such issues, it was our responsibility to do so here. I respectfully dissent from what I view as the court's abdication of that responsibility.

This case concerns the Hatch-Waxman Act's skinny-label provisions, enacted to "speed the introduction of lowcost generic drugs to market." *Caraco Pharm.*

Labs., Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 405 (2012). Typically, brand-drug patents forestall generics' market entry. But all patents eventually expire. And, once patents no longer cover a brand drug itself and an FDA-approved use of it, a cheaper, generic version of that drug may come to market with a "skinny" label—one that copies the brand's label but omits, or "carves out," any uses for which the brand still holds a patent (leaving behind just unpatented uses). Regulations require the brand to identify exactly what label language corresponds to its patented uses, thus eliminating any guesswork as to what needs omitting to avoid infringement. This is the pathway Congress paved for generics. It sorts out the patent issues up front and assures generics that they may launch a product for unpatented uses without violating a brand's patent rights.

Teva, the generic here, followed that pathway. The patent on carvedilol expired in 2007. Teva then sought to market a generic version of carvedilol, which had three FDA-approved uses: hypertension, left ventricular dysfunction following myocardial infarction ("post-MI LVD"), and congestive heart failure ("CHF"). GSK, the brand, had provided a sworn declaration to the FDA that identified *only* the CHF use as still patent-covered. So, Teva carved out the CHF language GSK identified and came to market with its FDA-blessed, brand-compliant skinny label.

GSK sued nonetheless. It alleged that, by leaving post-MI LVD language on the skinny label, Teva induced infringement—i.e., intentionally encouraged something it knew was infringing, *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 760, 766 (2011). Never mind that GSK hadn't said this language was

patent-covered. GSK's theory was that, even with the CHF language properly carved out, remnants of the skinny label pertaining to post-MI LVD could be pieced together to spell out the patented CHF use, thus showing Teva's culpable intent—the hallmark of inducement, *see Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 934-37 (2005). A jury found for GSK, the district court granted JMOL of no inducement, and GSK appealed.

The panel majority reinstated the inducement verdict, though it needed a couple of tries to justify how. Its first opinion was difficult to defend and was quickly abandoned. Its revised opinion (designated "per curiam" this time) is, ironically, more problematic than the first. That's because it leans heavily on the skinny label itself—with the CHF language carved out—as evidence that Teva induced infringement of the patented CHF method. In particular, the panel majority embraces GSK's theory that Teva's culpable intent could be found in various remaining portions of the label that "met" or mentioned the elements of the patent claim. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1328-29 (Fed. Cir. 2021). As to the statutory and regulatory process that gave rise to the skinny label— including that GSK's sworn filings never said this language was patent-covered—the panel majority's treatment is quite unsatisfactory. It refuses to confront the obvious question: how could this label, which faithfully followed what the brand said about its own patents and which the FDA required Teva to use, *itself* be evidence that Teva *intentionally encouraged* something it *knew* would infringe?

Now, no skinny-label generic is safe. Using this statutory pathway—and following the brand's directions—becomes just another fact thrown into the mix when assessing a generic's intent. And, as amici observe, because most skinny labels contain language that (with clever expert testimony) could be pieced together to satisfy a patent claim, essentially all of these cases will now go to trial. *See, e.g.*, Apotex Amicus Br. 7 (lamenting that brands will always "be able to present expert testimony at trial showing that physicians will subjectively 'understand' the generic's label to 'show' or 'meet' elements of the claimed methods" (cleaned up)); Mylan Amicus Br. 1 (noting that, under the panel majority's "'Where's Waldo?' approach to reading labels," "[g]enerics cannot know if their labels are 'true' carve-outs until the jury speaks—years into litigation, itself filed years after the product launched").

The system can't work like this. Congress enacted the skinny-label provisions as a way for generics to *avoid* inducement liability—and thus litigation itself. Under the statute, "a generic drug must bear the same label as the brand-name product," *Caraco*, 566 U.S. at 406 (citing 21 U.S.C. §§ 355(j)(2)(A)(v), (j)(4)(G)), except for certain acceptable differences allowed by FDA regulation, including the "omission of an indication or other aspect of labeling protected by patent," 21 C.F.R § 314.94(a)(8)(iv). The FDA "rel[ies] 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" to determine "whether an ANDA applicant can 'carve out' the method of use." Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676, 36,682 (June 18, 2003).

