No. 18-1976, -2023

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

GLAXOSMITHKLINE LLC and SMITHKLINE BEECHAM (CORK) LIMITED,

Plaintiffs-Appellants,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Cross-Appellant.

Appeal from the United States District Court for the District of Delaware (Stark, J.)
Civil Action No. 1:14-cv-00878-LPS-CJB

PRINCIPAL AND RESPONSE BRIEF OF DEFENDANT-CROSS-APPELLANT TEVA PHARMACEUTICALS USA, INC. [CORRECTED]

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March 11, 2019

CERTIFICATE OF INTEREST

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

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

Teva Pharmaceuticals USA, Inc.

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

N/A

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

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

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

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

5. The title and number of any case known to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal: *GlaxoSmithKline LLC et al. v. Glenmark Pharmaceuticals Inc., USA*, No. 1:14-cv-877 (D. Del.)

/s/ William M. Jay
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the ’067 patent	U.S. Patent No. 4,503,067
the ’069 patent	U.S. Patent No. 5,760,069
the ’821 patent	U.S. Patent No. 5,902,821
ACC	American College of Cardiology
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STATEMENT OF RELATED CASES

No appeal has been taken from this action in any court of appeals. The following case may be affected by this decision: *GlaxoSmithKline LLC et al. v. Glenmark Pharmaceuticals Inc., USA*, No. 1:14-cv-877 (D. Del.).

STATEMENT OF ISSUES ON APPEAL

1. Whether the district court correctly held that substantial evidence did not support a reasonable jury finding that Teva actually induced physicians to infringe at a time when Teva's label "carved out" the sole patented indication.

2. Whether the district court correctly held that substantial evidence did not support a reasonable jury finding that Teva caused physicians to infringe once Teva amended its label at FDA direction, where the undisputed evidence showed no change in physicians' behavior or GSK's market share after the label amendment.

STATEMENT OF ISSUES ON CONDITIONAL CROSS-APPEAL

If judgment as a matter of law is set aside:

1. Whether the lost-profits award should be vacated, because the district court instructed the jury and excluded Teva's evidence based on the erroneous legal conclusion that GSK could recover lost profits even for carvedilol sales that would have been captured by the other generic carvedilol manufacturers.

2. Whether the district court erred in failing to rule on the merits of Teva's motion in the alternative for a new trial.

INTRODUCTION

To induce infringement means "to influence" the infringer—"to prevail on" the infringer to commit the act of infringement. *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 760 (2011) (citations omitted). Talk by the alleged inducer is not enough; the infringer must both listen and be moved. Without evidence that the defendant actually *caused* anyone to infringe, therefore, there can be no inducement liability.

That is this case. GSK sought to hold Teva liable for inducing infringement by doctors, even though when GSK obtained the patent-in-suit, doctors were already prescribing carvedilol for the patented use and pharmacists were already substituting generic versions of carvedilol. In an instruction that GSK does not challenge on appeal, the district court told the jury that GSK would have to prove through competent evidence that Teva, not some other factor, caused doctors to infringe. And GSK's ambitious all-or-nothing trial strategy—aimed at maximizing its damages—required it to prove that Teva induced doctors *as a class* to infringe, not just particular doctors. In other words, GSK argued that Teva was responsible *every time* that *any doctor* infringed by prescribing carvedilol in accordance with the narrow method claim at issue here, if the pharmacy filled the prescription with Teva's product rather than one of the many other generics on the market. No reasonable jury could find on this record that GSK carried that burden.

For ten years before generic launch, GSK heavily promoted and sold carvedilol under the brand name Coreg, which over time was approved by FDA to treat congestive heart failure ("CHF") and for two other indications. In September 2007, GSK's patent on the compound expired, and GSK had no patent on the indications other than CHF. Teva and seven other companies launched generic carvedilol products, labeled only for the unpatented indications. All eight obtained FDA approval by "carving out" the patented CHF indication from their labeling pursuant to "Section viii," 21 U.S.C. § 355(j)(2)(A)(viii), a provision of the Hatch-Waxman Amendments to the Food, Drug, and Cosmetic Act. Within a few months, GSK had lost nearly 93% of its market share to generic competition.

Only after all these developments, in January 2008, did GSK obtain the '000 reissue patent, which claims one narrow way of treating CHF using carvedilol. As the trial record showed, the reasons why physicians performed the steps of that method had nothing to do with inducement by Teva. Both before and after generic launch, doctors' experience, professional guidelines, and extensive medical literature taught the benefits of using carvedilol to treat CHF. Appx10668-10669, Appx10676-10678, Appx11151-11154. In fact, every expert cardiologist who testified—including GSK's inducement expert, Dr. McCullough—said that he was influenced by *that* information.

As the district court recognized, no reasonable jury could have found on this record that *Teva* caused doctors to practice the infringing method. Teva's "skinny" label omitted the CHF indication, and doctors (including GSK's expert) *did not read* generic labels before writing prescriptions. Nor could Teva induce infringement through marketing materials that accurately stated FDA's therapeutic-equivalence finding and did not even mention the patented indication or method—materials indistinguishable from FDA's own statements. Appx15-18. Indeed, what GSK really wants is to impose an "unprecedented" and unfounded duty on generic drug companies—to go beyond "carving out" patented indications by affirmatively "disclaim[ing]" them. Appx17. As the district court correctly concluded, and as GSK's counsel conceded, GSK's arguments have no basis in any statute or precedent. Appx12205.

GSK likewise failed to present substantial evidence that Teva caused infringement during the later period after FDA instructed Teva to amend its label in 2011. By that time, GSK had already lost 99.3% of its market share. GSK's counsel and GSK's expert who surveyed physicians about their prescribing practices both conceded that there was no market impact from the label change. Appx12204-12205; Appx10754. Dr. McCullough likewise testified that there was "no difference in [his] prescribing habits from when Teva had its skinny label to after Teva amended to have its [amended] label." Appx10699. Because the trial

evidence shows both that the skinny label did not cause infringement and that the label amendment had no effect on doctors or the market, it follows that the amended label likewise did not cause infringement.

Even if GSK had presented evidence of causation that could withstand JMOL, the jury's lost-profits award cannot be sustained. GSK failed to provide any evidence that, but for Teva's infringement, Teva's carvedilol sales would have been captured *by GSK* rather than by the other generic carvedilol manufacturers that have never been accused of infringing and whose products were lawfully on the market. The district court erroneously considered those sales irrelevant and precluded Teva from offering evidence about them to the jury.

Teva also preserved numerous additional challenges to the verdict that the district court did not need to address. If this Court does not affirm, it should vacate the lost-profits award and remand for the district court to consider these challenges and Teva's motion for a new trial.

STATEMENT OF THE CASE

This appeal is about the last in a series of patents on carvedilol. Since the drug was approved in 1997 under the name Coreg, GSK has marketed and sold carvedilol for multiple uses, only one of which involves treating CHF. After the patent claiming the compound expired in September 2007, Teva and others

launched generic versions of carvedilol, but did not label their products for the treatment of CHF.

Several months later, in January 2008, GSK obtained the patent-in-suit, the '000 patent, as a reissue of one of its method patents. By the time that patent issued, GSK could overcome the prior art only by limiting the claims to one highly specific method of using carvedilol to treat CHF over a lengthy period. The only independent claim is Claim 1, which claims:

> 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 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.

Appx45.

Thus, the '000 patent is not infringed unless a doctor administers carvedilol to a patient suffering from CHF "to decrease a risk of mortality caused by [CHF]" and in the manner specifically required by the claims. According to GSK's expert, just 17.1% of doctors' carvedilol prescriptions directly infringed. Appx10781-10784.

I. GSK Enjoyed a Long Period of Market Exclusivity on Carvedilol.

A. Physicians Began Looking to Beta-Blockers to Improve the Treatment of CHF.

Carvedilol is a beta-blocker. These compounds have been used since the 1960s to treat cardiovascular diseases, including high blood pressure and hypertension. Appx4; Appx10357.

By the early 1990s, physicians recognized a need for an improved treatment for CHF—a chronic and often fatal disease that results in the heart being unable to deliver enough oxygenated blood to the body. Appx3. Heart failure can be asymptomatic (Class I) or symptomatic (Classes II-IV). Appx10378-10379. This case is about symptomatic CHF patients with reduced ejection fraction, which occurs when the heart's pumping function is impaired. Appx11131-11132.

While using beta-blockers to treat CHF did not become the standard of care until after Coreg was approved by FDA, the prior art disclosed treating CHF patients with beta blockers in the late 1970s and early 1980s, as one of the inventors acknowledged. Appx7699-7714; Appx7658-7663; Appx7696-7698; Appx10394-10396. A 1993 paper disclosed a study examining the use of carvedilol in CHF patients at the same dose, on the same schedule, and with the same concomitant drugs as the later '000 patent. Appx6810-6814 (Kelly); *see also* Appx7118-7121 (Garg); Appx11710-11711. Another study that same year found

improvements in "both symptoms and cardiac function" in CHF patients administered carvedilol. Appx7657 (Olsen).

B. GSK Sought Patent Protection for a Method of Using Carvedilol to Treat CHF.

Inventors from GSK's development partner, Boehringer Mannheim, first obtained a patent on the carvedilol compound in 1985—the '067 patent, which expired in 2007. Appx11271, Appx6331. In 1995, GSK sought the patent that became the '069 patent (which in turn was later reissued as the patent-in-suit). That patent claimed a method of decreasing mortality caused by CHF by administering carvedilol in conjunction with one or more of three types of therapeutic agents. Appx257; Appx261. GSK also obtained the '821 patent, which claimed a method of up-titrating the carvedilol dosage to treat CHF. Appx266. The '069 patent was to expire in 2015 and the '821 patent in 2016. Appx7831.

C. GSK Obtains FDA Approval to Market Carvedilol for Multiple Indications.

FDA approved GSK's New Drug Application for immediate-release Coreg in 1997. Appx3055. GSK launched the product with two indications: the management of hypertension and the treatment of mild-to-moderate CHF, later amended to mild-to-severe CHF (the "CHF indication"). Appx3054; Appx7665. A third indication was added in 2003, to treat patients whose hearts had very

recently (within 21 days) been damaged by a heart attack (the "post-MI LVD indication"). Appx6953; Appx11164; Appx7992. The post-MI LVD indication was to reduce cardiovascular mortality in patients who had survived a recent heart attack. Appx11184-11185, Appx11513, Appx11522-11523; Appx7992.

When GSK sought FDA approval to market carvedilol, it was required to publicly identify which "indication or method of use information" it claimed was patented, by drafting a corresponding "use code" to include in the Orange Book. Appx6881-6882; Appx7830-7834; Appx10521, Appx11041-11042; *see* 21 C.F.R. § 314.53(c)(2). GSK was required to certify that this information was "accurate and complete" under penalty of perjury. 21 C.F.R. § 314.53(c)(2)(ii)(R).

GSK informed FDA that Coreg was covered by the '067 patent on the carvedilol compound (set to expire in 2007) and the two method-of-use patents (set to expire in 2015 and 2016). Appx6889-6907. GSK certified that its method-of-use patents claimed the CHF indication, and only the CHF indication. Appx6894-6907; Appx7831-7834; Appx10888-10890. GSK *never* told FDA or asserted to any generic drug company that using carvedilol to treat post-MI LVD or hypertension would infringe *any* method-of-use patent—until it filed this lawsuit in 2014. Appx11019; Appx11043.

D. GSK Spent Hundreds of Millions of Dollars Convincing Doctors to Prescribe Carvedilol to Treat CHF.

Once GSK received FDA approval, GSK heavily promoted Coreg and its use for treating CHF. Between 2002 and 2006 alone, GSK spent $650 million in "field force expenses" for its sales representatives to educate doctors about Coreg, and $300 million on advertising and promotional expenses, including sales aids, brochures distributed during physician visits, seminars, radio announcements, and web conferences. Appx10507-10511, Appx11172-11173. GSK directed its promotional activity at the CHF indication: GSK's Vice President of Strategy and Commercial Operations testified that GSK's marketing strategy was to pitch Coreg as "a heart failure drug." Appx11114-11115; *see also* Appx10351.

