IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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

DEFENDANT TEVA PHARMACEUTICALS USA, INC.'S OPENING BRIEF IN SUPPORT OF ITS MOTION FOR JUDGMENT AS A MATTER OF LAW, OR IN THE ALTERNATIVE FOR A NEW TRIAL

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
David M. Fry (No. 5486)
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
dfry@shawkeller.com
Attorneys for Defendant Teva Pharmaceuticals USA, Inc.

OF COUNSEL:
Ira J. Levy
Andrew E. Riley
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018
(212) 813-8800

Daryl L. Wiesen
J. Anthony Downs
Christopher T. Holding
Elaine Herrmann Blais
Lana S. Shiferman
Robert Frederickson, III
Alexandra Lu
GOODWIN PROCTER LLP
100 Northern Avenue
Boston, MA 02210
(617) 570-1000

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PTX-1089.1	Letter to Teva, Attn: Jean W. Zwicker from Department of Health & Human Services re supplemental drug application dated 3/14/11 re labeling

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PTX-1192.1	Patent Certification - Revision of certification to U.S. Patent Nos. 5,760,069 and 5,902,821
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INTRODUCTION

At trial, GSK made the strategic decision to put all its eggs in one basket: it intentionally proceeded on the sole theory that Teva should be held liable because its conduct necessarily induced ***all*** direct infringement that occurred with Teva's generic carvedilol product. GSK argued that Teva's conduct induced doctors "as a class," asserting that Teva actively encouraged and caused 100% of the class of doctors who directly infringed to write 100% of the infringing prescriptions. But GSK failed to offer sufficient evidence to allow a reasonable jury to find in GSK's favor on this theory, and the evidence supports no other. In fact, *no* direct evidence was presented that anything Teva did caused any doctor to infringe. To the contrary, the jury heard extensive evidence, including from GSK's own expert, that other things such as medical guidelines and GSK's marketing caused doctors to prescribe carvedilol to patients with congestive heart failure ("CHF"). As this Court previously found, and the Federal Circuit has affirmed, such a failure to prove the only liability theory presented to the jury requires entry of judgment in favor of Teva. *See PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1354 (Fed. Cir. 2007). JMOL of no inducement, or at least no lost profits damages, is required.

GSK was on notice of the riskiness of its strategy to proceed solely on its "class effect" theory. Before trial, Teva disputed whether GSK had any evidence that Teva's allegedly inducing conduct *caused* doctors to write prescriptions in a manner that directly infringed the patent. GSK survived summary judgment by arguing that its expert, Dr. McCullough, "testified that he's seen the generic labeling, uses it to decide if carvedilol is right for a particular patient, and sometimes asks patients to bring it in" and that "Dr. McCullough directly contradicted that evidence [that doctors do not rely on generic labels] in testifying that doctors do 'follow' Defendants' labeling instructions and that he's read the generic label for carvedilol." (D.I. 403 at 7-8.) But the Court warned GSK that merely pointing to an inducing instruction was not enough:

"A generic drug manufacturer who has launched its product and whose label instructs others to use that product in an infringing manner might nonetheless escape inducement liability if the patentee fails to prove the elements of an induced infringement claim…." (D.I. 411 ¶ 5.)

At trial, however, GSK provided no evidence that Teva caused doctors—let alone the class of doctors—to directly infringe the '000 patent. Dr. McCullough never addressed or even acknowledged the causation element. Indeed, he admitted that many other things caused doctors to write prescriptions, and he never testified that he (or any other doctor) "followed" Teva's label or that Teva's label "caused" him (or anyone) to write an infringing prescription. Even after Teva's oral JMOL motion at the close of GSK's case-in-chief, when the Court gave GSK the opportunity to introduce evidence of causation in its rebuttal case, GSK failed to do so. Rather, GSK affirmatively elicited testimony that Teva's label ***did not*** cause Dr. McCullough to write infringing prescriptions: "Q: Now, before you started administering generic carvedilol to your patients … did you read Teva's generic label? A. ***No, I didn't.*** Q. Why not? A. I just assume they were the same." (Tr. at 1662:25-1663:5 (emphasis added).)

