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,

APPEALS FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE, CASE NO. 14-CV-878-LPS-CJB, DISTRICT JUDGE LEONARD P. STARK

GSK'S RESPONSE AND REPLY BRIEF [CORRECTED]

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March 5, 2019

CERTIFICATE OF INTEREST

1. The full name of every party represented by me is: GlaxoSmithKline LLC and SmithKline Beecham (Cork) Ltd.

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

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

4. The names of all law firms and the partners or associates that appeared for the party now represented by me in the trial court or agency or are expected to appear in this Court are: Fish & Richardson P.C.: Juanita R. Brooks, Jonathan E. Singer, Craig E. Countryman, Michael A. Amon, Douglas E. McCann, Elizabeth M. Flanagan, Michael J. Kane, William R. Woodford, John Farrell, Phillip Goter, Jeremy Anderson, Robert M. Yeh, Ryan O'Connor, Jeremy Saks, W. Chad Shear, Limin Zheng*, Santosh Coutinho*. * = No longer with firm.

5. The title and number of any case known to counsel 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, et al.*, Case No. 14-cv-877-LPS-CJB (D. Del.).

Dated: March 5, 2019

/s/ Michael A. Amon
Michael A. Amon

TABLE OF CONTENTS

Page

TABLE OF CONTENTS (continued)

Page

TABLE OF AUTHORITIES

Page(s)

Cases

TABLE OF AUTHORITIES (continued)

Page(s)

Other Authorities

INTRODUCTION

Teva induced infringement under well-established precedent applied to the jury's well-supported factual findings. *Grokster* and *Power Integrations* hold that a jury may find inducement when the defendant promotes using its product to infringe. The jury found that Teva did just that. Teva communicated press releases, product guides, web pages, and product labels that encouraged doctors to use its product just as they used COREG®. The jury inferred this meant doctors should use it for *all* COREG®'s uses, including the infringing use. The jury also had direct evidence beyond what precedent requires—testimony from a cardiologist that Teva caused him to infringe.

Teva's main response is to ask for a new, heightened inducement standard. But the Supreme Court and this Court have rejected those arguments. And with good reason. Teva's standard would let willful infringers like itself escape liability by pointing to the innovator's earlier efforts to educate doctors on a new treatment method, even where the generic intentionally promotes its product by tying it to the patented method. That would gut patents to new treatment methods. Teva's back-up cross-appeal argument on lost profits fares no better. It contradicts this Court's well-established rule that the "but for" world must exclude all infringement, and, if adopted, would eliminate an innovator's ability to recover its investments.

With Teva's legal errors exposed, its remaining quibbles are with the jury's fact-finding. But Teva ignores the substantial evidence that supports the verdict, which properly tied damages to only the infringing use and should be reinstated in full.

ARGUMENT

I. The Jury's Inducement Verdict Should Be Reinstated.

A. Substantial Evidence Supports the Jury's Causation Finding.

1. The Jury Was Legally Permitted to Find Causation Based on Teva's Intentional Encouragement of the Infringing Use.

GSK asks only that the Court apply existing law, while Teva argues (at 30–39) for an overly onerous causation standard that contradicts well-established law. Precedent permits a jury to infer the defendant caused direct infringement where, as here, the defendant promotes the infringing use and infringement follows. "The classic instance of inducement is by advertisement or solicitation that broadcasts a message designed to stimulate others to commit violations." *Metro-Goldwyn-Meyer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 937 (2005). This Court has thus "affirmed induced infringement verdicts based on circumstantial evidence of inducement (*e.g.*, advertisements, user manuals) directed to a class of direct infringers (*e.g.*, customers, end users) without requiring hard proof that any individual third-party direct infringer was actually persuaded to infringe by that material." *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1335 (Fed. Cir. 2016). Teva's attempts to add further legal hurdles contradicts that precedent. The sole question under *Groskter* and *Power Integrations*—a factual one—is whether Teva's marketing materials encouraged (and therefore caused) infringement. The jury could reasonably infer they did, given that Teva encouraged doctors to use its product just as they had used COREG®.

Indeed, the Supreme Court in *Grokster* determined that a jury could find inducement based on advertisements that were quite similar to Teva's. The *Grokster* defendants marketed their services as a replacement to Napster, which customers had used to infringe copyrights by downloading popular music and movies. *Grokster*. 545 U.S. at 924–25 (noting that "StreamCast developed promotional materials to market its service as the best Napster alternative," while Grokster inserted codes into its website so that former Napster users would find it through web searches and chose a "name" that "is an apparent derivative of Napster"). The Court held that a "factfinder could conclude" these advertisements, which communicated the defendants' products would "perform the same services" as Napster, "would readily have been understood in the Napster market as the ability to download copyrighted music files." *Id.* at 937–38. A jury could thus conclude the defendants "communicated an inducing message to their software users" and infringed. *Id.*

Teva did the same thing here. It targeted doctors who had previously used COREG® to perform the patented method and advertised that Teva's generic could be used just as COREG® was used. (*See* pp. 10–31; Blue Br. at 9–18.) Teva did this through a press release trumpeting that its generic could be used for *all* COREG®'s uses, through product guides and a website communicated Teva's product was interchangeable with COREG®, and through product labeling that described every claim limitation. (*Id.*) Given that evidence, the jury rightly concluded that Teva purposely connected its product to doctors' existing use of COREG® for the patented

method and thereby encouraged doctors to use the generic in the same way. That was enough to prove inducement, just as it was in *Grokster*.

Teva's contrary arguments can be readily dispensed with. Teva begins (at 31) with a red herring argument about the jury instruction on causation. But GSK accepts the jury instruction for present purposes—*i.e.*, that GSK was required to show that "Teva's alleged inducement, as opposed to other factors, actually caused the physicians to infringe." (Appx11802.) The instruction also said, however, that the jury could use circumstantial evidence to find causation:

> [T]his final element of induced infringement can be proven by circumstantial evidence. GSK is not required to present hard proof of any direct infringer physician stating, for example, that she read Teva's labels or other Teva materials and that these labels or other Teva materials caused her to prescribe Teva's generic carvedilol in an infringing manner.

(Appx11802–11803.) Teva does not challenge that part of the instruction. And the instruction adopted the *Grokster* and *Power Integrations* standard, permitting the jury to infer causation if it found Teva's marketing materials encouraged infringement. The jury found in GSK's favor on both issues, so the only question now is whether that finding is supported by substantial evidence. We show below that it was. That said, to the extent the Court agrees with the *amici* who suggest the jury instruction adopted a higher, albeit incorrect causation standard, the jury's factual finding under such a standard dictates infringement under the lower, *Grokster*/*Power Integrations* standard.