Using beta blockers, including carvedilol specifically, became the "standard of care" for treating patients with symptomatic CHF that students learned during medical school and residency programs. Appx10385, Appx11147-11149. The method for treating CHF using carvedilol was incorporated into the official guidelines for the diagnosis and management of CHF provided to doctors by the American College of Cardiology (ACC) and the American Heart Association (AHA), and detailed in medical textbooks and treatises, long before any generic version had launched. Appx10666-10669; Appx11164-11167; Appx3276. It was also taught by medical publications, including the *New England Journal of*

Medicine and the *British Heart Journal*, that doctors read and relied upon. Appx10676-10677.

E. After GSK Enjoyed 10 Years of Market Exclusivity, Generic Manufacturers Received FDA Approval to Market Carvedilol as the AB-Rated "Generic Version" of Coreg.

Teva and others sought FDA approval to market generic versions of carvedilol. Appx5429; Appx10442-10443. In May 2002, Teva submitted a Paragraph III certification that it would not market generic carvedilol until the '067 compound patent expired in 2007, and a Paragraph IV certification that the '069 and '821 method-of-use patents covering the CHF indication were invalid and unenforceable. Appx5463. GSK did not sue on the method-of-use patents. Appx10893. Instead, GSK elected to put the '069 patent into reissue proceedings to narrow the scope of the claims. Appx32.[1] In reissue proceedings, GSK admitted that the patent was at least partially invalid because it failed to include narrowing limitations requiring (i) administering daily maintenance dosages (ii) for a maintenance period (iii) of greater than six months, and (iv) administering carvedilol for the specific purpose of "decreas[ing] a risk of mortality caused by congestive heart failure." Appx7017-7018.

In 2004, while the '069 patent was in reissue proceedings, FDA granted tentative approval to Teva's ANDA, with final approval expected upon expiration

[1] GSK delisted the '821 patent from the Orange Book and did not seek its reissue. Appx6873-6882.

of the ’067 patent. Appx7788-7792. Teva’s press release announcing the tentative approval noted that its generic carvedilol tablets were “the AB-rated generic equivalent of GlaxoSmithKline’s Coreg® Tablets and are indicated for treatment of heart failure and hypertension.” Appx7437. At that time, Teva had received tentative approval for and planned to include all three indications; those plans changed before final approval, however.

In 2007, with expiration of the compound patent quickly approaching, Teva learned that its generic competitors had likewise sought approval for generic carvedilol. Appx10899. But unlike Teva, the other generics had proposed to omit the one patented use—the CHF indication—from their labels. *Id.* This option, known as a “Section viii carve-out” (after its statutory subdivision, 21 U.S.C. § 355(j)(2)(A)(viii)), allows a generic manufacturer to “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 patented uses.’” *Takeda Pharm. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 630 (Fed. Cir. 2015) (citation omitted)) .

Teva decided to do what its generic competitors were doing: carve out the CHF indication and label its product only for the unpatented hypertension and post-MI LVD indications. Appx7793; Appx6176-6182. FDA provided Teva with a mock-up label effecting the carve-out, which omitted all content related to the

CHF indication based on the information that GSK had provided to FDA about the uses its patents covered. Appx6908-6952; Appx11024-11026. FDA instructed Teva to use that mock-up label (the "skinny label"), which Teva did. Appx5504-5530; Appx6350-6351; Appx10904-10908.

In early September 2007, FDA announced that it had approved "the first generic versions of Coreg (carvedilol)," including Teva. Appx7116. By then, GSK had enjoyed 10 years of market exclusivity, earning $7.1 billion. Appx10795. FDA's press release stated that Coreg is "FDA-approved to treat high blood pressure, mild to severe chronic heart failure and left ventricular dysfunction following a heart attack." Appx7116. FDA noted that generic drugs "use the same active ingredients as brand-name drugs and work the same way." *Id*. It also noted 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.*

Teva also issued a press release, stating that FDA had "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." Appx6342. That press release made no mention of the CHF indication.

Eight companies launched generic carvedilol that month, all with the carved-out label, and all AB-rated to Coreg. Appx6768; Appx10899; Appx6861-6862.

Generic carvedilol sold at a fraction of the cost of Coreg: at launch, generic carvedilol sold for three-and-a-half cents per pill versus $1.50 for Coreg. Appx6755; Appx7956, Appx6755. By 2008, generic carvedilol had decreased to two cents per pill while Coreg's price had *increased* to $2.33. Appx6754; Appx6755.

GSK rapidly lost market share. As witnesses for both parties testified, state pharmacy laws allow or require the substitution of generic drugs with AB ratings for brand-name drugs irrespective of the indications on the label. Appx10750-10751 (Reisetter); Appx11031, Appx11037-11038 (Karst); Appx11076-11077, Appx11083-11087 (Kinsey); Appx10675, Appx10678-10679 (McCullough). As a result, within one month of generic launch, GSK's market share had decreased from 100% to 13.3%, and by January 2008 (when the '000 patent issued), GSK had only 7.7% of the carvedilol market. Appx6768-6769. Eventually, ten generic manufacturers entered the carvedilol market. Appx6770.

II. GSK Obtained the '000 Patent, Claiming a Specific Method of Treating CHF, and Delisted the Predecessor Patent, Prompting a Label Amendment.

Four months after generic launch, in January 2008, GSK obtained the '000 reissue patent, surrendered the '069 patent, and delisted the '821 and '069 patents from the Orange Book. Appx31-45; Appx6873-6883. GSK then listed the '000 patent in the Orange Book and, when certifying what uses the patent covered,

listed *only* the CHF indication and use code. Appx6880-6887; *see* Appx6868, Appx6871. GSK did not sue any of the generics for infringement at that time.

In 2011, FDA sent Teva a letter noting that the '069 and '821 patents had been delisted and instructing Teva to "revise [its] labeling to include the information" that had been omitted in 2007 when Teva submitted its carve-out statement. Appx5557-5559. Teva amended its label as directed by FDA, and FDA approved it. Appx7652.

FDA's letter also noted GSK's '000 patent, but because that patent had issued *after* approval, Teva did not file and FDA did not require a certification to that patent. Appx5554; *see* 21 C.F.R. § 314.94(a)(12)(viii)(C)(2).

III. Nearly Seven Years After Generic Launch, GSK Sued Teva and Glenmark, but not Eight Other Generics that Sold Carvedilol, for Inducing Infringement.

Almost seven years after the first generic launch, more than three years after Teva amended its carvedilol label, and less than a year before the '000 patent expired, GSK sued only two generic manufacturers—Teva and Glenmark. Appx50; Compl., *GlaxoSmithKline LLC v. Glenmark Generics Inc., USA*, No. 14-cv-00877 (D. Del. filed July 3, 2014). GSK sought nearly $750 million in damages from Teva for induced infringement, from July 2008[2] until expiration of the patent in June 2015. Appx12279, Appx12281-12282. During that time, Teva

[2] Because GSK waited so long to file suit, any damages claim before July 2008 was time-barred. *See* 35 U.S.C. § 286.

had earned $74.5 million in revenues from all carvedilol sales, resulting in a net *loss* of $13 million. Appx10875-10876.

A. GSK Avoided Invalidity By Advocating a Very Narrow Claim Scope.

Both during reissue and while litigating this case, GSK emphasized that the scope of the asserted claims was much narrower than simply the use of carvedilol to treat CHF. The reissue '000 patent included several new claim elements, including the administration of a daily maintenance dosage, a maintenance period of greater than six months, and the administration of carvedilol for the specific purpose of "decreas[ing] a risk of mortality caused by congestive heart failure." Appx45.

At claim construction, to "distinguish the claimed invention from prior art," which disclosed the "use of carvedilol to treat the symptoms of CHF patients," GSK convinced the district court that the specific treatment objective articulated in the preamble to Claim 1 ("[a] method of decreasing mortality caused by [CHF] in a patient in need thereof") was a claim limitation. Appx12255-12256; Appx138-139; Appx96-104.

B. The District Court Excluded from the Lost-Profits Analysis Any Evidence that Generic Carvedilol Would Have Been Lawfully on the Market Even Without Teva's Product.

Teva moved for partial summary judgment regarding lost profits, contending that even if Teva's generic had never been on the market, GSK would have lost

exactly the same sales to other generic manufacturers that have never been accused of inducement. The district court disagreed on the law, holding that all sales of generic carvedilol to treat CHF in the manner claimed by the '000 patent must be disregarded even if those sales were not induced by anyone and instead resulted from pharmacy substitution practices. Appx221-223.

Thus, at trial, Teva was prohibited from presenting evidence of other lawful generic carvedilol products that would have captured Teva's sales and prevented GSK from earning profits on them, and GSK's expert was permitted to ignore those alternatives. Appx221-224. The district court's ruling was integrated into the instruction that the jury could not consider "the use of generic carvedilol supplied by companies other than Teva" in assessing lost profits. Appx195.[3]

C. The Jury Awarded GSK $235 Million in Damages Despite GSK's Failure to Present Evidence of Causation or to Quantify the Allegedly Induced Sales.

GSK took the position that a label or marketing materials instructing a patented method were alone sufficient to establish liability for inducement, and that it did not need to adduce evidence that those materials actually caused anyone to infringe. Appx215-217; Appx11414-11415, Appx11430-11431. The district

[3] The court acknowledged that the final jury instructions would reflect its prior rulings while preserving the parties' ability to appeal those rulings. Appx11701; *see also* Appx12431 n.3 (expressly preserving Teva's right to appeal the legal ruling made at summary judgment during the parties' submission of proposed jury instructions).

court rejected that position and held that GSK was required to prove causation through admissible evidence at trial. Appx215-217. The court instructed the jury that for GSK to prevail, it was required to prove that physicians directly infringed; that Teva took affirmative action intending to cause direct infringement; that Teva was aware of the '000 patent and aware that the infringing acts would cause direct infringement; and—the element GSK disputed—"that Teva's alleged inducement, as opposed to other factors, actually caused the physicians to directly infringe." Appx11797-11798; Appx11696-11697.

1. GSK first attempted to prove its inducement theory through Dr. McCullough. But Dr. McCullough did not even mention causation when he described the elements of inducement. Appx10615-10617.[4] Unsurprisingly, then, during GSK's case-in-chief, Dr. McCullough offered no testimony about whether the skinny label, the amended label, or any other communication from Teva actually induced him to infringe, much less induced doctors as a class to infringe. To the contrary, Dr. McCullough testified directly that "doctors would follow" AHA and ACC guidelines in prescribing carvedilol, Appx10668; that he "didn't actively switch" his patients to generic carvedilol when generics launched and instead his patients were "automatically switched" to generic carvedilol, Appx10675; and that after generic launch he "relied on all those same things" he

[4] Similarly, GSK's economist, Dr. Maness, stated that his model did not have to show that sales were caused by Teva's inducement. Appx10833-10835.

had relied upon before generic launch in prescribing carvedilol to his patients—the guidelines, his years of experience, GSK's marketing efforts, and academic research, Appx10676-10678. Dr. McCullough presented no testimony attempting to quantify how many doctors had supposedly been induced *by Teva* to infringe.

2. GSK then introduced a survey expert, Dr. Reisetter, who had conducted an internet survey of 200 physicians. Appx10706, Appx10710, Appx10723. The nine-question survey gathered information about the percentage of carvedilol prescriptions, over a nine-year period, that were written under conditions that could infringe. Appx5379-5381. For example:

> Please think about all your prescriptions, from 2007 through 2015, for carvedilol IR to treat CHF, during the maintenance period for patients **who achieved a maintenance period of longer than 6 months** … Please indicate the percentage of those prescriptions that you wrote for patients who, at that time, were also taking <u>at least one</u> of the following [three] agents in addition to carvedilol IR ….

Appx5380. Despite asking for specific, quantitative answers, Dr. Reisetter "instructed the doctors not to consult any record … even if it was accessible to them." Appx10743. The survey instructed physicians that there were "no right or wrong answers" and that doctors were simply being asked for their "opinions." Appx5376.