This testimony was a reversal of the prior arguments made by GSK at summary judgment and at trial. By the end of the case, GSK's theory of inducement had completely transformed, as GSK argued to the jury that Teva should be held liable as an inducer ***not*** because doctors were induced by Teva's label (GSK's original position, which the evidence failed to support), but instead because doctors did not bother to look at Teva's label to determine if it was the same or different from COREG's. According to GSK, doctors do not understand the patent and regulatory nuances of the Hatch-Waxman Act. Even if that were true, it could not suffice to establish Teva's liability. GSK seeks to impose on Teva (and the entire industry) an affirmative duty to correct the incorrect ***assumption*** that doctors purportedly make by misunderstanding the

FDA's AB-rating designation, or risk being held liable for ***all*** conduct of the doctors. This unprecedented theory runs contrary to controlling law and cannot support the verdict here.

Neither the survey evidence GSK presented at trial, nor any other evidence, fills the critical evidentiary gap related to causation. GSK used its survey to determine what percentage of Teva's product was used to treat patients with CHF under the other claimed conditions—17%—but GSK's proof stopped there. GSK did not ask if doctors read or relied on a generic label (much less Teva's label) or if doctors relied on *any* material from any generic company (or from Teva specifically) when prescribing carvedilol to treat CHF. GSK could easily have asked those questions in its survey, but it chose not to, and thus was left with no evidence to support its theory. With extensive evidence of multiple alternate causes for doctors prescribing carvedilol without having to rely on any alleged inducement from Teva, no reasonable jury could conclude that 100% of the alleged direct infringement was caused by Teva. As this was the only theory by which GSK attempted to prove liability, JMOL in Teva's favor should be entered.

At the very least, GSK's failure of proof dooms its claim for lost profits. In order to recover lost profits damages, GSK was required to present substantial evidence that would allow a jury to determine the amount of damages with reasonable certainty. GSK provided no evidence by which a jury could reasonably have determined how much infringement was actually caused by Teva's conduct. GSK offered only one ***assumed*** amount—100% of the sales GSK lost. The myriad alternative causes of the doctors' actions makes that number unreasonable. GSK chose to offer no evidence to support its assumption and no basis for any other conclusion, necessarily making any award of lost profits improperly speculative. Even if the Court were to deny JMOL on liability, at a minimum JMOL of no lost profits is required.

GSK also failed to provide substantial evidence to support the jury's conclusion that Teva

induced infringement during the so-called Skinny Label Period. There was not substantial evidence from which a jury could reasonably conclude that Teva's Skinny Label constituted an affirmative act that instructed, encouraged, or promoted the patented method, which required the intentional treatment of CHF (and other elements), or that Teva intended to induce infringement. Finally, JMOL, or a new trial, is required on willfulness and because the claims are invalid.

LEGAL STANDARD

Under Rule 50(a), judgment as a matter of law ("JMOL") is appropriate if "the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for [a] party." Fed. R. Civ. P. 50(a)(1). "To prevail on a renewed motion for JMOL following a jury trial, a party 'must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusion(s) implied [by] the jury's verdict cannot in law be supported by those findings.'" *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348 (Fed. Cir. 1998). Under Rule 59(a), "[a]lthough the standard for granting a new trial is less rigorous than the standard for granting judgment as a matter of law—in that the Court need not view the evidence in the light most favorable to the verdict winner—a new trial should only be granted where 'a miscarriage of justice would result if the verdict were to stand,' the verdict 'cries out to be overturned,' or where the verdict 'shocks [the] conscience.'" *Comcast IP Holdings I, LLC v. Sprint Commc'ns Co. L.P.*, 2015 WL 4730899, at *2 (D. Del. Aug. 10, 2015).

ARGUMENT

I. THE COURT SHOULD ENTER JMOL OF NO INDUCEMENT OR NO LOST PROFITS BECAUSE NO JURY COULD REASONABLY CONCLUDE THAT TEVA CAUSED DOCTORS "AS A CLASS" TO INFRINGE

As this Court found and instructed the jury, causation is an essential element of both GSK's claim for inducement and its claim for lost profits damages. (*See* D.I. 440, §§ 4.2.4 (Inducement), 6.3.5 (Lost Profits)); *Power Integrations, Inc. v. Fairchild Semiconductor, Int'l,*

Inc., 843 F.3d 1315, 1330-31 (Fed. Cir. 2016) ("*Power II*"). More specifically, GSK bore the burden of proving both that it was Teva's challenged conduct that actually caused direct infringement and the amount of direct infringement Teva caused. GSK chose to advance only one theory of causation for inducement and lost profits: that Teva caused physicians "as a class" to directly infringe. (*See, e.g.*, Tr. at 947:14-948:10 (arguing, "[s]o, yes, the evidence is that ***all*** of those sales were induced." (emphasis added)).) The trial record firmly established, however, that there were many alternative reasons that would cause a doctor to directly infringe, independent of Teva's acts. In view of this undisputed evidence, no jury could reasonably find that 100%—i.e., the "class"—of doctors were actually induced to infringe by Teva's actions.