Teva then attacks (at 31–33) a strawman, characterizing GSK as arguing that a plaintiff can "assume" rather than "prove" causation. That is not, and has never

been, GSK's position. The plaintiff must certainly prove causation. But the Supreme Court and this Court have permitted the jury to find that causation is proven through circumstantial evidence "(*e.g.*, advertisements, user manuals) directed to a class of direct infringers" is more than sufficient to do so. *Power Integrations*, 843 F.3d at 1335; *see also Grokster*, 545 U.S. at 937 ("The classic instance of inducement is by advertisement or solicitation that broadcasts a message designed to stimulate others to commit violations."); *id.* at 940 n. 13 ("[T]he distribution of a product can itself give rise to liability where evidence shows that the distributor intended and encouraged the product to be used to infringe. In such a case, the culpable act is not merely the encouragement of infringement but also the distribution of the tool intended for infringing use."). That is exactly what we have here. Teva's marketing materials told doctors to use Teva's product just as they used COREG®, and thus caused them to use Teva's product to infringe. Indeed, GSK went beyond what was legally required, presenting direct evidence from its expert that Teva's communications caused him to infringe.

Teva's treatment (at 32–33) of precedent is unpersuasive. *Teva* largely ignores *Grokster*, seemingly inviting this Court to adopt a higher (albeit conflicting) standard in this case. That is doubly wrong. The Supreme Court has warned against contorting common law doctrines to create different rules for patent cases. *See, e.g., eBay Inc. v. Mercexchange, LLC*, 547 U.S. 388, 391–94 (2006). And it would be particularly bad

here, because *Grokster* drew its discussion of inducement from the patent context. *See* 545 U.S. at 935–37. Even Teva admits (at 33) that *Grokster* applies to patent law.

Teva also fails to acknowledge that *Power Integrations* precludes adopting a stricter, patent-specific rule that requires direct evidence. Teva is silent on the key sentence in *Power Integrations* quoted above (and at p. 26 of the blue brief), which holds that the defendant's advertisement of the infringing use is sufficient. Teva instead notes that *Power Integrations* ordered a new trial where a jury had been instructed that direct "infringement need not have been actually caused by the [defendant's] actions," and that it was enough the defendant "took steps to encourage or assist that infringement, *regardless of whether that encouragement succeeded, or was even received.*" *See* 843 F.3d at 1330, 1332. The jury was told the opposite here—that it must find Teva's actions "actually caused infringement." (Appx11802.) And there was no risk that the jury relied on something the defendant "d[id] not successfully communicate" to doctors. *Cf. id.* at 1330–31. Substantial evidence supports the jury's finding that doctors received Teva's marketing materials. (*See* pp. 10–21.)

The evidence here was at least as strong as in *Power Integrations*, where Teva admits (at 33) that "circumstantial evidence that the defendant actually induced direct infringers as a class was available in spades." Here, as there, Teva's advertisements encouraged the infringing use, and Teva intended doctors to use its product to infringe, so it could make more money. *Cf. Power Integrations*, 843 F.3d at 1334 (noting

evidence the defendant promoted its products complied with U.S. energy standards and sent samples to U.S. customers, knowing that U.S. imports infringed).

Teva's characterization (at 33–34) of this Court's other cases fares no better. Teva dismisses some of GSK's cited cases as not standing for the proposition that "causation can be inferred." But this Court cited two of them for the proposition that an inducement verdict can stand based on the defendant's promotion of the infringing use without "hard proof that any individual third-party direct infringer was actually persuaded to infringe by that material." *Power Integrations*, 843 F.3d at 1335, *citing Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201 1220, 1222 (Fed. Cir. 2014); *Arthrocare Corp. v. Smith & Nephew, Inc.*, 406 F.3d 1365, 1377 (Fed. Cir. 2005). Here, GSK presented not only circumstantial evidence, but direct testimony of a particular doctor who was influenced by Teva's actions—the very "hard proof" that *Power Integrations* said is not required. The other cases are similarly probative, because they allow juries to infer that direct infringement by customers followed when the defendant encouraged infringement in its marketing materials. *See, e.g., Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1323 (Fed. Cir. 2009); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.3d 1261, 1272 (Fed. Cir. 1986); *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1365 (Fed. Cir. 2012). The marketing materials in those cases necessarily caused the direct infringement—that is why the Court found inducement. *Cf. Grokster*, 545 U.S. at 938 ("Proving that a message was sent out, then, is the preeminent but not exclusive way of showing that active steps were taken with the purpose of bringing

about infringing acts, and of showing that infringing acts took place by using the device distributed.").

The Court should also reject Teva's attempt (at 34–35) to distinguish Hatch-Waxman precedent. Teva does not dispute that the Hatch-Waxman cases infer causation and find inducement where, as here, the defendant's label describes the infringing use. *See* Blue Br. at 27–28 (collecting cases). In all of those cases, as here, the innovator has already taught doctors how to use the drug, and the generic is proposing a product that it will tell doctors to use just like the innovator's product. If that is sufficient to show the defendant will cause infringement in a Hatch-Waxman case, there is no reason why it should not also suffice here. A Hatch-Waxman plaintiff has to prove the same elements of inducement that GSK had to prove—there is no "inducement-lite" for Hatch-Waxman cases. So this Court's Hatch-Waxman precedent dictates that Teva's behavior here was inducement.

It is no answer for Teva to say that those cases involve an injunction rather than damages. As the blue brief says at p. 34, an injunction is a *broader* remedy that prohibits *all* sales (even for non-infringing purposes). So those cases should apply equally here, where GSK seeks a narrower damages remedy limited only to sales of products actually used to infringe. Teva ignores that point.

Teva instead says (at 35) that, post-launch, "there is no need to hypothesize" about causation. This isn't hypothesis or speculation. It is a permissible inference based on circumstantial evidence—Teva's marketing of the infringing use. The

inference is not "one-size-fits-all," as Teva suggests. A defendant's encouragement of infringement does not *require* a jury to find causation as a matter of law. But here, the properly-instructed jury, which was instructed that it had to find causation, looked at all the evidence and found for GSK. That was legally permissible.