In the end, Dr. Reisetter did not draw any conclusions from his survey about what percentage of carvedilol prescriptions were infringing. Appx10741-10742. Nor did he attempt to determine whether any of the doctors surveyed had been

actually induced to infringe by anyone, much less Teva. Appx10742. He said he was not asked by GSK to survey doctors about whether Teva's label or any of Teva's communications led them to prescribe generic carvedilol, and he did not include any such questions in his survey. Appx10742-10743. He did not even ask whether physicians had seen Teva's label or marketing materials. Appx5376-5381.

3. Dr. Maness, GSK's damages expert, admitted that he also did not conduct his own analysis to determine what percentage of infringing sales were actually induced by Teva. Appx10825-10826. Instead, he first combined figures from Dr. Reisetter's survey to estimate the percentage of *total* carvedilol prescriptions that infringed (17.1%),[5] and he applied that percentage to *Teva's* sales, unmodified. Appx10781-10784. He then *assumed* that 100% of that infringement was induced by Teva. Appx10832. He said he relied on the "belief" of Dr. McCullough, the inducement expert, "that all of them, all the infringing sales were induced," Appx10825-10826, even though Dr. McCullough had nowhere provided any testimony or opinion to this effect.

[5] That figure combined four different percentages from the survey, seeking to eliminate prescriptions to patients who did not have CHF; who did not simultaneously take an ACE inhibitor, a diuretic, or digoxin; or who did not achieve the 6-month maintenance period, as well as prescriptions written before the maintenance period began. Appx10782-10784. Dr. Maness separately discounted by a fifth percentage from the survey, involving alternatives to carvedilol. Appx10785-10786.

Finally, Dr. Maness testified that, if lost profits were unavailable, the reasonable royalty was $1.4 million. Appx10841-10842.

4. Following GSK's case-in-chief, Teva moved for judgment as a matter of law, arguing that GSK had failed to prove that Teva caused doctors to infringe. Appx10931-10932. The court noted that there was no direct evidence from Dr. McCullough that he or any other doctors were actually induced *by Teva* to prescribe generic carvedilol, and the inference of causation GSK asked the court to draw was contrary to the considerable direct evidence that doctors relied on *other* sources of information. Appx10959-10962. GSK's counsel made an "offer of proof" that GSK could recall Dr. McCullough, saying that he would "absolutely" testify that he read and relied upon Teva's label. Appx10958-10959. The court reserved judgment on the motion and allowed trial to proceed. Appx10966. But when GSK recalled Dr. McCullough, he testified unequivocally that he did *not* read Teva's generic label before he started administering generic carvedilol; he "just assume[d]" Teva's generic drug was the same as Coreg. Appx11662-11663. He also testified that he would not have prescribed carvedilol to treat CHF if he had read the skinny label because it was missing "too much information" about the CHF indication. Appx11660-11661.

5. Teva's expert evidence confirmed that physicians did not rely on the generic labeling in their CHF treatment decisions. Doctors were already very

familiar with carvedilol from other sources, including GSK's promotional activities, the guidelines, and the Coreg label itself. Appx11151-11152. And both Teva's experts and Dr. McCullough agreed that a doctor would *not* rely on the *post-MI LVD* indication in Teva's label to treat *CHF*. Appx11660-11661; Appx11152-11154.

6. During closing arguments, GSK also argued to the jury that it had proved causation through (a) evidence that Teva knew it would receive sales of generic carvedilol prescribed for CHF despite carving out that indication, Appx11854-11855, Appx11848, and (b) evidence that Teva failed to affirmatively inform doctors, "in fine print" or using an "[a]sterisk," that its AB-rated generic carvedilol was "not approved for the use of congestive heart failure," Appx11859-11861; *see* Appx11849-11850 (arguing that Teva did not "disabuse[]" physicians of the impression that generic carvedilol could be used for all the same indications as Coreg).

7. About seven hours after closing arguments, the jury reached a verdict in GSK's favor and awarded $234.11 million in lost profits and $1.4 million as a reasonable royalty. Appx11936, Appx11952; Appx211.

IV. The District Court Granted Teva's Motion for Judgment as a Matter of Law.

After trial, Teva filed a renewed motion for judgment as a matter of law or, in the alternative, for a new trial. Appx12444-12482. Teva argued, among other

things, that GSK failed to present substantial evidence that Teva induced even a single doctor—and certainly not all doctors as a class, *see* pp. 30, 44-46, *infra*—to infringe. Teva also argued that GSK was not entitled to lost profits because GSK failed to quantify the profits that it alleged were caused by Teva's inducement.

The district court granted JMOL for Teva, concluding that the jury could not reasonably have found from the trial evidence that Teva caused doctors as a class, or even one doctor, to infringe. The district court emphasized that it was making only a narrow ruling based on the specific evidence presented, and not adopting any categorical rule for inducement. Appx23 n.14, Appx24 & n.15.

First, the court concluded that GSK presented no evidence that the skinny label caused physicians to infringe. The court noted that Dr. McCullough himself testified he would not prescribe generic carvedilol based on a label missing the CHF indication, and that "Dr. McCullough specifically stated that he did not read Teva's label prior to administering generic carvedilol." Appx13 (citing Appx11659-11663), Appx14-15.

The court also rejected GSK's argument that Teva induced infringement by stating in marketing materials that generic carvedilol was AB-rated to Coreg without specifying that generic carvedilol was not FDA-approved to treat CHF. The court held that these materials were not "legally sufficient evidence" to support a finding that Teva induced infringement because being AB-rated *does*

signify "that a generic drug is therapeutically equivalent to a branded drug," and an AB rating "necessarily requires a comparison between the generic drug and some branded reference drug." Appx16-18. The court stated that GSK's inducement theory sought to impose "unprecedented" duties on generic manufacturers to correct erroneous assumptions about the meaning of FDA's AB-rating designation, and to provide affirmative disclaimers about unapproved indications. Appx17 n.10.

The court noted the "vast amount of evidence" from *both* parties' experts that doctors were influenced to prescribe generic carvedilol not because of Teva's marketing materials but because of other sources, including GSK's promotional materials, the knowledge and experience that doctors had acquired from a decade of treating CHF with carvedilol, ACC and AHA guidelines, and research studies. Appx18-21. With no evidence of causation presented by GSK and substantial, uncontroverted direct evidence that other factors caused doctors to prescribe carvedilol, the court held that any inference of causation by Teva "was an unreasonable one for the jury to have drawn." Appx20-21.

Second, the district court concluded that GSK did not present substantial evidence to support a finding that Teva caused doctors to infringe during the amended-label period because physicians were already prescribing carvedilol to

treat CHF by the time Teva amended its label, and the evidence showed no change in physicians' practices or GSK's market share after 2011. Appx24.

The district court declined to address Teva's direct-infringement argument or its lost-profits argument and declined to expressly rule on Teva's alternative motion for a new trial. Appx11 nn.6-7. The district court's judgment dismissed without prejudice the remaining "claims and affirmative defenses" that could be addressed in the event of a "remand order from the Court of Appeals." Appx30.

SUMMARY OF THE ARGUMENT

I. The district court correctly concluded that GSK failed to present substantial evidence that Teva induced infringement by physicians as a class during the skinny-label period.

First, GSK did not provide substantial evidence that the class of physicians who prescribed carvedilol to treat CHF in an infringing manner were induced to do so *by Teva*. GSK's argument that causation can be inferred from the other elements of inducement is irreconcilable with the jury instructions, which GSK does not challenge; contrary to the cases GSK cites; and contrary to the aiding-and-abetting regimes GSK argues should apply. And its proposed inference would contradict evidence undisputed at trial.

As the district court correctly concluded, GSK provided no evidence that doctors were actually induced to infringe by Teva's skinny label. GSK's own

inducement expert testified that he did not read Teva's label before prescribing carvedilol and that he would not have prescribed carvedilol to treat CHF if he had read it because the label was missing "too much information" about the patented indication. Appx11660-11661. GSK likewise provided no evidence that Teva's press releases, product guides, or website had any impact on physicians' prescribing practices, which both parties' cardiologist experts testified did not change after generics entered the market. To the contrary, experts for both sides provided unrebutted testimony that their decision to prescribe carvedilol was influenced by the same factors before and after generic launch—their knowledge of Coreg and their experience using carvedilol to treat CHF, ACC and AHA guidelines instructing physicians to use carvedilol to treat CHF, and the myriad studies describing the benefits of using carvedilol to treat CHF. Appx10668, Appx10677-10678; Appx11151-11152.

Second, and in the alternative, the district court correctly concluded that GSK failed to present substantial evidence that Teva actively encouraged the infringing use. The skinny label carved out the CHF indication, and the post-MI LVD indication that remained on the skinny label did not promote infringement. Indeed, despite the post-MI LVD indication appearing on the label for more than 10 years, GSK never asserted in its FDA submissions that this use was patented.

The non-label materials GSK relies on do not provide substantial evidence that Teva actively encouraged infringement either. The marketing materials Teva used after receiving FDA approval did not even describe, much less promote, the CHF indication. GSK contends that by referring to carvedilol as "AB-rated" to Coreg, and as the therapeutically "equivalent," generic "version" of Coreg, Teva's marketing materials actively promoted the infringing use. But as the district court concluded, accurately describing a generic drug's AB rating and therapeutic equivalence—just as FDA did—cannot sustain a finding that Teva actively encouraged an infringing use that is neither described nor promoted in these materials.

II. The district court correctly concluded that GSK failed to present substantial evidence that Teva induced infringement by physicians during the amended-label period beginning in 2011. By the time Teva amended its carvedilol label as instructed by FDA, GSK had already lost 99.3% of its market share. GSK's counsel and Dr. Reisetter both conceded that there was no market impact from the label amendment, and GSK's inducement expert testified that there was "no difference in [his] prescribing habits from when Teva had its skinny label to after Teva amended" its label. Appx10699. Just like during the skinny-label period, cardiologists relied not on generic carvedilol labels, but on the guidelines and their own knowledge.

III. Even if the Court concludes that substantial evidence supports the jury's finding of inducement, the Court should vacate the lost-profits award and instruct the district court to award only a reasonable royalty on remand. The district court erroneously concluded that the lost-profits analysis must ignore the sales that would have been made by numerous other generic carvedilol manufacturers lawfully on the market that have never been accused of wrongdoing. It permitted GSK and the jury to ignore, and prohibited Teva from presenting, evidence of these other lawful generic products that would have captured Teva's sales.

IV. No matter how this Court resolves the issues on appeal, it cannot simply reinstate the verdict. Teva raised other grounds for JMOL that the district court did not reach. The district court also erroneously failed to rule on the merits of Teva's motion for a new trial, which also would require a remand. *See, e.g.*, *Rhone Poulenc Rorer Pharm. Inc. v. Newman Glass Works*, 112 F.3d 695, 699 (3d Cir. 1997). If this Court does not affirm the judgment, it should remand for the district court to consider these issues in the first instance.

STANDARD OF REVIEW

This Court reviews the district court's JMOL decision de novo, using the standard that applies under regional circuit law. *Harris Corp. v. Ericsson Inc.*, 417 F.3d 1241, 1248 (Fed. Cir. 2005). Affirming an order granting JMOL is

appropriate if "it is apparent that the verdict is not supported by legally sufficient evidence." *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1166 (3d Cir. 1993). Because GSK has not challenged the district court's jury instruction regarding induced infringement, the "sufficiency of the jury charge" is not before this Court, and the only question to be considered is the "sufficiency of the evidence" at trial. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1382-83 (Fed. Cir. 1998) (opinion of Bryson, J., joined by Mayer, C.J.). "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 could properly find a verdict for that party." *Lightning Lube*, 4 F.3d at 1166 (citation omitted). In making this determination and reviewing the record as a whole, the Court must draw inferences in GSK's favor if they are "reasonable and logical," but must also "give[] credence" to evidence supporting Teva that was "uncontradicted and unimpeached" at trial. *Integra Lifesciences I, Ltd. v. Merck KGaA*, 496 F.3d 1334, 1345 (Fed. Cir. 2007) (citation omitted).

Where a district court announces an interpretation of the legal standard for lost-profits damages, and bases its jury instructions and evidentiary decisions on that legal interpretation, this Court reviews the legal interpretation *de novo*. *See Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1225 (Fed. Cir. 2014); *Sulzer Textil A.G. v. Picanol N.V.*, 358 F.3d 1356, 1363 (Fed. Cir. 2004).