When a generic plays by the skinny-label rules, the FDA-required label can't be evidence of intent. Even *if* remaining label language might be pieced together to "meet" the elements of a patent claim, the extent to which that's true is an unreliable gauge of a generic's "intent" in this highly regulated area; it can't meaningfully separate the liable from the lawful. That's especially so given that it's the *brand* who dictates what label language is omitted— and thus what language *remains*. Indeed, the panel majority's decision doesn't just eliminate a generic's ability to depend on the skinny-label system; it also gives brands a powerful tactic: neglect to identify language as patent-covered, then sue a generic for including that very language.

Ultimately, if playing by the skinny-label rules doesn't give generics some security from label-based liability, generics simply won't play. And who could blame them? The risk is too great. Generics sell their products for considerably less than brands, so a jury's award of lost profits to the brand can dwarf whatever profits a generic could make. Here, for example, Teva's *revenues* (it made no profit) from selling carvedilol were $74 million, yet it owes GSK $234 million in lost-profit damages. It seems implausible that Congress, when enacting the skinny-label provisions against the backdrop of the inducement statute, intended to put generics in this position.

The Hatch-Waxman Act was a seminal patent act— containing hard-fought compromises as the product of extended negotiations and stakeholder involvement. Congress's effort deserved better from this court.

* * *

To conclude, I offer a few comments about the concurrence.

The panel majority and dissent agreed on one thing: the undisputed facts of Teva's skinny-label compliance are relevant to inducement. *Compare, e.g.*, *GlaxoSmithKline*, 7 F.4th at 1331 (panel majority recognizing that "GSK's failure to identify the post-MI LVD use" in its patent declarations "is relevant to intent to induce infringement"), *with id.* at 1342 (Prost, J., dissenting) (questioning why "the majority finds it reasonable to infer that Teva *intentionally encouraged* infringement …. even though Teva, by carving out everything that GSK said would infringe, was trying to *avoid* having its label encourage infringement"). The opinions' disagreement concerned the legal significance of these facts. The majority dismissed the skinny-label compliance as mere "contrary or equivocal evidence" over which the jury could have still found that the skinny label showed inducement. *Id.* at 1331. I maintained in dissent—as I do now—that these facts prevent the skinny label from showing inducement. *Compare, e.g.*, *id.* at 1351, 1357 ("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."), *with supra* at 4 ("When a generic plays by the skinny-label rules, the FDA-required label can't be evidence of intent."). This was, and remains, the dispute. None of this is new.

What's new is the concurrence's justification for the panel majority's decision. Still lacking a persuasive response to the argument that Teva's skinny-label compliance prevents its label from showing inducement, the concurrence now urges that the argument

was never really there—that we didn't discuss it at length. In particular, the concurrence now offers a hodgepodge of forfeiture-like rationales to suggest that the argument wasn't made specifically enough. Moore Concurring Op. 1-2. None of these rationales appeared in the panel majority's opinion (which is unsurprising, given that the panel majority addressed and rejected the argument on its merits). *GlaxoSmithKline*, 7 F.4th at 1331-33. That uncomfortable fact makes it rather awkward for the concurrence to now maintain, here at the last minute, that the argument wasn't properly before us after all.[1] If it were *really* the case that this argument (or some aspect thereof) wasn't properly before us, I imagine the panel majority would have said so.

But of course, it's not the case. Teva made this straightforward argument to the panel. It argued that "[GSK's] attempt to cobble together scattered references to 'heart failure' is not proof of inducement *given Teva's actions in carving out this very indication*." Teva's Principal & Resp. Br. 50 (emphasis added). Teva then highlighted GSK's failure to identify the post-MI LVD use in its patent declarations, argued

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[1] For example, the concurrence says that "Teva cited GSK's representations to the FDA to try to refute GSK's contention that one of the indications Teva retained on its partial label (use for post-MI LVD) was an infringing use, not to present the broader legal positions" this dissent advances. Moore Concurring Op. 2. Yet the panel majority didn't understand Teva's argument to be so narrow; it allowed that GSK's FDA representations were relevant *both* "to whether the post-MI LVD use infringe[d]" *and* "to intent to induce infringement." *GlaxoSmithKline*, 7 F.4th at 1331. The concurrence declines to acknowledge this portion of the opinion.

that "[t]he very purpose of use codes is to give generic manufacturers notice of what uses they would need to carve out to *avoid infringement*," and explained that it "carved out the listed CHF indication so it could launch, precisely as Congress intended." *Id.* at 50-52 (emphasis added) (citing GSK's patent declarations at J.A. 6880-87, 6894-907); *see also id.* at 9, 12-15 (outlining the statutory carve-out process, related regulations, GSK's patent declarations, and how the FDA instructed Teva to use the skinny label based on GSK's representations).