Teva's attempt (at 36 & n.9) to distinguish aiding and abetting fares no better. Teva acknowledges that civil aiding and abetting is tortious where the defendant gives "encouragement or assistance" that is "a substantial factor in causing the resulting tort." RESTATEMENT (SECOND) OF TORTS § 876. That describes this case to a T, given the jury's findings. That § 271(b) imposes stricter intent requirements than the Restatement only underscores why a higher causation standard is unnecessary. Truly innocent defendants are already protected from liability by the intent requirement. Adopting a causation requirement out of step with other areas of law would only give otherwise guilty infringers a windfall, while preventing GSK from recovering money it can reinvest in other ground-breaking medical treatments.

Teva's reliance on *Columbia Pictures Industries, Inc. v. Fung*, 710 F.3d 1020 (9th Cir. 2013), is odd, because the case supports GSK. *Fung* interpreted *Grokster* to stand for the proposition that "if one provides a service that could be used to infringe copyrights, with the manifested intent that the service actually be used in that manner, that person is liable for the infringement that occurs through the use of the service." *Id.* at 1037. *Fung* added that "the only causation requirement is that the product or service at issue was used to infringe the plaintiff's copyrights" and rejected the

argument that "the acts of infringement must be caused by the manifestations of the distributor's improper object—that is, by the inducing messages themselves." *Id.* GSK has certainly met that standard—Teva distributed carvedilol, and the jury found that Teva intended doctors would infringe and took affirmative steps to encourage that. (Appx171.) *Fung* also noted that the intent requirement mitigates the "potential severity" of a "loose causation" standard, and, here, the jury's finding that Teva acted with bad intent is well-supported and unchallenged on appeal. (*See* Blue Br. at 51–52.)

Finally, applying *Power Integrations* and permitting an inference of causation based on the defendant's encouragement of infringement will not have any of the negative consequences that Teva suggests (at 35–37). It will not improperly "'enlarge the scope of monopolies' over products that are 'capable of non-infringing uses,'" because GSK did not seek liability or damages on any non-infringing use. GSK limited its liability and damages theories to Teva's sales of products that were actually used to infringe. Nor will it "impose strict liability" for a "single statement" that doesn't "actually affect[] anyone." There is no strict liability—a plaintiff must still prove, as GSK did prove, that the defendant intended to induce infringement. Moreover, the jury absolutely must find, as this jury did find, that Teva's repeated statements affected customers. Teva's real complaint is with *Grokster* and *Power Integrations*. But that precedent permits juries to use and rely on circumstantial evidence. The jury here followed the proper law, and having done so, it properly tied damages to harm actually caused by Teva.

2. The Jury Could Properly Find Teva Caused Infringement During the Partial Label Period.

Under the correct legal standard, substantial evidence supports the jury's finding that Teva caused doctors to directly infringe. The jury had substantial circumstantial evidence—Teva's press releases, product guides, website, and partial label—that Teva caused doctors to infringe by encouraging them to use its product just as they had used COREG®. (*See* Blue Br at 9–16.) The jury also had direct evidence of causation from GSK's expert, who testified that Teva's advertisements caused him to think the product was approved for *all* COREG®'s uses, and that, without those materials, he would not have used carvedilol in an infringing manner. (*See* Blue Br. at 16–18.) The jury also knew that Teva designed and intended for its product to infringe, that it solicited that infringement through its press releases and product guides, and facilitated it through detailed instructions on the partial label. (*See* Blue Br. at 9–18.) The jury reasonably credited this evidence and rejected Teva's contrary arguments. Teva now seeks (at 38–46) to reargue the jury's factual finding on causation, which it cannot do given the standard of review.

Teva begins (at 38–39) by attacking GSK for what it did not present—survey results showing a particular percentage of doctors who said they received a particular document from Teva and were persuaded by it. But that is precisely what *Power Integrations* says is not required: "we have affirmed induced infringement verdicts based on circumstantial evidence of inducement (*e.g.*, advertisements, user manuals)

directed to a class of direct infringers (*e.g.*, customers, end users) *without requiring hard proof that any individual third-party direct infringer was actually persuaded to infringe by that material*." *See* 843 F.3d at 1335. The Court also rejected the notion that the patentee has to tie any particular act by the defendant to a particular end-customer. *Id.* The defendant's "affirmative acts to induce third parties" were "sufficient to allow the jury to find that Fairchild had induced its customers (including HP, Acer, and Samsung) to infringe as a class," even though they could not "be directly linked" to a particular end-customer. *Id.* No survey was presented in *Power Integrations*, yet the Court there still found the evidence could support a jury verdict of inducement.

Teva's response to the evidence that GSK did present fares no better. Teva attacks the evidence piece-by-piece, without grappling with the evidence as a whole. These "discrete attacks" on individual documents show that Teva "misses the forest for the trees." *Power Integrations*, 843 F.3d at 1334. Even if "each piece of evidence may not individually be sufficient to establish [the defendant's] liability," the evidence "as a whole" is certainly sufficient. *Id.* That said, each of Teva's attacks is unfounded.

The Press Releases. The two press releases show Teva encouraging doctors to use its product for the infringing use from the very beginning. One expressly told doctors that Teva's drug was the "equivalent" of COREG®, that it had been tentatively approved "for the treatment of heart failure" and that Teva expected final approval in 2007, when the patent on the carvedilol molecule expired. (Appx6347.) The other, announcing the FDA's final approval, characterized Teva's product as a

"cardiovascular agent," which doctors understood to refer to using it for congestive heart failure. (Appx6353; Appx11659–11660.) Both press releases give doctors the impression that they should use Teva's product just as they used COREG®, which would satisfy all limitations of the asserted claims. (Appx10622–10631; Appx11659–11660.) So both press releases encourage using Teva's product to infringe, (*id.*), and GSK's expert testified that doctors read the press releases. (Appx11655–11656.)

Teva complains (at 40–41) that the press releases were first sent before the patent issued in 2008. But they did not disappear upon publication. The jury was instructed that it could find inducement if Teva "continued to take an action that began before the '000 patent issued, after the '000 patent was issued." (Appx168.) Teva does not challenge that instruction on appeal. Nor could it. *See, e.g., Barry v. Medtronic, Inc.*, __ F.3d __, 2019 WL 302886, at *17 (Fed. Cir. Jan. 24, 2019) (affirming inducement verdict where the defendant's encouragement began years before patent issuance but continued those acts after patent issuance). The jury's verdict thus reflects its reasonable finding that Teva continued to broadcast the press releases even after patent issuance. Indeed, Teva does not dispute that it distributed the press releases on its website throughout the entire infringement period. (*See* Blue Br. at 9–10, 12–13.) Therefore, Teva's citation to *National Presto Industries, Inc. v. W. Bend Co.*, 76 F.3d 1185 (Fed. Cir. 1996), is inapplicable, because there, the defendant's inducing acts all occurred before patent issuance and did not continue after patent issuance.