ARGUMENT

I. The District Court Correctly Concluded that Substantial Evidence Did Not Support Inducement Liability During the Skinny-Label Period.

There are two independent grounds on which this Court may affirm the district court's conclusion that a reasonable jury could not have found that Teva induced infringement during the skinny-label period. First, GSK failed to present substantial evidence that Teva's actions caused doctors to directly infringe the '000 patent. Second, neither the skinny label, which carved out the infringing indication, nor Teva's marketing materials, which made no mention of the infringing method, affirmatively encouraged doctors to infringe.

A. GSK Did Not Present Substantial Evidence to Support a Jury Finding that Teva Caused Doctors as a Class to Infringe.

1. The Unchallenged Jury Instructions Required GSK to Prove the Causation Element.

GSK litigated this case using a class-based theory that Teva caused doctors "as a class" to practice the method of treatment claimed by the '000 patent. Appx12; *see Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1266 (Fed. Cir. 2004) (describing individual and class-based basis theories of infringement); GSK Br. 26. To win at trial, GSK was required to prove a causal relationship between Teva's alleged inducement and physicians' infringement as a class.

Now, however, GSK argues that the jury could *infer* causation from two other elements of an inducement claim—active encouragement and intent—without needing proof that Teva caused anyone to infringe. GSK Br. 25. But the district court rejected this argument before trial and instructed the jury that GSK was required to prove that "Teva's alleged inducement, as opposed to other factors, actually caused the physicians to infringe." Appx11802. During JMOL briefing, GSK did not argue that the district court should assess the jury's verdict under a legal standard different from the one the jury applied. Appx21 n.13. Nor has GSK challenged the jury instructions on appeal. GSK Br. viii. GSK therefore forfeited any argument that it can survive JMOL without providing evidence of causation. *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1319 (Fed. Cir. 2006); *see also C.R. Bard*, 157 F.3d at 1382 (opinion of Bryson, J., joined by Mayer, C.J.) (considering only the "sufficiency of the evidence" under the jury instructions, and not the "legal sufficiency of the jury charge," because the appellant "did not challenge" the jury instructions on appeal).[6]

2. This Court's Precedents Required GSK to Prove the Causation Element, Not Assume It.

Even if GSK were forthrightly attacking the jury instruction, its attack would fail. GSK's argument would create a new type of strict liability for attempted

[6] GSK's amici argue that the jury instructions embraced an erroneous causation standard, but amici cannot raise an issue that GSK has failed to raise as an issue on appeal. *E.g.*, *Christian v. United States*, 337 F.3d 1338, 1345 (Fed. Cir. 2003).

inducement that this Court has already rejected. And its reliance on an unsupported inference—where there's promotion of a product that can infringe, there must be causation of infringement, *see* GSK Br. 25—would make no sense in a case like this one: a mountain of uncontradicted evidence demonstrates that doctors were taught to treat CHF using the patented method well before any generic launch, and continued to rely on that information after generic launch.

This Court rejected an attempt to dispense with the causation element of inducement in *Power Integrations, Inc. v. Fairchild Semiconductor International, Inc.*, 843 F.3d 1315 (Fed. Cir. 2016). The jury was erroneously instructed that "[direct] infringement need not have been actually caused by the [alleged inducer]'s actions," *id.* at 1332 (brackets in original), and that "[a]ll that is required is that the party took steps to encourage or assist that infringement, regardless of whether that encouragement succeeded, or was even received," *id.* This Court vacated the verdict, holding that the instruction "left the jury with the incorrect understanding that a party may be liable for induced infringement even where it does not successfully communicate with and induce a third-party direct infringer." *Id.* at 1330-1331. The Court concluded that "[t]o prevail under a theory of indirect infringement, [plaintiff] must first prove that the defendants' actions *led to* direct infringement." *Id.* at 1331 (emphasis added) (brackets in original) (citation omitted)). It instructed that, on remand, the jury must "be asked to determine

which of [defendant's] customers were induced to infringe by [defendant]." *Id.* at 1329 n.14.

GSK contends (at 26) that *Power Integrations* actually held the opposite—that no proof of causation is necessary. To be sure, this Court stated that the plaintiff was not required to provide "hard proof" of causation. 843 F.3d at 1335. But the proposition that an element can be proven with circumstantial, rather than direct, evidence is unremarkable; the element is still an element. *Id.* In *Power Integrations*, circumstantial evidence that the defendant actually induced direct infringers as a class was available in spades, which is why this Court remanded for a new trial: among other evidence, the defendant specifically designed the chips to make direct infringement possible at its customers' request. *Id.* at 1333-1334.

The other cases GSK cites only reinforce the principle that evidence of encouraging communications is not enough to make a defendant liable for any and every act of infringement that may occur thereafter. Rather, individuals who encourage infringement are liable only "for the *resulting* acts of infringement." GSK Br. 25 (emphasis added) (quoting, *e.g.*, *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1305-1306 (Fed. Cir. 2006) (en banc)). The Supreme Court's copyright-inducement decision in *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913 (2005), which applies equally in patent cases,[7] made this same

[7] *See Takeda*, 785 F.3d at 631 n.3.

point, holding that one who induces infringement, "as shown by clear expression or other affirmative steps taken to foster infringement, is liable *for the resulting acts* of infringement by third parties." *Id.* at 936-937 (emphasis added). The Court's reference to "*resulting* acts of infringement by third parties" indicates that "the inducement principle" includes "causation" as an "element[]." *Columbia Pictures Indus., Inc. v. Fung*, 710 F.3d 1020, 1024, 1032, 1037 (9th Cir. 2013) (so interpreting *Grokster*). GSK simply disregards the key word confirming that induced infringement must *result from* the inducement.

None of the cases GSK cites (at 25-27) for the proposition that causation can be inferred actually discusses this issue. Instead, they address whether other elements of inducement were proven.[8] GSK also cites a number of pre-launch Hatch-Waxman cases in which including a patented indication on the label was sufficient to establish inducement liability. GSK Br. 27-28. But as the district court correctly held (Appx23 n.14), those cases do not bear on the causal showing required to impose *damages* liability for inducement. Before launch, courts address an "artificial" act of infringement—filing an ANDA. *Zeneca Ltd. v. Mylan*

[8] *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1272 (Fed. Cir. 1986) (direct infringement); *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1365 (Fed. Cir. 2012) (same); *DSU*, 471 F.3d at 1306-06 (intent); *Arthrocare Corp. v. Smith & Nephew, Inc.*, 406 F.3d 1365, 1377 (Fed. Cir. 2005) (direct infringement and active encouragement); *Ericsson*, 773 F.3d at 1222 (intent); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1323 (Fed. Cir. 2009) (intent); *Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 244 F.3d 1365, 1379 (Fed. Cir. 2001) (intent and knowledge of the patent).

Pharm., Inc., 173 F.3d 829, 836 (Fed. Cir. 1999). In that posture, the court asks whether the defendant would be *expected* to induce infringement if the generic drug were approved based upon the ANDA. *See Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997); *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365-66 (Fed. Cir. 2003).

Making this distinction clear, this Court noted that the distinguishing characteristic of Hatch-Waxman "artificial infringement" lawsuits under 35 U.S.C. § 271(e)(2)(A) is that "the inquiries … are hypothetical because the allegedly infringing product has not yet been marketed." *Warner-Lambert*, 316 F.3d at 1365. But outside this "hypothetical" context, whether "a generic maker" has "induce[d] someone to infringe can only be determined when that act occurs." *Id.* In the post-launch context, there is no need to hypothesize, and certainly no reason to adopt a one-size-fits-all inference: the court can assess, based on evidence, whether an allegedly inducing communication actually caused infringement. And considering the real-world evidence is critical because, as the Ninth Circuit explained when it applied *Grokster* to an inducement claim for injunctive relief and damages, "the potential severity of a loose causation theory for inducement liability" could lead to liability of an "enormous reach." *Fung*, 710 F.3d at 1037. An overly loose causation standard could effectively "enlarge the scope of" monopolies over products that are "capable of substantial non-infringing uses" and

undermine the balance of interests that intellectual-property laws strike. *Id.* at 1037-1038.

Finally, GSK's effort to avoid proving causation is contrary to the aiding-and-abetting liability regimes that GSK argues are an appropriate analogue to inducement. GSK Br. 46-47 (citing Restatement (Second) of Torts § 876(b) and criminal aiding-and-abetting laws). The Restatement makes clear that giving "encouragement or assistance" is tortious *only* "[i]f the encouragement or assistance is a substantial factor in causing the resulting tort." Restatement (Second) of Torts § 876, Comment on Clause (b); *see also Montgomery v. Aetna Plywood, Inc.*, 231 F.3d 399, 413 (7th Cir. 2000); *Mosier v. Stonefield Josephson, Inc.*, 815 F.3d 1161, 1167–68 (9th Cir. 2016). Criminal aiding-and-abetting laws (and criminal law in general) likewise require the causal showing GSK now eschews. *See, e.g.*, *United States v. Nelson*, 277 F.3d 164, 213 (2d Cir. 2002); N.C. Pattern Jury Instruction 202.20, Aiding and Abetting—Felony, Misdemeanor.[9]

[9] GSK's aiding-and-abetting argument is, however, misplaced for other reasons. The Supreme Court has already rejected the notion that § 271(b) adopted a criminal aiding-and-abetting theory for a civil tort. *See Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2119 (2014) ("[W]e think it unlikely that Congress had this particular doctrine in mind when it enacted the Patent Act …."). And the civil aiding-and-abetting standard in the Restatement is inconsistent with § 271(b): the Restatement permits liability even where a defendant acts negligently, while § 271(b) requires knowledge and intent. Restatement (Second) of Torts § 876 (1979), Comment on Clause (b); *see also United States v. Hitachi Am., Ltd.*, 172 F.3d 1319, 1336-1338 (Fed. Cir. 1999) (patent infringement requires "actively and knowingly aiding and abetting," not negligently doing so). Thus,

In short, inferring causation from evidence of encouragement and intent would impose strict liability on any defendant that makes a single statement that a jury thinks amounts to encouraging infringement, whether or not that statement actually affects anyone.[10] That result would be wholly inconsistent with the cornerstone concept of the tort system: damages are awarded for harm caused by the defendant. *See, e.g.*, *Univ. of Texas Sw. Med. Ctr. v. Nassar*, 133 S. Ct. 2517, 2522 (2013); *see also Wordtech Sys., Inc v. Integrated Networks Sols., Inc.*, 609 F.3d 1308, 1313 (Fed. Cir. 2010) ("Patent infringement is a tort." (citation omitted)).

In some cases, proving this causal connection will be "a straightforward task." *Fung*, 710 F.3d at 1038. In *Power Integrations*, the defendant's chips necessarily infringed the patent if imported into the United States, and the defendant not only designed its chips to meet U.S.-specific standards at customers' request, it affirmatively solicited and facilitated U.S. sales. 843 F.3d at 1333-1335. But in other cases—where, for example, numerous "individuals and entities

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while courts have colloquially compared inducement under § 271(b) to aiding and abetting, Teva is unaware of any court that has actually imported any of the varying *legal standards* for aiding and abetting rather than using the standards for § 271(b) inducement set by this Court and the Supreme Court.

[10] GSK conclusorily attempts to limit its rule to infringement committed after materials are "successfully communicated to customers," GSK Br. 26, perhaps seeking to distinguish the facts (but not the reasoning) of *Power Integrations*. But GSK in fact relies on documents that were *not* communicated to infringing doctors. *See* pp. __, *infra*.

provide services identical" to the alleged inducer, "causation … cannot be assumed." *Fung*, 710 F.3d at 1038.[11] Here, for instance, myriad sources (including GSK's marketing materials) taught the claimed method for ten years before Teva entered the market; generic carvedilol was on the market lawfully and most of its uses were non-infringing, including uses for unpatented indications; substitution is automatic under the laws of most states; *and* nine other generic manufacturers provided a generic carvedilol product "identical to" Teva's. Especially under these circumstances, causation *by Teva* instead of one of these many other factors "cannot be assumed"; it must be proven.