I therefore don't see how the concurrence can credibly maintain, for example, that "Teva never argued that there was a conflict between the FDA regulatory framework and patent law," or that the skinny label was "impermissible for deciding inducement." Moore Concurring Op. 2; *see id.* (maintaining that "Teva did not argue" that "GSK's representations to the FDA constituted a bar to … satisfaction of the inducement liability standard during the partial label period"). Nor is it credible to say that this dissent "advance[s] … legal positions that Teva has not asserted or developed." *Id.* at 1.[2]

As to rehearing, Teva's petition set forth the statutory carve-out provision (21 U.S.C. § 355(j)(2)(A)(viii)) and presented its first question for review as: "Where a product has substantial noninfringing uses *and the defendant has deleted instructions to practice the*

[2] Although the concurrence at times says that this dissent has "not raised" or has even "abandon[ed]" a point included in the panel dissent, Moore Concurring Op. 1, 4, I maintain the points made in my panel dissent, *see GlaxoSmithKline*, 7 F.4th at 1342-61.

patented method from its labeling, may the plaintiff prove active inducement … ?" Teva's Pet. for Reh'g vii-viii (emphasis added). It complained that the majority "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." *Id.* at 2; *see id.* at 4-5 (describing the carve-out process and GSK's sworn declarations), 11 (noting that Teva "carv[ed] out the CHF indication as FDA instructed"), 18 (arguing that "the panel opinion makes clear that following FDA's instructions, based on the brand's explicit claims, is no safe harbor").[3] And amici uniformly made this point in supporting rehearing. Ass'n for Accessible Meds. Br. 7; Apotex Br. 8-9; Law Professors' Br. 3-5; Mylan Br. 5, 10-11; Waxman Br. 6-7.

Put simply: this argument was made to the panel, the panel addressed it on its merits, and the majority resolved it against Teva. *GlaxoSmithKline*, 7 F.4th at 1331-33.[4] If the concurrence now truly believes that this argument is somehow new, then the panel majority should revise its opinion (yet again) to say as much, thus leaving the argument open for a future skinny-

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[3] The concurrence insists that the "focus" of Teva's rehearing petition concerned what language remained on the skinny label. Moore Concurring Op. 3-4. But if Teva's argument relied solely on the post-carve-out label language—to the exclusion of the carve-out *itself*—there would have been little point in explaining the regulatory process, or why it removed the language it did.

[4] Although the concurrence now suggests that this case involves just an ordinary substantial-evidence question, Moore Concurring Op. 2, I note that such questions at this court typically do not produce two panel opinions, two dissents, two rehearing processes, and over a dozen amicus briefs throughout.

label generic to make. But it won't do that. It keeps binding precedent that rejects this argument on its merits, while justifying that decision by acting as though the argument was never really there.

Regardless of how it's styled, the concurrence has to admit that there's a problem here. Moore Concurring Op. 5 ("It would be troubling to hold Teva liable for relying on GSK's representations to the FDA."). But instead of *inducement*, the concurrence maintains that the facts surrounding Teva's Hatch-Waxman compliance go only to the judge-made doctrine of equitable estoppel—a position that no party has endorsed. Nevertheless, I address that theory briefly.

I have doubts that an equitable-estoppel theory applies here. For one, the panel majority already undercut that theory. As the concurrence (accurately) observes, equitable estoppel requires Teva to have relied on GSK's conduct (i.e., GSK's patent declarations). Moore Concurring Op. 4-6. Yet the panel majority characterized Teva's expert as having "agreed that a generic *may not rely* upon the Orange Book use codes provided by the brand for patent infringement purposes," somehow implying that Teva may not rely on the skinny label itself. *GlaxoSmithKline*, 7 F.4th at 1332 (emphasis added); *id.* at 1331-32 (emphasizing a generic's purported independent duty to analyze a brand's patents).

More globally, however, equitable estoppel is a general defense—"no[t] subject to resolution by simple or hard and fast rules"—for which the accused infringer bears the burden, and whose application rests with the trial court's discretion. *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1041-43 (Fed. Cir.

1992) (en banc), *abrogated on other grounds by SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC*, 137 S. Ct. 954 (2017). I'm not aware of any indication that Congress, when enacting this specific statutory skinny-label system (implemented by copious detailed regulations), intended to stake the efficacy of that system on a generic's case-by-case equity showing.