The consequence of such a failure of proof of GSK's "class" theory of liability is two-fold. First, because GSK failed to provide sufficient evidence that Teva had in fact caused the "class" of doctors to infringe, and failed to argue or present evidence that any percentage of doctors lower than 100% had been induced by Teva to infringe, the appropriate remedy is to dismiss GSK's claim in its entirety on JMOL. *See PharmaStem*, 491 F.3d at 1354; *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1274-78 (Fed. Cir. 2004). Second, and independently, GSK's failure is fatal to its lost profits claim because GSK presented no evidence whatsoever of what portion of the allegedly infringing prescriptions or sales of carvedilol were written by doctors *because of* Teva's inducement. *See Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 711 F.3d 1348, 1374 (Fed. Cir. 2013) ("*Power I*"); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1334-1335 (Fed. Cir. 2009). JMOL should be granted.

A. JMOL of No Inducement Is Appropriate Because There Is Not Substantial Evidence that Teva Induced the Class of Doctors

1. There Is Not Substantial Evidence to Support a Conclusion that Teva Caused Doctors as a Class to Infringe the '000 Patent

GSK did not attempt to prove that Teva successfully communicated with and caused

infringement by any one doctor—or even a subset of doctors. In fact, Dr. McCullough did not even acknowledge the causation requirement of an inducement claim in his testimony. (*See, e.g.*, PDX-4.9; Tr. at 615:3-617:13.) Instead, GSK took the position that Teva directed allegedly inducing statements to an entire "class" of doctors.[1] (*See, e.g.*, Tr. at 1699:16-1700:7.) Once that allegation was made, GSK argues, it was not required to parse out whether Teva—or other factors—actually caused the alleged direct infringement. (*See, e.g.*, Tr. at 947:14-948:10.) GSK is wrong. Even assuming that GSK's theory of "class" inducement is viable generally, GSK was still required to ***actually prove*** that Teva caused the class of doctors to infringe.

Before and during trial, GSK relied on *Dynacore* to support its theory that Teva induced class wide direct infringement. In *Dynacore*, the Federal Circuit recognized that plaintiffs have two ways to prove indirect infringement. First, "Plaintiffs who identify ***individual*** acts of direct infringement must restrict their theories of vicarious liability—and tie their claims for damages or injunctive relief—to ***the identified act.***" *Id.* at 1274. To prove infringement on this theory, a plaintiff must "point to a specific instance of direct infringement and restrict its suit to liability stemming from that specific instance." *Id.* at 1276. Second, "Plaintiffs who identify an entire category of infringers (e.g., the defendant's customers) ***may*** cast their theories of vicarious liability more broadly, and ***may*** consequently seek damages or injunctions across the entire category." *Id.* at 1274 (emphasis added). Such a claim is not proven merely by allegation. Rather, the plaintiff must demonstrate that the accused conduct "necessarily infringe[s]" the asserted patent. *Id.* at 1275-76. In *Dynacore*, the plaintiff pursued a "class infringement" theory and although the plaintiff argued that ***some*** of the defendant's products could be used in an

[1] Using the survey conducted by Dr. Reisetter, GSK sought to identify (1) the percentage of Teva's sales that were used in an infringing manner and (2) the percentage of those infringing sales that GSK would have made "but for" Teva's infringement. The result of GSK's survey was that 17% of the sales of Teva's carvedilol were used by doctors in an infringing manner. GSK argued, of that 17%, Teva induced ***all*** of that direct infringement. (Tr. at 947:14-948:10.)

infringing manner, it fell short of demonstrating that all devices necessarily would be used in an infringing manner. *Id*. at 1277-78. As a result, the Federal Circuit affirmed a finding of summary judgment of no infringement, because the plaintiff had failed to prove the class effect on which it solely relied. *Id*. at 1278; *see also PharmaStem*, 491 F.3d at 1354; *Veritas Operating Corp. v. Microsoft Corp.*, 562 F. Supp. 2d 1141, 1287 (W.D. Wash. 2008) ("[Patentee] may identify 'an entire category of infringers.'… To do so, however, [patentee] must demonstrate that the accused products necessarily infringe. Failing that, [patentee] must limit its damages to the specific instances of direct infringement that it can identify.").