3. GSK Did Not Present Substantial Evidence that Teva Caused Physicians to Directly Infringe.

Given the specificity of the patented method and the numerous sources advising doctors on how to prescribe carvedilol for maintenance treatment—including GSK's own promotion activity—GSK had every reason to anticipate that it would have to prove that it was *Teva*, "as opposed to other factors," that caused doctors to infringe. Indeed, GSK's expert Dr. Reisetter surveyed physicians about their prescription practices. But his survey made no effort to determine whether physicians who prescribed carvedilol even saw the communications GSK now says

[11] GSK's amicus BIO argues (at 23) that evidence of "copying" will "often, but not always, be evidence from which causation can be inferred in generic pharmaceutical cases." BIO cites no authority for this proposition. And because a generic is required to demonstrate bioequivalence to receive FDA approval, BIO's argument would eliminate causation in all ANDA cases.

induced infringement (*i.e.*, Teva's label or marketing materials), much less whether those communications *caused* the physicians to prescribe carvedilol in an infringing way.[12] Dr. Reisetter testified that GSK never asked him to make any effort to obtain this information from doctors, and if it had, he would have designed his survey differently. Appx10742-10743. GSK appears to have specifically avoided collecting this information in the hopes of holding Teva responsible for inducing *every* act of direct infringement that involved the patient taking a Teva product.

Instead, GSK relies (at 28-34) on the skinny label and Teva's marketing materials. But there is no substantial evidence that *any* of these materials actually induced infringement by physicians as a class (or any sub-set of infringing physicians).

The skinny label: As explained above, every expert cardiologist at trial—including GSK's expert—testified that he did not read Teva's label before prescribing carvedilol to treat CHF patients. Appx11151 (Zusman); Appx11296-11297 (Rosendorff); Appx11662-11663 (McCullough). Dr. McCullough even testified that *if* he had read Teva's skinny label, he would not have prescribed

[12] Dr. Reisetter's data even included prescriptions written for "Coreg" rather than carvedilol, but for which pharmacies substituted generic carvedilol because physicians did not expressly specify the brand-name drug. Appx10751.

carvedilol to treat CHF because it was "missing too much information." Appx11660-11661.

GSK repeatedly cites Dr. McCullough for the carefully crafted—but misleading—proposition that "doctors do read generic labels." GSK Br. 15, 33, 34. Dr. McCullough's admission was unambiguous: "[Q.] Now, before you started administering generic carvedilol to your patients, … did you read Teva's generic label? A. No, I didn't." Appx11662-11663. Dr. McCullough testified that he relies on *brand-name* drug labels, not generic drug labels. Appx11653-11654 (questioning was "only talking about innovator labels now"). The only mention Dr. McCullough made of seeing Teva's generic label was his statement that patients sometimes bring their medications in to ask him questions about safety or drug interactions—which would have occurred *after* he prescribed generic carvedilol and a pharmacy filled that prescription with Teva's product. Appx11663.

Press releases: Teva's press statements were released before the '000 patent issued and therefore could not serve as a basis for liability. *See Nat'l Presto Indus., Inc. v. W. Bend Co.*, 76 F.3d 1185, 1196 (Fed. Cir. 1996) ("§ 271(b) does not reach actions taken before issuance of the adverse patent"). Citing no record evidence, GSK asserts (at 29) that Teva's 2004 and 2007 press releases remained

online after the '000 patent issued—but makes no attempt to show that any physician read them during that time.

Moreover, not a single witness testified that physicians rely on press releases to make prescribing decisions or for instructing how to practice a specific method of treatment. Instead, Dr. McCullough testified that press releases are relevant to him because they inform him "when drugs are going generic." Appx11655. And, he testified, "going generic" had no effect on his behavior—pharmacies "automatically" substituted carvedilol for Coreg, and physicians do not choose or even know which generic manufacturer's AB-rated version will be dispensed. Appx10675, Appx10678-10679.[13] On the record here, therefore, press releases did not drive Dr. McCulloch's prescribing practices, or anyone else's.

Websites: Similarly, Dr. McCullough did not testify that physicians looked to Teva's website for information before prescribing carvedilol. Indeed, the only website Dr. McCullough testified about was a *2015* Teva website, and he simply described the website; he did not testify that physicians even read, much less relied upon, this website or any generic-drug website in making prescribing decisions. Appx10686-10688 ("Q. And you are not trying to suggest to the jury here that this

[13] GSK erroneously argues (at 18) that "the jury heard evidence that doctors directly infringed by prescribing Teva's product." There is no support for this assertion in the trial record. Indeed, Dr. McCullough said exactly the opposite: "Q. And then as a physician, as a cardiologist, you don't specify which generic product a patient will get; correct? A. That's correct." Appx 10678.

website had anything to do with the partial label or skinny label period, are you? A. You know, I just don't know.").

Product guides: GSK provided no evidence that doctors who prescribed carvedilol even received Teva's product guides, which Dr. McCullough conceded are "communication[s] from Teva directly to patients," not to physicians. Appx10688-10689. Dr. McCullough testified that he had no idea whether any of Teva's product guides were "actually given to doctors." Appx10686. Communications that the infringer never receives do not cause infringement. *Power Integrations*, 843 F.3d at 1330-31.

What did influence doctors: A "vast amount" of unrebutted direct evidence, including from Dr. McCullough, established that prescribing decisions were driven by other sources entirely. Appx20. He acknowledged, for example, that ACC and AHA guidelines "by 2005 specifically recommended that doctors give carvedilol to heart failure patients," and he agreed that these guidelines were "something that influences the decisions of doctors for how to treat their patients." Appx10668. He also acknowledged myriad sources of information that influenced *his own* decision to prescribe carvedilol, both before and after generic launch: his knowledge and experience as a practicing cardiologist, the ACC and AHA guidelines, the "research that has been published about carvedilol," including articles in the *New England Journal of Medicine* and the *British Heart Journal*,

and GSK's marketing. Appx10676-10677 ("Q. And come September of 2007, when the generics launch, you relied on all those same things; right? A. Sure."). Drs. Zusman and Rosendorff testified that the same sources influence physicians' decision to prescribe carvedilol to treat CHF. Appx11151-11152; Appx11296-11297.

Furthermore, undisputed evidence from *both* parties showed that physicians' prescription practices remained identical before and after generic launch; the only change happened "automatically" at the pharmacy level. Appx10675 (McCullough) ("Q. And when the generics launched, you switched your patients over—right?—to the generic. A. No, I didn't actively switch. I continued to prescribe it. It was automatically switched."); Appx11175-11176 (Zusman).

In fact, doctors do not even prescribe a particular generic. As Dr. McCullough testified, the pharmacy, not the physician, chooses which generic product is dispensed for any given prescription; physicians "are generally unaware of which generic manufacturer of carvedilol the pharmacies will be carrying at any given time." Appx10679; *accord* Appx11088-11089; p. 41 & n.13, *supra*.

All Dr. McCullough did when infringing was write a prescription, without reviewing any generic label or specifying any particular generic. And he based his prescribing decisions on medical knowledge and experience, and on GSK's marketing. Appx10676-10677. Dr. McCullough's testimony therefore does not

provide substantial evidence that he was induced by Teva, "as opposed to other factors," as the unchallenged jury instructions required. Appx11802.

4. GSK Did Not Present Substantial Evidence that Teva Caused Physicians *as a Class* to Directly Infringe.

The defect in GSK's proof is even more fundamental than its mistaken reliance on Dr. McCullough's testimony. As noted above, GSK specifically chose not to try identifying specific physicians, or a specific population of physicians, whom it thought Teva had induced to infringe. Instead, GSK "only asserted a 'class' theory of liability—that is, that Teva induced doctors as a class to infringe"—and sought to recover damages from Teva for *all* physicians' infringing prescriptions whose sales were captured by Teva. Appx12; *see* Appx11833, Appx11837-11838, Appx11922-11923.[14] As this Court has explained, GSK must face the "'all-or-nothing' consequences" of that litigation strategy: if the plaintiff's liability theory presupposes 100% infringement (here, infringement by inducement), then the plaintiff must actually prove 100% infringement to avoid JMOL. *See Pharmastem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1354 (Fed. Cir. 2007) (granting JMOL "simply h[olds the plaintiff] to the consequences

[14] The district court acknowledged that "GSK only asserted a 'class' theory of liability" and later sought to sustain the verdict using a new and distinct theory—that "at least one" doctor was induced to infringe. Appx12. The court concluded that because GSK did not prove either theory, the court need not address whether the "at least one" theory was properly before it. Appx13 n.8.

of the strategy it adopted at trial"); *see also Dynacore*, 363 F.3d at 1274-1275 (describing class-based and individual theories of liability).

Thus, even if Dr. McCullough's testimony were substantial evidence that *he* was induced by Teva, evidence that *one* doctor was induced could not support the jury's verdict of liability for *millions* of infringing uses by doctors across the country; that would be irreconcilable with principles of "fault-based liability derived from the common law," *Fung*, 710 F.3d at 1038 (citing *Grokster*); *see also Dynacore*, 363 F.3d at 1274 (explaining that class-based liability theories permit recovery "across an entire category" of infringers, but plaintiff asserting "individual" liability theories must "tie their claims for damages" to individual acts); *PharmStem*, 491 F.3d at 1354. Unlike in cases in which there is a "single producer" of the accused product, *Fung*, 710 F.3d at 1038, there could be no reasonable assumption that Teva caused every single infringing prescription that happened to be filled with Teva's product rather than another generic's—something doctors do not control, *see* p. 41 & n.13, *supra*.

Further, the evidence at trial of physicians who were *not* induced by Teva only underscores why an inference that *all* infringing uses were induced by Teva "was an unreasonable one for the jury to have drawn." Appx21. In this case, ten generic manufacturers launched after GSK spent ten years educating doctors how to use carvedilol. And each of the expert cardiologists in this case testified that his

prescription practices were informed by the exact same information (not Teva-produced) before and after generic launch. Appx10668, Appx10676-10678, Appx11151-11152.

A patentee cannot seek damages across an entire category of alleged infringers without substantial evidence that the defendant actually induced the entire class of infringers to directly infringe. On these facts, and others, GSK cannot simply assert *without proof* that Teva's communications caused *the class of doctors* to infringe.

B. GSK's Failure to Present Substantial Evidence that Teva Actively Encouraged the Infringing Method Provides an Alternative Ground for Affirmance During the Skinny-Label Period.

If the Court disagrees with Teva and the district court regarding causation, it may nonetheless affirm because GSK failed to present substantial evidence that Teva actively encouraged doctors to practice the claimed method.

To prove active inducement, GSK was required to prove that Teva "took an affirmative act to encourage" physicians to perform "every single step" in the patented method. *Power Integrations*, 843 F.3d at 1332; *Ericsson*, 773 F.3d at 1219; *see also* Appx11797. And the patented method requires more than just the use of carvedilol to treat CHF, which the prior art already taught. Appx12264; pp. 6-8, 11, 16, *supra*. Additional steps include the specific treatment objective of decreasing mortality caused by CHF, the use of a maintenance dose, concomitant

treatment with one of three specified therapeutic agents, and a treatment period of at least six months. *See* pp. 6, 16, *supra*.

GSK has argued that Teva actively encouraged physicians to infringe through the skinny label and through promotional materials, including Teva's press releases, product guides, and website. GSK Br. 32-33, 35. The district court correctly rejected these arguments and concluded that Teva did not actively encourage infringement of the claimed method. Appx15-18 & nn.9-10.

1. The Skinny Label Does Not Encourage the Infringing Method.

GSK contends that Dr. McCullough testified that the skinny label, which *carved out* the CHF indication and all content FDA found related, nonetheless "instructed doctors to perform each step of the claimed method." GSK Br. 32. But as the district court observed, Dr. McCullough's testimony "does not show Dr. McCullough stating what GSK seems to think he said." Appx13.

a. Dr. McCullough was never asked whether the label "instructed" or "encouraged" the treatment of CHF. Instead, GSK sought to elicit testimony from him about whether a physician *could* find "enough information" in disparate portions of labeling that, when combined, *could* satisfy each of the claim's limitations. Appx10622-10623. Dr. McCullough testified, for example, that "[i]n the Section 5.4" of the skinny label, "there's a mention that worsening heart failure or fluid retention may occur during the up-titration of carvedilol" that he believed

corresponded to the first claim limitation. Appx10623. He also testified that the skinny label could satisfy the third claim limitation because "in the description of the studies" discussed in Section 14.1 of the skinny label, ACE inhibitors and diuretics are "mentioned." Appx10625; *see* Appx5523.