Teva next nitpicks (at 41) GSK's expert testimony about the press releases, but these are jury arguments that were properly rejected. Both sides' experts testified that they read the press releases. (Appx11655–11656; Appx11238–11241.) GSK's expert added that all Teva's marketing materials (including the 2004 and 2007 press releases) caused him to think Teva's product should be used to infringe, and that, had he not thought so, he would not have used it to infringe. (Appx11657, Appx11659–11661, Appx11663.) Teva nevertheless contends that GSK's expert monitored press releases to see whether a given drug was "going generic," rather than for how to use the products. But that ignores his other testimony that the press releases, along with Teva's additional behavior, caused him to think that Teva's product was approved for the infringing use, which in turn impacted whether he prescribed it for that use. (*Id.*) It also ignores that no direct testimony about the press releases was needed in the first place. An advertisement touting the patented use is sufficient evidence of causation, even without "hard proof that any individual third-party direct infringer was actually persuaded to infringe by that material." *Power Integrations*, 843 F.3d at 1335.

The Product Guides and Website. Teva's product guides (catalogs) and website were additional examples of it encouraging doctors to use the accused product to infringe. Teva advertised the accused product as an AB-substitute, and, critically, directly compared it to COREG® and said the two were "equivalent." (*See* Blue Br. at 13–14.) The jury properly found this communicated to doctors that they should use the accused product just as they had used COREG®, including for the

infringing heart failure use. The jury reasonably inferred this based on GSK's experts, who explained that doctors and the FDA understand the materials to convey that message. (Appx10634–10636; Appx10544–10545, Appx10582–10583.)

Teva's primary response (at 42) on the product guides is to assert that there was "no evidence that doctors who prescribed carvedilol even received them." That is wrong. GSK's expert testified that "we [doctors] get product catalog information, and we get pointed to it through a variety of means," and he specifically disagreed with contrary testimony from Teva's expert. (Appx11663–11664.) He gave examples of how doctors are pointed to the product guides, including the Internet and Teva's Monthly Prescribing References (MPR), (Appx11664), the latter of which Teva expressly directed to "Healthcare Professional[s]", including doctors. (Appx6194, Appx6200; Appx10607–10608.) The jury could reasonably credit all this testimony and therefore find that doctors received and are influenced by the product guides. It doesn't matter whether Teva also gives or addresses the product guides to patients. (Appx10688–10689.) GSK's expert testified that they "end up with doctors," (Appx10685–10686), and later reaffirmed that doctors get the information they contain and are pointed to it by Teva. (Appx11663–11664.)

Teva's discussion (at 41–42) of its website is incomplete. Teva mentions only an exemplary exhibit showing the 2015 version of its website, (Appx4245–4246), while ignoring the admission of its Director of Marketing that its website compared the accused product to COREG® and noted the AB-rating since 2007. (Appx10991–

10992.) The jury could thus infer that Teva used the website to induce infringement throughout the entire infringement period (2008–2015). Indeed, Teva's product guides also directed doctors to look at the website, (Appx6056, Appx6323, Appx6329), and GSK's expert reaffirmed that he visited the website. (Appx11664.) But, again, the expert testimony wasn't even necessary, because a plaintiff doesn't need "hard proof that any individual third-party direct infringer was actually persuaded to infringe by that material." *Power Integrations*, 843 F.3d at 1335.

The Partial Label. Teva's partial label encouraged doctors to infringe GSK's patent because it described every limitation of the claimed method. (Appx5506–5530.) For example, it told doctors to use the product "to reduce cardiovascular mortality" in post-MI LVD patients "with" symptomatic "heart failure," (Appx5508), and it provided extensive clinical data showing use of the drug for that purpose. (Appx5523–5524.) It also told doctors to co-administer Teva's product with other drugs (as claimed), for longer than 6 months, to reduce the risk of mortality. (Appx10622–10631; Appx5506–5530.) What's more, Teva told doctors to read its label. Teva's Monthly Prescribing References, directed to "Healthcare Professional[s]," said that "[t]he clinician must be familiar with the full product labeling" of "every product he or she describes," (Appx6196, Appx6205), and that "if any questions arise," doctors should "verify it against the labeling" or by contacting Teva. (*Id.*) GSK's expert interpreted Teva's statements as telling doctors to read Teva's label. (Appx10608–10612.) The jury could conclude doctors do just that.

Teva ignores this evidence and seeks to reargue (at 39–40) other trial testimony. That is insufficient, given the standard of review. It also ignores this Court's directive that a plaintiff can rely on the defendant's marketing materials to show causation without "hard proof that any individual third-party direct infringer was actually persuaded to infringe by that material." *Power Integrations*, 843 F.3d at 1335. It was unnecessary to elicit testimony from a doctor who was influenced by the label, given the circumstantial evidence of Teva telling doctors to read its label, and the label encouraging the infringing use. *Power Integrations* held that a jury could infer causation based on marketing materials even without testimony from a customer who saw or was persuaded by that material. The same is true here, especially given Hatch-Waxman cases finding inducement based solely on a label that encourages the infringing use. It is not as if the partial label or any of Teva's other materials were internal draft documents never distributed. They were all publicly distributed. Thus, the jury could reasonably rely on them to find inducement of GSK's patent.

Pre-Existing Knowledge about Using COREG®. Teva next argues (at 42–44) that doctors' prescribing practices were really influenced by medical guidelines for carvedilol. But that is insufficient to set aside the verdict for multiple reasons.

First, the fact that doctors used Teva's accused product consistently with the medical guidelines for COREG® supports inducement, just as it did in *Grokster*, where people used the defendants' software just as they had used Napster. As the blue brief explains at pp. 43–49, Teva told doctors they could use the accused product just as

they used COREG®, including for the infringing use. Teva connected its product to COREG® knowing that doctors would follow the existing guidelines and also knowing that this would result in infringement of GSK's patent. Indeed, Teva's Monthly Prescribing References made the point expressly, telling doctors to consult "the relevant medical literature" when prescribing Teva's products. (Appx6196, Appx6205.) Teva cannot avoid liability by pointing to the guidelines, any more than the *Grokster* defendants could avoid their statements touting themselves as a Napster-replacement. It's also no surprise that "physicians' prescription practices remained identical before and after generic launch." Teva gave doctors the impression its product could be used just like COREG®, which caused doctors to think they should use it to infringe. (*See, e.g.,* Appx11659–11663.) Teva ignores all this, even though it was presented in the blue brief. That silence speaks volumes.