Here, there is not substantial evidence from which a jury could find or infer that *all* doctors who directly infringed did so—for every directly infringing prescription—because of Teva's conduct. No jury could reasonably disregard the multiple admissions from Dr. McCullough and other evidence that many factors other than Teva's conduct caused doctors to infringe GSK's patent. GSK's expert Dr. McCullough admitted that when Teva's generic carvedilol product launched in 2007, he did not read or rely on Teva's label to make any prescribing decisions, but just continued his same practice of prescribing carvedilol. (Tr. at 674:25-675:9, 1662:25-1663:3.) Teva's expert, Dr. Randall Zusman, testified that guidelines published by the American Heart Association and the American College of Cardiology "taught the method" claimed by GSK's patent and that they "continue to be very important documents in establishing treatment protocols, treatment regimens for heart failure patients." (Tr. at 1165:20-1168:5.) Dr. McCullough agreed, admitting that by 2005—before Teva launched—these guidelines "specifically recommended doctors give carvedilol to [CHF] patients" and that the recommendation "influence[d] the decisions of doctors" to prescribe carvedilol. (Tr. at 668:6-15.) That influence continued after generics launched. (Tr. at 677:11-16.)

The undisputed evidence at trial established additional causes of doctors' prescribing conduct. In the five years before generics launched, GSK spent nearly $1 billion detailing doctors and advertising and promoting the use of COREG. (Tr. at 508:9-509:11 (Vojir).) Dr. Zusman testified that advertising and promotion was effective to "influence [doctor's] selection [of] COREG" and "promote its use." (Tr. at 1169:15-1170:11, 1171:11-1175:21.) Dr. McCullough agreed that this influenced his decision to administer carvedilol to patients with CHF. (Tr. at 677:21-24.) Dr. McCullough further admitted other factors, independent of Teva, influenced his prescribing decisions after generic carvedilol launched, including: (1) his years of experience before generic carvedilol; (2) clinical guidelines; (3) publications concerning carvedilol clinical research; and (4) GSK's label. (Tr. at 676:9-677:10.) He testified that these factors continued to influence his prescribing behavior after 2007 when Teva's carvedilol product was available. (Tr. at 677:11-20.) The many alternative causes for the conduct of doctors make it unreasonable to accept even an inference of GSK's only trial theory—that all doctors "as a class" relied upon Teva's label or other statements in directly infringing.

2. There Is Not Substantial Evidence that the Class of Doctors Directly Infringed by Giving Carvedilol to "Decrease Mortality Caused by CHF"

GSK's class-wide theory of direct infringement suffered from a separate and independent flaw. Having convinced the Court that the "decreasing mortality" limitations required the administration of carvedilol for the intentional purpose of attempting to reduce the risk of mortality caused by CHF,[2] GSK was required to prove that the class of doctors actually administered the drug with that specific intent. Administering carvedilol, even to treat symptoms of CHF, is not infringing. (Tr. at 1135:8-24 (Zusman).) Dr. McCullough agreed, distinguishing

[2] (*See* D.I. 76 at 6-8; D.I. 90 at 11 ("The claimed method requires the administration of the claimed drugs with the intent to decrease the risk of mortality caused by CHF in a patient in need thereof, and does not cover administration of the drugs for solely other purposes, *e.g.*, to treat the symptoms of CHF."); D.I. 188 at 5-6 (same); *see also* D.I. 132 at 21.)

prior art based on the intent of the doctor. (Tr. at 1683:21-1686:15.) At no point did GSK offer any evidence that any doctor—let alone ***all*** doctors—administer carvedilol with the specific intent to decrease mortality instead of to treat symptoms or for other purposes. In fact, Teva's Amended Label was indicated not only for increasing survival but also "to reduce the risk of hospitalization." (Tr. at 630:7-15 (McCullough).) GSK's survey did not ask any question to parse out the underlying purpose for which carvedilol was administered to CHF patients, only what disease the patients had. (*See* PTX-989A.)

GSK therefore failed to establish the class-wide direct infringement on which its class inducement theory depends. Even if there was enough evidence to infer that some doctors administer the drug with the required intent, that evidence does not amount to substantial evidence that supports a verdict that ***all*** doctors "as a class" administered the drug for that infringing purpose. *See Pharmastem*, 491 F.3d at 1354; *Dynacore*, 363 F.3d at 1274.