This testimony is not evidence of active inducement. An inducing drug label must "encourage, recommend, or promote" the infringing method, not merely contain isolated statements that, cobbled together in hindsight, might allow a doctor to infer an infringing method-of-treatment. *Takeda*, 785 F.3d at 631; *cf. Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1322-1323 (Fed. Cir. 2012) ("mentions" of elements of patented uses that are carved out from a label's "Indications and Usage section" do not "recommend[] or suggest[]" that physicians administer the drug for carved-out indications). For products with legitimate, non-infringing uses, like carvedilol, "showing that infringement was encouraged" is necessary to "overcome[] the law's reluctance to find liability when a defendant merely sells a commercial product suitable for some lawful use." *Grokster*, 545 U.S. at 936. This showing is particularly important in the generic-drug context because the Section viii carve-out was created specifically to allow a generic manufacturer to "avoid liability 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 purposes.'" *Takeda*, 785 F.3d at 631 (quoting

Caraco Pharm. Labs. v. Novo Nordisk A/S, 566 U.S. 399, 415 (2012)). This was so even though Congress *knew* that carve-outs "would result in some off-label infringement." *Id.* at 631.

GSK therefore cannot rely on "vague label language … combined with speculation about how physicians may act to find inducement." *Takeda*, 785 F.3d at 632; *Warner-Lambert*, 316 F.3d at 1365 (ANDA seeking approval for unpatented use "does not induce anyone to perform the unapproved acts required to infringe"). Instead, only where a carved-out label's references "would inevitably lead [doctors] to practice the claimed method" can the label induce infringement. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010); *see also Takeda*, 785 F.3d at 634 (distinguishing *AstraZeneca* from typical carve-out label that does not encourage patented method).

Bits of "vague label language" and speculation about how doctors might put them together are all that GSK offers. GSK presented no evidence that the isolated statements taken from disparate portions of Teva's carved-out label would "inevitably lead" doctors to prescribe generic carvedilol using a method that was intentionally omitted from the label. Indeed, GSK's expert rejected GSK's own theory: Dr. McCullough testified that a label omitting the CHF indication and warnings, as the skinny label did, is "missing too much information" to encourage him to prescribe carvedilol for CHF. Appx11660-11661. Thus, Dr. McCullough's

"'scholarly scavenger hunt' through the label to identify statements that may inferentially but not inevitably tie a physician's thoughts or acts … necessarily fails" as a method of proving inducement. *United Therapeutics Corp. v. Sandoz, Inc.*, No. 12-CV-01617, 2014 WL 4259153, at *19 (D.N.J. Aug. 29, 2014).

b. GSK also argues (at 10) that "this wasn't a true section viii carveout" because "the label still included the post-MI LVD indication." GSK's apparent position is that the post-MI LVD label is also infringing because it includes several references to "heart failure," such as "language warning of the risk of 'worsening heart failure' when patients first use its product" and language stating that carvedilol can be used to treat patients who survived a recent heart attack and have reduced ejection fraction "with or without symptomatic heart failure." GSK Br. 11.

First, this attempt to cobble together scattered references to "heart failure" is not proof of inducement given Teva's actions in carving out this very indication—as another district court correctly concluded in a factually similar case, granting summary judgment of no inducement where the label carved-out a heart-failure indication but still made some "reference to heart failure" in "the 'Warnings' and 'Precautions' sections." *Aventis Pharma Deutschland GmbH v. Cobalt Pharm., Inc.*, 355 F. Supp. 2d 586, 599 (D. Mass. 2005).

If GSK thought otherwise, it would have listed treatment of post-MI LVD in the Orange Book, but it did not. GSK drafted its own "use code" for FDA to identify which indications were covered by its patents. Appx6881-6882; Appx7831-7834; Appx11041-11042; 21 C.F.R. § 314.53(c)(2)(ii). The very purpose of use codes is to give generic manufacturers notice of what uses they would need to carve out to avoid infringement. *Caraco*, 566 U.S. at 420; Appx10888-10890; Appx11056. This listing provision "provides the basis for a lawsuit" by the brand drug company if a generic manufacturer seeks approval of *one of the listed uses*. *Warner-Lambert*, 316 F.3d at 1361. But if the generic manufacturer seeks approval of *other* uses, this Court has been unwavering: the brand-name company *cannot* sue to keep that generic manufacturer off the market, even if generic launch would naturally lead to off-label infringing sales. *E.g.*, *id.* at 1361-1362; *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1334 (Fed. Cir. 2003).

Yet at no time until after this lawsuit was filed in 2014 did GSK ever indicate that the post-MI LVD indication was covered by the '000 patent or its predecessor, the '069 patent. Instead, signing under penalty of perjury, GSK informed FDA that the CHF indication—and only the CHF indication—was claimed by its method-of-use patents. Appx6894-6907; Appx6880-6887; Appx11039-11044. As a result, the Orange Book never listed post-MI LVD as an

infringing use. *E.g.*, Appx6865-6872; Appx6863; Appx7831-7834; Appx10888-10890. Teva carved out the listed CHF indication so it could launch, precisely as Congress intended. *Warner-Lambert*, 613 F.3d at 1361.

Indeed, GSK's regulatory expert conceded that Teva's label "was not" approved for CHF. Appx10584. GSK therefore would have been prohibited from suing to keep Teva off the market, *Warner-Lambert*, 613 F.3d at 1361-1362, and it would be a perverse result indeed if GSK were nevertheless permitted to lie in wait for years and then sue for hundreds of millions of dollars in supposedly lost sales for uses that GSK never claimed as covered by the '000 patent in the Orange Book. Such a result would *undermine*, not advance, Congress's goal "of making available 'more low cost generic drugs'" through the Section viii carve-out. *Id.* at 1359; *see also Allergan*, 324 F.3d at 1333 (allowing a patent-infringement lawsuit for induced infringement of off-label method-of-use patents "would 'confer substantial additional rights on pioneer drug patent owners that Congress quite clearly did not intend to confer'" (citation omitted)).

Second, GSK gains no support from the fact that "some post-MI LVD patients have … heart failure," GSK Br. 41; *see also id.* at 33. The '000 patent does not claim the use of carvedilol in "patients [who] have heart failure," GSK Br. 41. Nor, contrary to GSK's repeated assertions (*e.g.*, at 11, 12, 13, 16, 17, 18, 19,

20, 30, 32), does it even claim the use of carvedilol to *treat* heart failure. The prior art already taught that use.

Rather, the '000 patent claims a particular use of carvedilol to treat CHF with the specific intent to decrease mortality *caused by symptomatic CHF*. Appx45; Appx138-139. As Dr. Zusman testified without contradiction, this is different than using carvedilol when treating post-MI LVD, where doctors "are treating them to help them survive their heart attack"; they are "not treating heart failure." Appx11183. This testimony was not only unrebutted and therefore must be "giv[en] credence," *Integra Lifesciences*, 496 F.3d at 1345, it was buttressed by the testimony of one of the inventors: Dr. Shusterman described the CAPRICORN study that served as the basis for FDA approval of the post-MI LVD indication as a trial that asked specifically about the use of carvedilol for "postmyocardial infarction therapy." Appx11522. While GSK now emphasizes (at 40) "overlap" between post-MI LVD patients and CHF patients, Dr. Shusterman testified that the CHF and post-MI LVD populations are "[f]undamentally different patient group[s]" with "[f]undamentally different physiology going on,"Appx11522-11523—so distinct that patients with post-MI LVD were excluded from the CHF clinical trials. *Id.*; Appx11183; Appx11515.

Indeed, the skinny label makes clear that whether a patient has symptomatic CHF is irrelevant to the post-MI LVD indication: the indication is for post-MI

LVD patients "*with or without* symptomatic heart failure." Appx5508 (emphasis added). Language, like this, that is "indifferent to" a key claim limitation cannot encourage an infringing use. *E.g.*, *Acorda Therapeutics, Inc. v. Apotex, Inc.*, No. 07-4937 (GEB-MCA), 2011 WL 4074116, at *18 (D.N.J. Sept. 6, 2011), (label's "with or without food" language did not encourage administration of drug with food), *aff'd*, 476 F. App'x 746 (Fed. Cir. 2012). Because the post-MI LVD indication instructs doctors to treat post-MI LVD irrespective of whether it is accompanied by symptomatic CHF, a reasonable jury could not have found that this indication instructs the infringing use.

Finally, even if GSK *had* presented evidence that the skinny label encouraged doctors to prescribe carvedilol to the subset of post-MI LVD patients who also had symptomatic CHF, this was not the basis of GSK's liability or damages theory at trial. GSK presented evidence (through Dr. Reisetter) about the percentage of carvedilol used to treat *all* patients with symptomatic CHF. Appx10706-10707. GSK has never made any attempt to quantify any subset of post-MI LVD patients who also had CHF, much less to quantify the percentage of carvedilol prescriptions used to treat this subset to reduce mortality caused by symptomatic CHF. This argument therefore cannot support the jury's verdict. *See PharmaStem*, 491 F.3d at 1355.

2. Teva's Press Releases Do Not Encourage the Infringing Method.

Teva's 2004 and 2007 press releases cannot serve as a basis for inducement liability because both were issued before the '000 patent was issued in 2008; they cannot have affirmatively encouraged infringement of claims that did not yet exist. *See Nat'l Presto*, 76 F.3d at 1196. But even disregarding timeframe, these press releases could not have actively encouraged the patented method.

The 2004 press release is the only communication that made any mention of CHF. But that press release was issued when Teva intended to launch with the CHF indication because, as it certified, the '069 and '821 patents were invalid. And GSK never contested that invalidity certification. Appx7017-7018; Appx3003-3019; Appx10893. The 2004 press release cannot be read to actively encourage different and narrower claims that did not yet exist, *cf. Global-Tech*, 131 S. Ct. at 2068 (inducement requires knowledge of the patent), even after Teva changed course, carved out the infringing use, and removed heart failure from all marketing materials. *See Worldwide Home Prods., Inc. v. Time, Inc.*, No. 11 Civ. 03633(LTS)(MHD), 2012 WL 6705876, at *2 (S.D.N.Y. Dec. 21, 2012) (no encouragement from acts two years prior to patent's issuance).

Furthermore, the 2004 press release simply stated that carvedilol was "indicated for treatment of heart failure and hypertension." Appx7437. Again, despite GSK's repeated and erroneous insistence, "treat[ing] heart failure" is not

"the patented use." GSK Br. 29; *accord id.* at 32 ("one of its press releases explicitly told doctors to use the product to 'treat heart failure' (the infringing use)"); *id.* at 44. Absent instruction on the narrow method of treatment GSK *actually* patented, the press release could not have encouraged infringement. *See Ericsson*, 773 F.3d at 1219.[15]

GSK suggests (at 29) that Teva's inclusion of Coreg's full revenues in the press releases encouraged infringement. This is an illogical proposition at best. Listing total product revenues does not even "describ[e] the infringing mode," much less teach the specific infringing use as is required to encourage infringement. *Takeda*, 785 F.3d at 631 (brackets in original). FDA likewise included information about Coreg's revenues, yet no one would reasonably suggest it encouraged infringement by doing so. Appx7116.

Inducement requires a "clear expression or other affirmative steps taken to foster infringement." *Grokster*, 545 U.S. at 918. This standard requires a "high degree of proof": evidence of affirmative encouragement "must be plain and must be affirmatively communicated through words and actions," or else inducement

[15] Similarly, GSK (at 29) argues that the description of generic carvedilol as a "cardiovascular agent" in the 2007 press release (Appx6353) would have indicated to doctors that the product could be used to treat "heart failure" (which, again, is not the patented method). But "cardiovascular" is a general term meaning "of, relating to, or involving the heart and blood vessels," which is not in any way specific to CHF and applies equally to post-MI LVD and hypertension, as well as treatment of *any* heart-related condition. *Webster's Third New International Dictionary* 338 (2002).

liability will "discourage[] the development of technologies with lawful and unlawful potential." *Fung*, 710 F.3d at 1034 (citing *Grokster*, 545 U.S. at 936-937). Press releases that do not mention, much less teach, the infringing method do not come close to meeting this standard.