Second, Teva's entire discussion asks this Court to reweigh testimony and find facts. That is not permitted on JMOL. The question is not whether a jury might have found for Teva based on its preferred spin on the facts. As shown above, Teva intentionally encouraged the infringing use in a variety of materials communicated to doctors. That is sufficient under *Grokster* and *Power Integrations*, especially when the evidence is considered as a whole, as it should be. The jury was permitted to find inducement and rejected Teva's attempts to deny that it promoted use of its products to infringe consistent with the medical guidelines.

Teva also seems to suggest (*e.g.*, at 3, 5–6, 14) that its actions after GSK's patent issued in January 2008 did not cause infringement, because GSK had already lost market share when the generics launched in 2007. But this too is wrong. For one thing, this is yet another factual dispute that the jury resolved against Teva. The jury was instructed that it could find inducement if Teva's encouragement of the infringing use after January 2008 continued to cause doctors to infringe the reissue patent. (Appx168.) The jury found Teva did this, which, as shown above, was well-supported based on Teva's continued efforts to encourage doctors to use its product just like COREG®. *Barry*, 2019 WL 302886, at *17. For another thing, GSK did have a patent (the '067 patent) on using carvedilol to treat heart failure when the generics launched, and it simply exchanged that for the narrowed reissue patent in January 2008. Teva had initially argued there was no patent when it launched, (Appx10324), but conceded error on this point in closing. (Appx11891 ("my bad"); *see also* Appx11831–11833 (GSK closing); Appx166.) So this is not a situation where innocent conduct suddenly became infringing. Teva knew the whole time that it was encouraging infringement, as the jury found, a point Teva does not challenge on appeal.

The "class" theory. The discussion here and in the blue brief demonstrates that GSK's evidence sufficiently proved Teva induced doctors as a class. The evidence here fits squarely within this Court's holding that a defendant's "affirmative acts to induce third parties" to infringe is "sufficient to allow the jury to find" the defendant "induced its customers" to "infringe as a class." *Power Integrations*, 843 F.3d

at 1335. Here, as there, "circumstantial evidence of inducement" (*e.g.,* the press releases, product guides, website, and partial label) that were "directed to a class of direct infringers" (*i.e.,* doctors) are sufficient to support an inducement verdict. *Id.* GSK's expert testimony confirmed Teva's inducement by showing an example of a doctor who Teva persuaded to infringe by convincing him he could use its product just as he had used COREG®. (Appx11659–11663.)

Teva's contrary arguments (at 44–46) simply ignore *Power Integrations,* the totality of the evidence, and the reasonable inferences the jury could draw from that evidence. The jury was entitled to disbelieve Teva's experts and instead find that Teva induced doctors as a class to infringe where Teva encouraged the infringing use, told doctors to read labels, and led doctors to believe they could use the accused product to infringe by following the same medical guidelines they'd used for COREG®. Teva's reliance on *Pharmastem Therapetuics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342 (Fed. Cir. 2007), is misplaced, because the plaintiff there presented no evidence of any direct infringement whatsoever, much less evidence that the defendant encouraged infringement. The record here contains both.

3. The Jury Could Properly Find that Teva Caused Infringement During the Full Label Period.

Substantial evidence supports the jury's finding that Teva continued to cause doctors to infringe during the full label period. The blue brief demonstrates (at 14–15 & 36–37) that Teva expanded its efforts to encourage infringement of GSK's patent

by adding material to its label in 2011. Doctors continued to administer Teva's accused product for the infringing use during that period (without change from the partial label period), because Teva continued to induce them to do so.

Teva's discussion (at 62–63) of the full label suffers from the same flaws as its points on the partial label. The jury could properly reject Teva's arguments about the lack of change to doctors' prescription practices by concluding that Teva had encouraged them to infringe all along. Teva's complaints (at 63) about the lack of direct testimony from physicians saying that Teva caused them to infringe during the full label period contradict *Grokster* and *Power Integrations*. Given the circumstantial evidence that Teva continued to encourage the infringing use from 2011–2015, the jury did not need "hard proof that any individual third-party direct infringer was actually persuaded to infringe by that material." *Power Integrations*, 843 F.3d at 1335. If anything, Teva's expanded efforts to encourage infringement simply reinforced its intent to encourage infringement—an intent that Teva does not even challenge on appeal. Contrary to Teva's suggestion (at 1, 15), the FDA did not force it to add that further encouragement to its label—it always had other choices. *Cf. Astrazeneca LP v. Apotex, Inc.*, 633 F. 3d 1042, 1060–61 (Fed. Cir. 2010); Appx10547–10550. Many other generics chose not to. The jury thus reasonably rejected Teva's arguments and found continued inducement during the full label period.

B. Substantial Evidence Supports the Jury's Factual Finding that Teva Encouraged Infringement.

The Court should reject Teva's attempt (46–62) to reargue the jury's finding that Teva actively encouraged direct infringement by doctors. The interpretation of Teva's marketing materials is an intensely factual question that this Court reviews for substantial evidence. *See, e.g., Ericsson*, 773 F.3d at 1222 ("Making findings of fact by weighing evidence—such as the evidence presented by the parties regarding induced infringement—is the role of the jury."). Here again, the jury could conclude that each category of materials—*i.e.*, the press releases, the website, the product guides, and the partial label—encouraged doctors to use the Teva's product just like COREG®, including for the patented use. GSK's experts testified, without contradiction, that the materials described the infringing use. And doctors who administered the accused product for treating heart failure by using it in the same way as COREG® (*i.e.*, co-administered with the same drugs, for greater than 6 months, to decrease the risk of death) infringed the claims. Teva barely disputed that at trial, and it cannot now seek to reweigh the evidence.

1. Teva's Press Releases Encouraged Infringement by Touting Use of Its Product for Heart Failure, Like COREG®.

The jury reasonably found that Teva's press releases encouraged infringement. The first press release tells doctors that its "Carvedilol Tablets are the AB-rated generic equivalent of GlaxoSmithKline's Coreg® Tablets and are indicated for the treatment of heart failure." (Appx6347.) By calling its product the "equivalent" of

COREG®, Teva was telling physicians to use it to perform the same patented heart failure treatment method that they practiced with COREG®, *i.e.*, co-administered with the same other drugs, in the same doses, for the same purpose (decreasing the risk of death), and for the same period (over 6 months). Teva's second press release was more coy, replacing the words "equivalent" and "heart failure" with the terms "generic version" and "cardiovascular agent." (Appx6353.) But GSK's expert testified, without contradiction, that the message was the same—it conveyed to doctors that Teva's product could be used for "all the indications" that COREG® had been used for, including heart failure. (Appx11659–11660; *see also* Appx11655–11663.) The press releases reinforced this message by including COREG®'s full revenue, suggesting the generic would be used for all COREG®'s uses (including the infringing one). (Appx6347; Appx6353; Appx10643–10644.)