Contrary to the concurrence's characterization, my concerns here do not go merely to fairness. My concerns go to what inducement law permits in view of the Hatch-Waxman Act. And, as I've said from the start, I do not believe that Teva's compliant skinny label supports an inducement finding.

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.

DYK, *Circuit Judge*, dissenting from the denial of the petition for rehearing en banc.

I join Judge Prost's dissent and write separately to further elaborate why there cannot be infringement liability for using a label required by the FDA during the partial label period at issue in this case.

Generic manufacturers are statutorily obligated to use "the same label as the brand-name product," *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 406 (2012) (citing 21 U.S.C. §§ 355(j)(2)(A)(v), (j)(4)(G)), except for certain differences allowed by FDA regulation, including the "omission of an indication or other aspect of labeling protected by patent," 21 C.F.R. § 314.94(a)(8)(iv). The "indication or other aspect of labeling protected by patent" is determined by the patentee's submissions to the FDA. The FDA relies on these patentee submissions to determine

"whether an ANDA applicant can 'carve out' [a] method of use." Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676, 36,682 (June 18, 2003); *see also* 21 C.F.R. § 314.53(b)(1) (Any applicant who submits an NDA must "separately identify each pending or approved method of use and related patent claim(s)" for each patent "with respect to which a claim of patent infringement could reasonably be asserted ….").

Here, GSK's brand label contained three indications: congestive heart failure, left ventricular dysfunction following myocardial infarction, and hypertension. GSK twice submitted patent information to the FDA identifying congestive heart failure as the only method of use claimed by its patents. The FDA provided Teva with a redline for its skinny label, carving out the patented indication for congestive heart failure from GSK's branded label and keeping the remaining uses in the label. Teva amended the label for its ANDA using the text provided by the FDA. Thus, Teva was obligated to use the label at issue.

In similar circumstances where states have sought to impose tort liability on generic drug manufacturers for using the label required under federal law, the Supreme Court has made clear that federal law preempts tort liability on the part of the manufacturers. *See Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 476 (2013) ("[S]tate-law design-defect claims that turn on the adequacy of a drug's warnings are pre-empted by federal law …."); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 609 (2011) ("[F]ederal drug regulations applicable to generic drug manufacturers directly conflict with, and thus pre-empt" state-law tort claims). The Supreme Court has recognized that "[i]nfringement,

whether direct or contributory, is essentially a tort ...." *Carbice Corp. of Am. v. Am. Pats. Dev. Corp.*, 283 U.S. 27, 33 (1931). Here, as in *Mutual* and *PLIVA*, there is a direct conflict between the FDA-required labelling and the supposed requirements of federal patent infringement law. Canons of statutory construction demonstrate that the more specific and later-enacted provisions of the Hatch-Waxman Act override the general infringement provisions of the Patent Act. *See, e.g.*, *United States v. Estate of Romani*, 523 U.S. 517, 532 (1998) ("later" and "more specific" statute governs); *Morton v. Mancari*, 417 U.S. 535, 550-51 (1974) ("Where there is no clear intention otherwise, a specific statute will not be controlled or nullified by a general one, regardless of the priority of enactment." (first citing *Bulova Watch Co. v. United States*, 365 U.S. 753, 758 (1961); and then citing *Rodgers v. United States*, 185 U.S. 83, 87-89 (1902))). It is hard to see how Congress could have intended that a mandated label could be used as evidence of infringement.

The concurrence recognizes that there is a potential fairness issue but suggests that the problem can be solved by an affirmative defense of equitable estoppel. Moore Concurring Op. 4-6. This theory is a poor fit for the facts of this case. The problem is not with GSK's submissions to the FDA,[1] but with GSK's reliance on

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[1] FDA regulations provide that "[i]f the method(s) of use claimed by the patent does not cover an indication or other approved condition of use in its entirety, the applicant must describe only the specific approved method of use claimed by the patent for which a claim of patent infringement could reasonably be asserted ...." 21 C.F.R. § 314.53(b)(1). GSK accurately described the patent scope to the FDA. *See* GSK Opening Br. at 33; GSK Reply Br. at 31.

the FDA-required skinny label as evidence of intent to induce infringement.

Finally, the concurrence suggests that Teva forfeited these arguments. Moore Concurring Op. 1. As Judge Prost notes in her dissent, Teva fairly raised these issues in its briefing and petition for rehearing. Prost Dis. 6-8. I respectfully dissent.

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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.

REYNA, *Circuit Judge*, dissenting from denial of the petition for rehearing en banc.