3. Truthfully Disclosing An "AB" Rating Does Not Encourage the Infringing Method.

The marketing materials Teva issued after the '000 patent issued do not "recommend[]," or even describe, the infringing method of treatment. *Takeda*, 785 F.3d at 631; *see, e.g.*, Appx6214 (product catalog, which simply lists Teva's generic pharmaceuticals along with a reference to their respective brand-name reference drugs). Instead, GSK argues that Teva promoted infringement by stating in these materials that generic carvedilol was the "AB-rated," "generic version" of Coreg or that Coreg was the "Brand Equivalent" of carvedilol. GSK Br. 29-30. GSK argues that Teva led doctors to believe that the brand-name and generic versions were "therapeutically equivalent." *Id*.

But truthfully disclosing an AB rating of a product with multiple non-infringing uses cannot be inducement. An AB rating *does* indicate therapeutic equivalence. The AB-rating system is literally called a "*therapeutic equivalence* evaluation," as GSK's regulatory expert, Prof. Lietzan, testified. Appx10544-10545 (emphasis added); *see also* Appx10533-10534 ("AB rated is shorthand for therapeutically equivalent."); Appx6256 (describing AB rating and therapeutic

equivalence evaluation). The Orange Book includes the same AB listing and carvedilol-Coreg comparison. Appx6866-6867. And when FDA approved generic carvedilol in 2007, its press release made this comparison too, stating: "The U.S. Food and Drug Administration today approved the first *generic versions* of Coreg (carvedilol)." Appx7116 (emphasis added). It also identified the therapeutic equivalence of generic drugs: "Generic drugs … use the same active ingredients as brand-name drugs *and work the same way*." *Id.* (emphasis added). GSK's position would accuse *FDA* of inducing infringement.

As the district court concluded, AB ratings and generic drugs approved through Hatch-Waxman's abbreviated approval process are *inherently* comparative. Appx17. The entire point of abbreviated drug approval is that a generic manufacturer must prove that its generic drug "is bio-equivalent to" and uses "the same active ingredients as *the reference drug*." *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348, 1350 (Fed. Cir. 2012) (emphasis added). Saying that a generic drug is "AB-rated" alone would be akin to saying a product "is comparable" or "is equivalent" without stating what the product is comparable or equivalent *to*.

Moreover, listing the AB rating cannot by itself encourage the infringing use that was omitted from the skinny label because, as Prof. Lietzan testified, "AB rating means that it's therapeutically equivalent *as labeled* …. [W]hat it means is

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." Appx10542 (emphasis added); *accord* Appx10534.[16]

Operating under this regulatory scheme and making the same truthful comparisons FDA makes—comparisons that are necessary for the *non*-infringing uses—cannot subject Teva to liability. *See Organon, Inc. v. Teva Pharm., Inc.*, 244 F. Supp. 2d 370, 379 (D.N.J. 2002) (marketing a generic "as an AB-rated bioequivalent … is the only realistic way to market their product at all"), *dismissed sub nom. Organon Inc. v. Mylan Pharm., Inc.*, 56 F. App'x 497 (Fed. Cir. 2003). This is why GSK's complaint (at 45) that Teva's marketing "piggybacked on GSK's prior marketing" is misplaced: a generic drug company "necessarily 'piggybacks'" on the brand company's work. *Warner-Lambert*, 316 F.3d at 1362. That is exactly how the Hatch-Waxman system is set up, including the carve-out option. If GSK is dissatisfied with this system, it should seek legislative relief, rather than seek to upend this Court's inducement doctrine.

GSK cites a series of inapposite cases to show that Teva's materials actively encouraged infringement. GSK Br. 31. Most do not even discuss the encouragement element; they address whether the claimed methods were directly

[16] GSK has never cited any authority suggesting that a direct infringer's *erroneous interpretation* of objectively non-encouraging language could "promote" or "instruct" an infringing use, nor is Teva aware of any authority to this effect.

infringed, and whether the knowledge and intent elements were satisfied. *Ericsson*, 773 F.3d at 1222; *Toshiba*, 681 F.3d at 1365; *Moleculon*, 793 F.2d at 1272; *Mentor*, 244 F.3d at 1379.

The three cases that do discuss active encouragement involved precisely the type of "high degree of proof" and "clear message" required. *Grokster*, 545 U.S. at 918; *Fung*, 710 F.3d at 1034. In *Power Integrations*, the defendant encouraged infringement (the importation of patented products) by specifically designing the infringing controller chips to meet U.S. standards and by indemnifying customers against claims for infringement of U.S. patents. 843 F.3d at 1315. In *Lucent*, the defendant likewise designed its software products to infringe and then provided tutorials instructing users how to operate those products in an infringing manner. 580 F.3d at 1301. In *Arthrocare*, the defendant's sales literature expressly instructed surgeons to use the accused medical device "to prevent tissue contact with the return electrode," which was the infringing method. 406 F.3d at 1377. None of these cases support GSK's argument that communications that do not even reference, much less instruct, the claimed method can express a clear message encouraging infringement.

4. GSK Has Abandoned the "Inducement by Silence" Theory It Emphasized to the Jury.

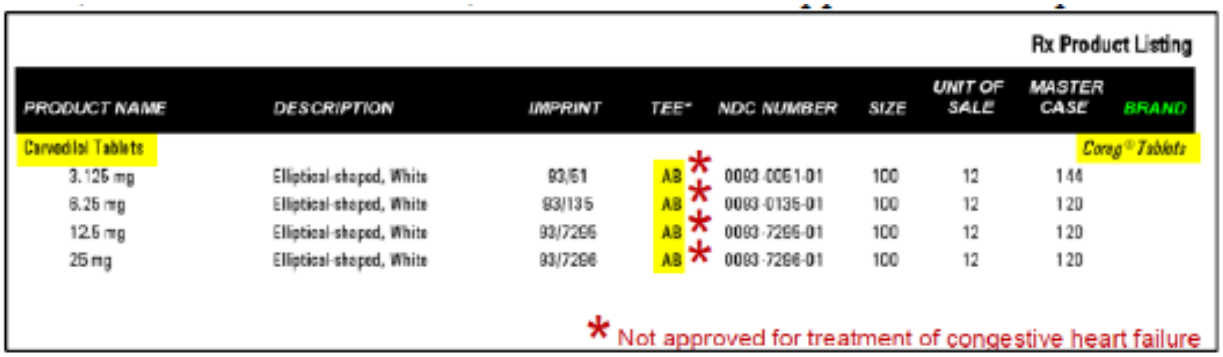
GSK repeatedly argued to the jury that Teva had failed to include an "asterisk" or "fine print" on its promotional materials expressly stating that its

product is not approved to treat CHF, and argued that "the import" was that Teva "induced doctors to infringe." Appx11859-11861. GSK even used demonstratives with asterisks and disclaimers to make the point:


Jerusalem, Israel, September 6, 2007 - Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA) announced today that the U.S. Food and Drug Administration (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, 3.125 mg, 6.25 mg, 12.5 mg and 25 mg. Shipment of this product will begin immediately.

The brand product had annual sales of approximately $1.7 billion in the United States for the twelve months ended June 30, 2007, based on IMS sales data.

* Not approved for treatment of congestive heart failure


Rx Product Listing

PRODUCT NAME	DESCRIPTION	IMPRINT	TEE*	NDC NUMBER	SIZE	UNIT OF SALE	MASTER CASE	BRAND
Carvedilol Tablets								Coreg® Tablets
3.125 mg	Elliptical-shaped, White	93/61	AB *	0093-0061-01	100	12	144	
6.25 mg	Elliptical-shaped, White	93/135	AB *	0093-0135-01	100	12	120	
12.5 mg	Elliptical-shaped, White	93/7295	AB *	0093-7295-01	100	12	120	
25 mg	Elliptical-shaped, White	93/7296	AB *	0093-7296-01	100	12	120	

* Not approved for treatment of congestive heart failure

Appx11859-11860; Appx12473; *see also* GSK Br. 35.

GSK has wisely dropped its inducement-by-omission theory on appeal, effectively conceding that a key argument that GSK used to win before the jury is incorrect as a matter of law under this Court's binding precedent. *See Takeda*, 785 F.3d at 632 n.4 ("[GSK] needs to show that [Teva] took affirmative steps to induce, not affirmative steps to make sure others avoid infringement.").[17] All that

[17] In its opening brief (at 35), GSK has repackaged its failure-to-disclaim argument, now using it to prove the intent to induce. But *Grokster* makes clear

remains, however, are accurate statements about carvedilol's AB rating and therapeutic equivalence to Coreg. These types of statements in promotional materials do not approach the type of "purposeful, culpable expression and conduct" that is required to prove encouragement. *Grokster*, 545 U.S. at 937.

II. The District Court Correctly Concluded that Substantial Evidence Did Not Support a Finding that Teva Caused Physicians to Directly Infringe During the Amended-Label Period.

GSK criticizes the district court's analysis of causation during the amended-label period as "brief." GSK Br. 21. But the court did not need to belabor its discussion: after the court correctly determined that GSK failed to provide substantial evidence of causation during the partial-label period, GSK's failure to prove causation during the amended-label period was virtually conceded.

It was undisputed that GSK lost nearly all of its market share immediately upon generic launch and before the '000 patent even issued. Appx6768. And by the time FDA instructed Teva to amend its label in April 2011, GSK had already lost 99.3% of its market share to generic manufacturers. Appx6770. GSK's counsel conceded at oral argument that there was minimal, if any, market impact as a result of the label amendment. Appx12204-12205. Indeed, during the amended-

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that the failure to discourage infringement "would not be independently sufficient" to prove intent. *Fung*, 710 F.3d at 1035 (citing *Grokster*, 545 U.S. at 939 n.12). And the only other evidence it cites to prove intent (at 35)—Teva's "expectation" that physicians would prescribe carvedilol off-label—is "legally irrelevant" to the intent element. *Warner-Lambert*, 316 F.3d at 1364.

label period, GSK's market share stayed virtually identical, and Teva's market share *decreased* from 46% to 31%. Appx6770-6772.

GSK's experts corroborated the lack of any causal connection during the amended-label period. Dr. Reisetter testified that among the 200 physicians he surveyed, there was no change in prescription patterns after Teva amended its label. Appx10754. Dr. McCullough similarly testified that there was "no difference in [his] prescribing habits from when Teva had its skinny label to after Teva amended to have its [amended] label." Appx10699. Not one expert cardiologist testified that he even knew Teva amended its label in 2011, much less that the amendment influenced prescribing decisions. *See, e.g.*, Appx11192-11193, Appx11207; Appx11296-11297.[18]

Given this unrebutted evidence conclusively demonstrating that the amended label had no impact on physicians' prescribing practices or GSK's market share, the district court correctly concluded that GSK failed to prove causation. Appx24.

[18] GSK also argues that Teva's "Prescribing References" instructed the infringing method. GSK Br. 36-37. But GSK provided no evidence that this document influenced the prescribing decisions of physicians, who had been prescribing carvedilol for nearly 15 years by that point. Indeed, Dr. McCullough testified that it was *not* his view that the Prescribing References encouraged the use of Teva's generic product, and he did not testify that this document influenced even his own prescribing decisions. Appx10680.

III. If this Court Does Not Affirm the JMOL, GSK Is at Most Entitled to a Reasonable Royalty on Remand.

If this Court does not affirm the district court's JMOL ruling, it should vacate the jury's lost-profits award and remand for the district court to award a reasonable royalty, because GSK failed to prove that, but for Teva's inducement, GSK would have captured and profited from Teva's sales. GSK's lost-profits analysis incorrectly ignored other generic drug companies that were lawfully on the market, that have never been accused of inducement, and that would have captured Teva's sales instead of GSK. The district court denied Teva summary judgment on this basis, and based on that ruling proceeded to make evidentiary and jury-instruction rulings that allowed GSK's damages expert to ignore, and prohibited the jury from considering, the effect of other generic manufacturers' carvedilol products lawfully on the market.