Teva's contrary arguments (at 55–57) were all matters the jury could reasonably reject. Teva again tries to explain away the press releases by noting it first distributed them before patent issuance, but that ignores the jury's reasonable inference (which is in fact true) that it continued to broadcast them throughout the infringement period. *See, e.g., Barry*, 2019 WL 302886, at *17. Indeed, Teva's continued inclusion of the first press release on its website, even after it amended its product labeling to remove some information, shows that it always encouraged and wanted doctors to use its product just like COREG®. Teva quibbles (at 56 n. 15) with the interpretation of "cardiovascular agent" in the second press release. But the jury was free to credit

GSK's uncontroverted expert testimony that this term conveyed to doctors that the product was approved for treating congestive heart failure. (Appx11659–11660.)

Teva also complains (at 55–56) that simply referring to "heart failure" isn't enough to induce infringement because there are additional claim limitations. That is wrong for several reasons. First, it ignores that the press releases also describe the accused product, respectively, as the "equivalent" and "generic version" of COREG®, and they both include revenue for uses that are indisputably patented. (Appx6347; Appx6353.) The jury could reasonably conclude that those statements, along with the references to heart failure, conveyed to doctors that Teva's product was approved for all the same uses as COREG®, including the infringing use. (Appx11659–11660.) In other words, by encouraging doctors to use the product as they had used COREG®, Teva encouraged them to use it for heart failure in a way that met all the other claim limitations—*i.e.,* co-administration with other drugs for more than 6 months to decrease the risk of death from heart failure. (Appx45 at 8:30–40; Appx11655–11663; Appx10622–10631.) This is just like *Grokster* where the defendants didn't need to explicitly tell customers to download copyrighted music—it was enough that the defendants told customers their products worked just like Napster, where Napster had been used to infringe. *Grokster*, 545 U.S. at 937–38. Second, Teva's argument ignores that the press release must be read in the context of Teva's other communications, which reiterate that the product should be used like COREG® and (in the case of the labels) explicitly describe all the claim limitations.

Teva's attempt to explain away its inclusion of the total revenue is similarly unpersuasive. Teva's reference to total revenue communicated that its product was a complete COREG® replacement, including for the infringing use. *Cf. Grokster*, 545 U.S. at 937–38. Teva's own employees recognized the implication before it issued the press release, questioning whether Teva should include the whole number when its product was not approved for heart failure. (Appx6173–6174; Appx10972–10974.) The jury reasonably inferred that Teva acted in that manner to give the impression that its product should be used for all COREG®'s uses, including the infringing one.

Teva's hypothetical (at 56) about the FDA is inapt. The FDA is not selling generic carvedilol, nor making all the other statements, nor acting with the intent to infringe. And its reliance on *Takeda Pharms., U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625 (Fed. Cir. 2015), is misplaced, because the materials there didn't reference total revenues or anything else that any expert testified made reference to the infringing use. The situation here is the opposite.

2. Teva's Product Guides and Website Encouraged Infringement by Juxtaposing its AB-Rating with COREG®.

The jury could reasonably conclude that Teva's product guides and website encouraged infringement. They included a direct comparison of Teva's product to COREG® and characterized the two as "equivalent." (*See* Blue Br. at 13–18.) GSK's experts testified that this would convey that Teva's product could be used for *all* COREG®'s approved uses, including the infringing use. (Appx10634–10636;

Appx10544–10545; Appx10582–10583.) In particular, the FDA believes that a direct comparison with the branded product "impl[ies] the use of the product," (Appx10545), and "impl[ies]" what "they're approved for." (Appx10583.) In other words, the direct comparison conveys that the generic is approved for all the same uses as the branded drug. GSK's cardiologist expert confirmed this, testifying the comparison conveys the products are "therapeutically *interchangeable*," (Appx10634–10635), which the jury reasonably understood to mean that they can be administered for all the same uses. Teva does not acknowledge or refute any of this testimony.

Instead, Teva simply ignores (at 57–62) the unique record in this case. Teva focuses largely on cases (*Momenta, Organon*, *Takeda*, and *Warner-Lambert*) and other testimony from Professor Lietzan dealing with an AB-rating alone. But no case has addressed the situation here, where the AB-rating is used with an explicit and intentional direct comparison to the branded product, and where expert testimony showed that this comparison encourages infringement. Moreover, no case dealt with the unique context here, where Teva was making those statements after having distributed press releases that doctors read as touting the product's use for heart failure. It doesn't matter if Teva's statements were technically "truthful" or not. They created the impression that its product was approved for the infringing use and thereby caused doctors to prescribe it for that use when they otherwise would not have. It is no answer for Teva to compare (at 58) its statements to what the FDA

said. The FDA was neither selling carvedilol nor acting with the intent to induce infringement, and it hadn't previously issued press releases referencing heart failure.

Teva's suggestion (at 59) that it was properly following the Hatch-Waxman scheme, including the section viii carveout provisions, is wrong. As an initial matter, this is *not* a section viii carveout case, because the jury properly found that Teva left the description of the infringing use on its label. That said, section viii certainly permits generics to sell their products for unpatented uses. That is why GSK is not seeking any damages for Teva's sales for non-infringing uses. But Congress did not intend section viii to eliminate a damages remedy against generics who do encourage infringement. To hold otherwise would give willful infringers like Teva a windfall, while undermining GSK's ability to recover its investment in new medical treatments.

Teva is also wrong to dismiss (at 60–62) its failure to tell doctors that its product wasn't approved for the infringing use. Contrary to Teva's suggestion, GSK hasn't "abandoned" that argument—it appears at p. 35 of the blue brief. The point is simple. Teva's marketing materials intentionally created the impression that its product was approved for the infringing use. Those are the "affirmative steps to induce" required by *Takeda*. Having done that, it is significant that Teva never tried to correct that impression, such as by adding a disclaimer telling doctors the truth. This underscores that Teva meant to (and did) encourage infringement through its other statements. And it shows that generics have an easy way to avoid infringement. But, of course, Teva did want to encourage infringement, which is why it acted as it did.