3. The Remedy for GSK's Failure of Proof Is JMOL of Non-Infringement

Just like any plaintiff that fails to prove an essential element of its case, the remedy for GSK's failed attempt to prove that Teva caused the class of doctors to directly infringe is entry of JMOL of no liability. Under similar circumstances, Judge Sleet and the Federal Circuit reached that very conclusion in *PharmaStem*, where the Court entered JMOL of no infringement after a jury trial and the Federal Circuit affirmed. *See PharmaStem*, 491 F.3d at 1354. There, the asserted claim required compositions containing stem cells "in an amount sufficient to effect hematopoietic reconstitution of a human adult." *Id.* at 1347. As GSK did here, the plaintiff made a strategic decision to proceed on a liability theory that 100% of sales of the accused products met this limitation. *Id.* at 1354. According to the Federal Circuit, the plaintiff's trial strategy was not without risk: "[b]ecause of the manner in which PharmaStem sought to prove infringement, it committed itself to a course that had 'all-or-nothing' consequences." *Id.* The

well-supported trial recorded established that not all of the defendants' stem cells produced the claimed effect given the variability in the products. Initially, the Court granted a new trial based on record evidence that "suggest[ed] that at least some of the defendants' cord blood units infringe[d]." *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 2004 WL 2127192, at *11 (D. Del. Sept. 15, 2004).[3] Defendants moved for reconsideration, arguing that the Court should have entered JMOL because the only theory presented at trial (100% of the units infringed) was not supported by the evidence. The Court agreed:

> In addition, Pharmastem presented no evidence to the court regarding how to quantify the defendants' infringement and damages flowing from the infringement. Instead, Pharmastem chose to offer the evidence of successful adult transplants to prove that 100% of the defendants' units infringe. However, evidence of one successful adult transplant with a single cord blood unit does not prove that any other unit has sufficient stem cells to reconstitute a human adult because … cord blood units are highly variable in their stem cell content. As such, the court will not infer that 100% of the defendants' units infringe based on the defendants' statements regarding adult transplantation. Pharmastem failed to present evidence to the jury from which it could conclude that any specific cord blood unit or units stored by any of the defendants contained stem cells in a sufficient amount to reconstitute a human adult. The court, therefore, cannot determine which or how many of the defendants' units infringe, or how to quantify damages for infringement. Thus, the defendants are entitled to JMOL because there was no legally sufficient evidentiary basis for a reasonable jury to find that all, or any specific number, of the defendants['] cord blood units infringed the '681 patent.

PharmaStem Therapeutics, Inc. v. ViaCell, Inc., 2004 WL 2898061, at *4 (D. Del. Dec. 14, 2004). Consistent with *Dynacore*, the Federal Circuit affirmed:

> [H]aving chosen not to try to prove that particular cord blood samples or categories of samples contained sufficient stem cells to effect hematopoietic reconstitution of an adult, PharmaStem took the risk that the court would conclude that it had failed to prove that any of the defendants' cryopreserved samples infringed. The district court's narrow disposition of the JMOL issue simply held PharmaStem to the consequences of the strategy it adopted at trial.

[3] Granting Teva a new trial will not help GSK to overcome this shortcoming. GSK never developed the necessary evidence of causation during expert discovery. Thus, while Teva requests a new trial under Rule 59 as an alternative remedy, that trial would inevitably result in a similar failure of proof.

See PharmaStem, 491 F.3d at 1354.

The trial record in this case suffers from the same flaws as the record in *Dynacore* and *PharmaStem,* which requires granting judgment under Rule 50 to Teva. As in *Dynacore* and *PharmaStem*, GSK could have developed evidence of direct infringement ***actually caused by*** Teva's inducement. GSK had already commissioned a survey on infringement. All GSK had to do was ask those doctors whether they were induced to prescribe carvedilol by ***Teva*** or by other factors; at least GSK could have asked whether doctors even saw a (Teva) generic label, press release or catalog. But GSK avoided asking those questions, no doubt fearing (correctly) that the answers would decimate its case. So, as Dr. Reisetter conceded, GSK did not ask those questions in the survey. (Tr. at 742:3-743:7.) Nor did GSK ask either of its other experts, Dr. Maness and Dr. McCullough, to attempt to determine what percent of doctors were caused to infringe by Teva. (Tr. at 824:25-826:10, 835:1-837:4; 662:2-7.) The record is clear that GSK made a deliberate, tactical decision to stake its case on proving that ***all*** doctors, as a class, were caused to infringe by Teva's actions and not by something else. But there is not substantial evidence to support GSK's sole theory at trial and the Court must enter JMOL of no inducement.