I dissent from the court's decision to abstain from addressing en banc the important issues sparked by the majority opinion. This court's Internal Operating Procedure No. 13(2)(b) provides that en banc consideration is warranted for issues of exceptional importance. As evidenced by the briefs, the majority opinion, the dissent, and the number of amicus briefs filed to date, I believe this case involves an issue of exceptional importance. I am concerned that, if left untouched, the majority's opinion may reasonably be read to mean that companies like Teva may be held liable for induced infringement despite demonstrated compliance with the statutory and regulatory requirements to carve out everything from a skinny label that the patent owner (GSK) itself designated as covered

by its patent. I am doubly concerned that the majority opinion could be read to support such a finding of induced infringement where evidence as to intent is scant at best. Combined, these two factors portend instability in the general ANDA process and, specifically, the skinny label process, an area of patent law where we should affirmatively seek to maintain certainty and predictability as best as possible.

APPENDIX F

STATUTORY AND REGULATORY PROVISIONS INVOLVED

1. 35 U.S.C. § 271 provides in pertinent part:

§ 271. Infringement of patent

* * * *

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

* * * *

2. 21 U.S.C. § 355 provides in pertinent part:

§ 355. New drugs

* * * *

(j) Abbreviated new drug applications

* * *

(2)(A) An abbreviated application for a new drug shall contain—

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(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.

* * * *

3. 21 C.F.R. § 314.53 provides in pertinent part:

§ 314.53 Submission of patent information.

* * * *

(b) *Patents for which information must be submitted and patents for which information must not be submitted*—(1) *General requirements*. An applicant described in paragraph (a) of this section must submit to its NDA the required information, on the required FDA declaration form, set forth in paragraph (c) of this section for each patent that claims the drug or a method of using the drug that is the subject of the NDA or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. * * * For approved NDAs, the NDA holder submitting information on the method-of-use

patent must identify with specificity the section(s) and subsection(s) of the approved labeling that describes the method(s) of use claimed by the patent submitted. * * *

(c) *Reporting requirements*—

* * * *

(2) *Drug substance (active ingredient), drug product (formulation or composition), and method-of-use patents*—(i) *Original declaration*. For each patent that claims a drug substance (active ingredient), drug product (formulation or composition), or method of muse, the applicant must submit Form FDA 3542a. The following information and verification is required, subject to the exceptions listed in paragraph (c)(2)(i)(S) of this section:

* * * *

(O) Information on each method-of-use patent, including the following:

(*1*) Whether the patent claims one or more methods of using the drug product for which approval is being sought and a description of each pending method of use and related patent claim of the patent being submitted;

(*2*) Identification of the specific section(s) and subsection(s) of the proposed labeling for the drug product that describes the method of use claimed by the patent submitted; and

(*3*) An applicant that submits information for a patent that claims one or more methods of using the drug product must also

submit information described in either paragraph (c)(2)(i)(M) or (N) of this section, regarding whether that patent also claims either the drug substance (active ingredient) or the drug formulation (composition/formulation).

(ii) *Submission of patent information upon and after approval.* Within 30 days after the date of approval of its NDA or supplement, the applicant must submit Form FDA 3542 for each patent that claims the drug substance (active ingredient), drug product (formulation and composition), or approved method of use. FDA will not list or publish patent information if it is not provided on this form or if the patent declaration does not contain the required information or indicates the patent is not eligible for listing. Patent information must also be submitted for patents issued after the date of approval of the NDA as required in paragraph (c)(2)(ii) of this section. * * * The following information and verification statement is required, subject to the exceptions listed in paragraph (c)(2)(ii)(T) of this section:

* * * *

(P) Information on each method-of-use patent, including the following:

(*1*) Whether the patent claims one or more approved methods of using the approved drug product and a description of each approved method of use and related patent claim of the patent being submitted;

(*2*) Identification of the specific section(s) and subsection(s) of the approved labeling for the drug product that describes the method of use claimed by the patent submitted;

(*3*) The description of the patented method of use as required for publication, which must contain adequate information to assist 505(b)(2) and ANDA applicants in determining whether a listed method-of-use patent claims a use for which the 505(b)(2) or ANDA applicant is not seeking approval (for example, if the method(s) of use claimed by the patent does not cover an indication or other approved condition of use in its entirety, then the applicant must describe only the specific approved method of use claimed by the patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product); and

(*4*) An applicant that submits information for a patent that claims one or more methods of using the drug product must also submit information described in either paragraph (c)(2)(ii)(N) or (O) of this section, regarding whether that patent also claims either the drug substance (active ingredient) or the drug product (composition/formulation).

* * * *