3. Teva's Partial Label Encouraged the Infringing Use By Describing Each Step of the Asserted Claims.

Substantial evidence supports the jury's conclusion that Teva's labels encouraged infringement. Teva doesn't even dispute that its full label encouraged infringement. Teva also doesn't identify any claim limitation that is missing from its partial label. Nor could it. The blue brief at pp. 10–11 & 32–33 collects the parts of the label that describe each claim limitation, along with GSK's expert testimony explaining why those parts of the label correspond to those limitations. Teva never offered any contrary testimony that a limitation was missing. The jury thus reasonably credited GSK's expert and found the partial label described the infringing use.

Teva's arguments (at 47–54) were all properly rejected by the jury. Teva first says a label that describes each claim limitation still might not "encourage, recommend, or promote" infringement. It is doubtful whether such a distinction actually exists—the Supreme Court and this Court have always treated documents that describe the infringing use as sufficient encouragement. *See* Blue Br. at 25–28. But, at most, this is a classic factual question for the jury that it resolved against Teva. The jury implicitly rejected Teva's position that these were "isolated statements" that had been "cobbled together in hindsight." That was reasonable, especially given all of Teva's other conduct to promote infringement. Teva's citations to *Takeda*, *Bayer Schering*, and *Aventis Pharma* are unavailing—none involved a label that described using the product in a way that met every limitation of the asserted claims. Allowing the

jury's finding here to stand poses no threat to section viii carve-outs. The jury simply found on the unique facts here that Teva did not actually remove the infringing use from the label. Liability is appropriate and damages were limited to the infringing use.

The evidence here was not, as Teva suggests (at 49), the "vague label language" and "speculation" presented in *Takeda*. In *Takeda*, the label said that the product's "safety and effectiveness" for treating gout flares (the infringing use) "has not been studied." *See* 785 F.3d at 630. The patentee nevertheless tried to show inducement by relying on the label's statement that "[i]f you have a gout flare while taking [the product], tell your healthcare provider," along with speculation that the doctor would "likely tell" the patient to take the product to treat that gout flare. *Id.* This was insufficient, because it was "neither an explicit nor implicit instruction to take [the product] for acute gout treatment," *id.* at 632, and because other evidence showed the doctor might recommend many other non-infringing treatments. *Id.* at 633–34. Here, by contrast, Teva's partial label describes every claim limitation and includes clinical data showing that the product successfully reduces the risk of death from symptomatic heart failure when used in an infringing way. (Appx10622–10631; Appx5506–5530.) A doctor who uses the product in that way inevitably infringes. This case thus falls squarely within prior cases where this Court concluded that a label's description of the infringing use proves inducement. (*See* Blue Br. at 27–28.)

Teva nevertheless tries to reargue the facts (at 49–50) by incorrectly characterizing GSK's expert testimony. Teva claims (at 49) that GSK's expert said "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." That was not what he said. The cited testimony does not mention Teva's partial label at all, much less agree with the premise that the label lacks information on the infringing use. (Appx11660–11661.) In fact, he testified that Teva's other materials led him to believe the product *was* a "complete replacement" for COREG® and thus approved for the infringing use. (Appx11661, Appx11663.) The jury properly credited that testimony and found it showed that Teva's acts had encouraged doctors to infringe.

Teva's observations (at 51–52) about the "use code" are again factual arguments the jury was entitled to reject. The use code described the patent as covering "decreasing mortality caused by congestive heart failure," (Appx6882), which covers all heart failure patients, including post-MI LVD patients. Teva's assertion that GSK "informed the FDA" that "only the CHF indication" was patented is wrong. None of the cited materials say that. (Appx6894–6907; Appx6880–6887; Appx11039–11044.) In fact, the use code is not tied to any particular indication, and the FDA tells generics that the use code is "not meant to substitute for the applicant's review of the patent and the approved labeling." 68 Fed. Reg. 36676, 36683 (June 3, 2003). The jury thus properly concluded that administering carvedilol to post-MI LVD patients with symptomatic heart failure, as the label instructs, is infringing. Teva's policy arguments are misplaced: that GSK did not try to enjoin *all* Teva's sales

(including for non-infringing uses), does not mean that Teva can escape damages for the subset of infringing sales. It is Teva who wants the windfall here, not GSK.

Teva is also wrong to distinguish (at 52–54) between administering carvedilol to post-MI LVD patients who have symptomatic heart failure and using it to "treat" the heart failure in those patients. The jury, as fact-finder, rightly rejected this argument. GSK's expert testified that the partial label met the claim limitation of "decreasing mortality *caused by congestive heart failure*" through its reference to administering Teva's product "to reduce cardiovascular mortality in patients with a left ventricular ejection fraction ≤ 40% (with or without symptomatic heart failure." (Appx10622–10623, *citing* Appx5508.) That made sense. The label language broadly includes decreasing *all* types of cardiovascular mortality, including from symptomatic heart failure—it is not limited to heart attacks. Teva's expert had a different view, (Appx11183), but the jury reasonably sided with GSK. That post-MI LVD patients have other unique attributes that prompted GSK to run another clinical trial doesn't change the fact that some also have symptomatic heart failure. Teva's partial label broadly instructs doctors to treat those heart failure patients in an infringing way.

Finally, Teva asserts (at 54) that, at most, its partial label would encourage treating only the subset of heart failure patients with post-MI LVD. But the other evidence—namely, the press releases, product guides, and website—was broader and encouraged the infringing use for all the infringing symptomatic heart failure patients for whom GSK sought damages. The partial label was one piece of the puzzle. Teva

overlooks the fact that "the evidence as a whole provided the jury substantial evidence upon which to find inducement" by Teva. *Power Integrations*, 843 F.3d at 1334.

C. Teva Does Not Challenge the Jury's Finding that Teva Acted with the Knowledge and Intent Required for Inducement.

The blue brief at pp. 35–36 & 51–52 showed that substantial evidence supports the jury's factual finding that Teva had the required knowledge and intent for inducement. *See, e.g.*, *Ericsson,* 773 F.3d at 1222 ("Questions of intent are quintessential jury questions."). Teva does not challenge the jury's findings that it acted with the required knowledge and intent in its red brief. The Court should thus reinstate the jury's inducement verdict and reverse the district court's grant of JMOL.

II. Teva's Cross-Appeal: The District Court Properly Determined that GSK Could Seek Lost Profits and Properly Denied a New Trial.