A plaintiff that establishes liability by a defendant "is entitled to damages to put it in the same position it would have occupied had the harmful act never occurred"—in patent cases as in all compensatory-damages cases. *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1284 (Fed. Cir. 2017). For a patentee to recover lost profits from an infringing competitor, the patentee must show "that but for the infringer's improper acts, [the patentee] would have made greater sales, charged higher prices or incurred lower expenses." 7 *Chisum on Patents* § 20.05 (2018); *accord Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538,

1545 (1995). This requirement exists because patent damages under 35 U.S.C. § 284 are intended only "to restore the owner to the financial position he would have enjoyed had the infringer not engaged in unauthorized acts in violation of the owner's exclusive patent rights." 7 *Chisum on Patents* § 20.01. They "make the patentee whole, as opposed to punishing the infringer." *Riles v. Shell Exploration & Prod. Co.*, 298 F.3d 1302, 1312 (Fed. Cir. 2002). Thus, the "determinative question" in awarding lost profits is: "had the Infringer not infringed, what would the Patent Holder-Licensee have made?" *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1350 (Fed. Cir. 1999) (citation omitted)). Here, the "Infringer" is Teva and Teva's alleged "unauthorized" or "harmful" acts were inducing doctors to prescribe generic carvedilol for a patented use. The damages inquiry, therefore, should ask what position GSK would have been in but for the challenged inducement.

GSK and its damages expert ignored these well-established principles by disregarding the eight generic carvedilol manufacturers that have never been accused of inducement and whose products concededly would have been lawfully available during the damages period. There has never been any dispute, as a factual matter, that GSK would not have made a single additional sale of Coreg in the absence of Teva's (or any other generic's) alleged inducement, based on the legal structures and economic realities that exist in the prescription-drug

marketplace. Congress created in Hatch-Waxman a mechanism for generic manufacturers to market and sell a generic version of a drug for which certain indications are claimed by method-of-use patents by carving out patented indications from the generic label. *Warner-Lambert*, 316 F.3d at 1360. Although drug manufacturers are not permitted to advertise unapproved indications, state pharmacy laws all permit or require substitution of AB-rated generic drugs for brand-name drugs irrespective of the indications on the label. Appx10751; Appx11031-11033, Appx11037-11038; Appx11076-11077, Appx11084-11087. Thus, even if generic manufacturers abide perfectly by all laws and regulations, and fully carve out patented uses from their labels, generic drugs will be dispensed by pharmacies for patented indications.

By all accounts, that is precisely what happened here. GSK has never suggested that any of the eight generic carvedilol manufacturers besides Teva and Glenmark engaged in any "improper" or "unauthorized" acts, yet their generic drugs were substituted for Coreg by pharmacies in large numbers. Indeed, the eight generic manufacturers that have never been accused of inducement account for more than half of the carvedilol market for the majority of the damages period. Appx6769-6772. GSK has never provided any evidence that, if those competitors' products are taken into consideration, GSK would have captured any of Teva's

sales. Indeed, by instruction of GSK's lawyers, Dr. Maness did not even consider this question. Appx12303; Appx10840-10841.

Despite GSK's disregard for the other generic manufacturers that "would have made the sales that were made by the infringer[s]" if Teva and Glenmark had never entered the market, *Rite-Hite*, 56 F.3d at 1545, the district court excluded that evidence from trial as *per se* irrelevant. Appx195; Appx221-224. The court concluded that the but-for world must, under *Panduit Corp. v. Stahlin Brothers Fibre Works, Inc.*, 575 F.2d 1152 (6th Cir. 1978), take into consideration only non-infringing "products." Appx223; *see also* Appx234-239.

The district court's conclusion was erroneous. Any damages analysis, including the but-for world, must be tethered to the type of infringement committed by "the infringer" being sued—here, Teva. *BIC Leisure Prod., Inc. v. Windsurfing Int'l, Inc.*, 1 F.3d 1214, 1217 (Fed. Cir. 1993); *see also Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 507 (1964) (plurality opinion) ("[T]o determine the damages that may be recovered from Aro here, we must ask how much CTR suffered *by Aro's [indirect] infringement*—how much it would have made *if Aro had not infringed*." (emphases added)); 7 *Chisum on Patents* § 20.01 ("The means of achieving this goal of full compensation necessarily varies with the circumstances of the case," including "*the nature and extent of the infringer's illicit acts*." (emphasis added)). Properly factoring infringement "out of

the economic picture," *Grain Processing*, 185 F.3d at 1350, does not require courts to ignore economic reality; it requires courts to disregard the defendant-competitor's "unauthorized" or "harmful" acts—here, inducement. *Mentor*, 851 F.3d at 1284, 7 *Chisum on Patents* § 20.01.

Indeed, the but-for world even has to account for steps the defendant *could have taken* to avoid infringement. *See Grain Processing*, 185 F.3d at 1350-1351; *Janssen Biotech, Inc. v. Celltrion Healthcare Co. Inc.*, 239 F. Supp. 3d 328, 331 (D. Mass. 2017); *Apple Inc. v. Samsung Elecs. Co. Ltd.*, No. 11-CV-01845-LHK, 2013 WL 5958172, *2–3 (N.D. Cal. 2013)). And here, according to GSK, Teva could have avoided infringing by inducement by omitting from its marketing materials information comparing Coreg as the brand-name, AB-rated "version" of carvedilol, and by labeling its product with only the hypertension indication, which GSK has never alleged to be an infringing use. GSK Br. 29-33. If Teva had done so, experts for both parties acknowledge that the result would have been exactly the same: Teva's product still would have been AB-rated, and pharmacies would have "automatically" substituted generic carvedilol for Coreg for off-label uses under state substitution laws, irrespective of the indication on the label. Appx10675; Appx11662 (McCullough); Appx11083-11085 (Kinsey); Appx11037 (Karst).

Courts faced with similar facts have previously recognized that the effect of allowing other generic products to remain on the market cannot be ignored if the requirement of a *realistic* market reconstruction is to have any teeth. *In re Gabapentin Patent Litigation*, No. CA 00-CV-2931 FSH, 2011 WL 1807448 (D.N.J. May 12, 2011), is one example. There, brand-name manufacturers sued some but not all generic manufacturers. The patentees asked the court to exclude from the but-for world the generic manufacturers that the patentees had chosen not to sue or had permitted to stay on the market after settling patent-infringement lawsuits against them. *Id.* at *5. The court denied the patentees' motion, holding that the presence of other generic versions of gabapentin were "relevant to the calculation of lost profits damages" because they "may alter the marketplace in a way that is relevant to lost profits." *Id.* at *6; *see also Abbott Diabetes Care Inc. v. Roche Diagnostics Corp.*, No. C05-03117 MJJ, 2007 WL 4166030, at *2–3 (N.D. Cal. Nov. 19, 2007) (similar).

GSK may argue that *Panduit* compels a contrary conclusion, but this Court has recognized that the *Panduit* factors are not always a good fit because they include "inherent assumptions" about the way the marketplace works that are sometimes misplaced, particularly when the market has more than two suppliers of a product. *BIC*, 1 F.3d at 1217-1218. Cases applying *Panduit* that GSK cited below, for example, involved infringing *products* that were not lawfully on the

market and competitors that directly infringed by making and selling those products. *See, e.g.*, *Panduit*, 575 F.2d at 1160. In such cases, disregarding those sales from the but-for world makes sense because the products were on the market unlawfully and it was the *competitors'* infringement that "interfered with [the patentee's] monopoly." *Yale Lock Mfg. Co. v. Sargent*, 117 U.S. 536, 553 (1886). GSK lacked a market monopoly for Coreg, however, and any interference with GSK's narrow method-of-use monopoly would have resulted from independent legal structures and market forces, even without infringement by any competitor. Applying *Panduit* here by factoring out direct infringement by doctors that were not induced by any generic competitor would distort the but-for world rather than assist in identifying it, as the test is intended. *See BIC*, 1 F.3d at 1218.

The ultimate question is not whether the *Panduit* factors are satisfied, but whether the patentee would have made the defendant's sales but for *the defendant's* infringement. *Grain Processing*, 185 F.3d at 1350. Making this determination is a "highly case-specific and fact-specific analysis," *Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359, 1366–67 (Fed. Cir. 2008), that "necessarily varies with the circumstances of the case," 7 *Chisum on Patents* § 20.01. "[T]he question of legal compensability is one to be determined on the facts of each case upon mixed considerations of logic, common sense, justice, policy and precedent." *Rite-Hite*, 56 F.3d at 1546 (quotation marks omitted).

As GSK has pointed out, this is "a very fact specific case that [the court] may not have ever seen before and may not ever see again." Appx12162, Appx12179, Appx12200. And on the specific facts of this case, logic, common sense, justice, federal and state policy, and case law all point in Teva's direction. While the but-for analysis is supposed to reconstruct a hypothetical market using "sound economic proof of the nature of the market," GSK's position and the district court's conclusion rely on a fictional market that both parties and this Court agree would never exist. *Grain Processing*, 185 F.3d at 1350. Pharmaceutical substitution of generic drugs for patented indications is precisely the way Hatch-Waxman "was designed" to work. *Takeda*, 785 F.3d at 631. GSK would not have been able to stop generic carvedilol manufacturers that properly carved out infringing indications from entering and remaining on the market, *see Warner-Lambert*, 316 F.3d at 1363-1366, nor would GSK have been able to stop pharmacies from substituting generic carvedilol for Coreg as required or permitted in every state, *see* Appx10675; Appx11662 (describing pharmacy substitution as "automatic[]"); Appx11076-11077, Appx11083-11084 (same); *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 645 (2d Cir. 2015). GSK should not be able to ignore these legal and economic realities either.

Allowing GSK to obtain hundreds of millions of dollars in "lost profits" it would not have earned, based on a market reconstruction that everyone agrees was

not possible, would not "restore" GSK to its position but for Teva's infringement or "make [GSK] whole." Rather, it would "punish[]" Teva for infringement and provide GSK with an unearned windfall. *Riles*, 298 F.3d at 1312; 7 *Chisum on Patents* § 20.01; *see also Grain Processing*, 185 F.3d at 1351 (expressing concerns with a damages standard that "systematically overreward[s] patented inventions" (citation omitted)). It would effectively allow GSK to extend its monopoly far beyond what was granted by the '000 patent. *See Paper Converting Mach. Co. v. Magna-Graphics Corp.*, 745 F.2d 11, 16 (Fed. Cir. 1984). And it would discourage generic manufacturers from invoking the Section viii carve-out that Congress created, which, of course, is precisely GSK's goal and directly contrary to Congress's intent.

Thus, even if this Court vacates the judgment, this Court should reverse the award of lost profits. The evidence can support no more than a reasonable royalty of $1.4 million;[19] at a minimum, the jury verdict cannot stand because of the court's legally erroneous evidentiary ruling and jury instruction.

IV. If this Court Vacates the District Court's Decision, It Should Remand for the District Court to Consider Teva's Motion for a New Trial and Other Unresolved Issues.

The district court declined to rule on Teva's motion for a new trial, concluding that a new trial would be futile in light of the court's decision granting

[19] $1.4 million was the agreed total reasonable royalty damages figure for the skinny- and amended-label periods, combined, if lost profits were not available.

JMOL. Appx11 n.10. This was erroneous. A district court that grants a renewed JMOL motion after trial "must also conditionally rule on any motion for a new trial." Fed. R. Civ. P. 50(c)(1). Thus, if this Court does not affirm the judgment, applying Third Circuit procedural law, it should remand for the district court to decide the merits of Teva's motion for a new trial in the first instance. *See Rhone Poulenc Rorer Pharm. Inc. v. Newman Glass Works*, 112 F.3d 695, 699 (3d Cir. 1997); *accord Isaksen v. Vermont Castings, Inc.*, 825 F.2d 1158, 1165 (7th Cir. 1987). A remand would be necessary in any event, given the JMOL arguments and other defenses that the district court never resolved.

CONCLUSION

The Court should affirm the judgment.

Respectfully submitted.

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I hereby certify that this brief complies with the type-volume limitation of Federal Circuit Rule 32(a). The brief contains 16,493 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b).

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March 11, 2019

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CERTIFICATE OF SERVICE

I, William M. Jay, hereby certify that I served a copy of the foregoing document on counsel of record on March 11, 2019 by Electronic Means via the CM/ECF system.

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