A. GSK Was Entitled to Lost Profits for Teva's Willful Infringement.

The district court properly denied Teva's attempt to prevent GSK from presenting its lost profits case to the jury. A patentee is entitled to "full compensation" for any damages, *Gen. Motors Corp. v. Devex Corp.*, 461 U.S. 648, 654 (1983), including "any foreseeable lost profits the patent owner can prove." *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F .3d 1341, 1349 (Fed. Cir. 1999). The patentee must "show a reasonable probability that, 'but for' the infringement, it would have made the sales that were made by the infringer." *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995) (*en banc*). The patentee can meet that requirement by proving (1) demand for the patented product; (2) absence of acceptable non-

infringing alternatives; (3) capability to exploit the demand; and (4) the amount of profit it would have made. *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152 (6th Cir. 1978). The district court correctly held that other generics' carvedilol is not a non-infringing alternative under factor 2. (Appx234–239; Appx220-225.)

Other suppliers' carvedilol is not a noninfringing alternative, because its use by doctors to perform the patented method would still directly infringe GSK's patent. The "but for" world must be constructed to include "likely outcomes *with infringement factored out of the economic picture*." *Grain Processing*, 185 F.3d at 1350. As a result, the "but for" world must exclude all direct infringement, not just the direct infringement induced by Teva and Glenmark. Doctors who performed the patented method with any generic substitute would directly infringe. The district court thus correctly concluded that "the generic carvedilol of these non-party manufacturers is an ***infringing alternative*** – and ***not*** a noninfringing alternative." (Appx222 (emphasis in original).) So the carvedilol of the other generic manufacturers has no place in the "but for" world.

Teva's arguments based on the assumption that doctors could use other generic carvedilol to perform the patented method are wrong. For example, Teva says (at 65) that other generics "concededly would have been lawfully available during the damages period," but they would not have been lawfully available for practicing the patented method. GSK absolutely would have made "additional sale[s] of Coreg," in the "but for" world, because doctors would not have been able to use other generics

to directly infringe, and GSK could have enjoined any such conduct by doctors if they tried. Although Teva says (at 66) that "generic drugs will be dispensed by pharmacies for patented indications," this does not change the fact that doctors who use them for that purpose are directly infringing, which isn't allowed in the "but for" world. Teva's repeated statements about what is "conceded," "not disputed," or agreed are all wrong. GSK's lost profits reflect economic reality in the proper "but for" world, with infringement excluded.

To prove infringement in this case, GSK demonstrated both direct infringement by doctors and inducement of that infringement by Teva. Nevertheless, Teva argues (at 67) that the "but for" world here should exclude only inducing actions of others, while permitting direct infringement by doctors. Teva does not cite a single case from this Court that has adopted such a rule or any logical reason to do so. Teva cannot avoid lost profits liability by assuming that its sales would be captured by another, different infringement of GSK's patent.

Teva's "pharmacy substitution" argument (at 68) is improper in the but-for world. Teva seems to suggest that other direct infringement should be ignored simply because it might be difficult to get individual injunctions to stop each infringing doctor from using other generics. Here again, Teva fails to cite a single case where a patentee had to prove not only that an alternative was infringing but also describe how it would stop that infringement. No such proof has ever been required and this case should not be the first. Moreover, individual injunctions would be available to

stop direct infringement by doctors who use the other generics, which is yet another reason why direct infringement should be excluded from the "but for" world.

The economic reality is that Teva's inducement has taken hundreds of millions in revenue from GSK. The "but for" world properly excludes *all* infringement—direct and induced—and asks what profits the patentee would have made. The jury properly applied that framework and concluded that GSK would have made an extra $234.1 million in profits. The jury also rejected Teva's assertion (at 68) that "the result would have been exactly the same" without its inducement, because it found Teva's actions caused direct infringement.

Teva's remaining points (at 70–72) are all policy points on how it thinks the Hatch-Waxman Act and generic substitution should work. But Teva once again overstates the rights it has from its section viii carveout. Nothing in the Hatch-Waxman Act or section viii allows Teva to induce infringement. Section viii only allows Teva to market its product for non-infringing uses, not to encourage infringement as the jury found Teva did here. Moreover, section viii does not prevent GSK from stopping (enjoining) any doctors from using carvedilol to infringe. It doesn't matter whether other generics could sell "properly carved out" carvedilol or what pharmacies do by way of generic substitution. Doctors' continued use of generic carvedilol was directly infringing, and GSK would have a legal right to stop it under § 271(a). The "but for" world thus properly excludes that activity. Recognizing that reality does not "allow GSK to extend its monopoly," because GSK obtained

damages only on sales for the patented use. Nor does it "discourage generic manufacturers from invoking the Section viii carve-out." Generic manufacturers who actually carve out the patented use and do not promote infringement have nothing to fear. The jury's full damages award should be reinstated.

B. Teva is Not Entitled to a New Trial on Any Issue.

Teva is not entitled to a new trial. Teva did not separately argue any unique reason for why it should get a new trial—it requested one only as an "alternate remedy" for its JMOL-arguments about the alleged insufficiency of evidence. (*See, e.g.,* Appx12461 n.3; Appx12464 n.5.) The district court recognized that the two requests rose and fell together, and, since it had granted JMOL of no inducement, it determined a new trial would be futile and denied it. (Appx11 n.6.)

If this Court reverses the JMOL, a new trial would be appropriate under any circumstances. There is no separate basis for one other than the erroneous JMOL arguments. *See, e.g., Uniloc USA, Inc. v. Microsoft Corp.*, 632 F. 3d 1292, 1310 (Fed. Cir. 2010) (reversing conditional grant of a new trial where it was not supported by any "analysis apart from [the] analysis of the JMOL infringement issues"). "[T]his is not a situation where the evidence falls within the zone where substantial evidence supports the verdict and the district court's discretion in granting a new trial trumps such evidence." *Id.* Indeed, to allow a new trial would improperly permit Teva to reargue intensely factual issues to a new jury, wasting court resources and contradicting the Seventh Amendment's directive against re-examining jury findings.

CONCLUSION

For the reasons above, the Court should reverse the JMOL of no inducement, reject Teva's lost profits arguments, affirm the denial of a new trial, and reinstate the jury's verdict.

Dated: March 5, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE AND FILING

I certify that I electronically filed the foregoing document using the Court's CM/ECF filing system on March 5, 2019. All counsel of record were served via CM/ECF on March 5, 2019.

/s/ Michael A. Amon
Michael A. Amon

CERTIFICATE OF COMPLIANCE

The undersigned attorney certifies that GSK's Response and Reply Brief complies with the type-volume limitation set forth in Fed. Cir. R. 28.1(b)(1)(A). The relevant portions of the brief, including all footnotes, contain 9,503 words, as determined by Microsoft Word.

Dated: March 5, 2019

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