B. The Court Should Grant JMOL of No Lost Profits Because GSK Failed to Quantify the Amount of Lost Profits "Caused By" Teva's Inducement

GSK's failure to account for the numerous factors that caused doctors to prescribe carvedilol in an infringing manner also dooms the jury's award of lost profits damages, even if the Court were not to grant JMOL of no inducement. GSK and its witnesses made it abundantly clear that GSK's damages demand ***assumed*** that 100% of the sales lost were induced by Teva. (*See. e.g.*, Tr. at 947:14-948:10 (GSK arguing, "Yes, and it is an assumption …").) For example, Dr. Maness admitted that the only number he provided to the jury was based on 100% of the lost sales allegedly being induced by Teva. (Tr. at 836:21-23.) But he made no attempt to parse the

number of lost sales that were induced by Teva as opposed to other factors. (Tr. at 825:24-826:2, 835:17-23, 836:4-7.) Dr. Maness's damages calculations were "totally based on Dr. Reisetter[]" and his survey, and he admitted he had "no alternative calculation" for lost profits. (Tr. at 827:6-15.) But, as Dr. Maness acknowledged, Dr. Reisetter did not "even ask[] what number were induced" in his survey (Tr. at 830:14-19), which Dr. Reisetter confirmed (Tr. 741:21-742:5). Dr. McCullough similarly made no effort to quantify the amount of infringement. (Tr. at 662:2-7.)

For the reasons set forth above, no jury could reasonably conclude that 100% of any direct infringement with Teva's products was caused by Teva's inducement as opposed to other factors. Thus, GSK's only lost profits calculation, relying on the assumption of 100% inducement, was not supported by substantial evidence. GSK made the decision not to put another alternative damages calculation in the record. On this record, the reasons why any given doctors infringed is simply an evidentiary black box. But the amount of lost profits damages cannot be based on mere speculation; there must be "sound economic proof" to allow the jury to estimate damages. *See Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1350 (Fed. Cir. 1999); *Hebert v. Lisle Corp.*, 99 F.3d 1109, 1119 (Fed. Cir. 1996). Here, the jury's award of lost profits amounts to pure speculation, and it must be discarded. *See Power I*, 711 F.3d at 1374 (rejecting damages award where plaintiff's expert "had no way to distinguish between infringing and noninfringing [products], and his assumption that all [products] incorporated an infringing [element] was speculation"); *Lucent Techs.*, 580 F.3d at 1334-35 ("But all the circumstantial evidence supports is the jury's implicit finding that at least one person performed the patented method one time in the United States sometime during the relevant period. Beyond that finding, all the jury had was speculation.").[4]

[4] GSK's *Panduit* analysis does not cure this problem with GSK's case. (*See* Tr. at 946:6-13.) Such an analysis would address how many of the allegedly infringing sales that were caused by

A finding of no lost profits does not leave GSK without any remedy. The jury also awarded $1.4 million in reasonable royalty damages (across both label periods). (D.I. 448 at 8.) Both damages experts agreed that this reasonable royalty would be appropriate if the Court found liability but not lost profits. (*See* Tr. at 841:23-842:15 (Maness); Tr. at 1599:4-20 (Addanki).) If the Court finds that GSK presented sufficient evidence of liability but not of lost profits damages, it should enter JMOL of no lost profits but leave the reasonable royalty award intact.[5]

II. THE COURT SHOULD ENTER JMOL OF NO INDUCEMENT DURING THE SKINNY LABEL PERIOD, OR ALTERNATIVELY, ORDER A NEW TRIAL

GSK failed to provide substantial evidence to support the jury's conclusion that Teva induced infringement during the Skinny Label Period. There was not substantial evidence from which a jury could reasonably conclude that Teva's Skinny Label constituted an affirmative act that instructed direct infringement. *See Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364-65 (Fed. Cir. 2003); *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1334 (Fed. Cir. 2003); *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1321 (Fed. Cir. 2012). Nor can Teva reasonably be held liable for inducement during this time period based on a product catalog that identified Teva's carvedilol as "AB-rated" to COREG. GSK's theory that Teva failed to include a disclaimer in its product literature when it referred to its AB-rating is both legally wrong and factually insufficient to support the verdict. *See Takeda Pharm. U.S.A, Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 630 (Fed. Cir. 2015). GSK also failed to present

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Teva's inducement would have been made by GSK instead, a figure that GSK put at 43%. (Tr. at 785:11-18 (Maness).) But, as was discussed extensively with the Court (*e.g.*, Tr. at 947:14-948:10; 955:5-21), the issue here involves a prior step in the causation analysis, which asks how much of the direct infringement was actually caused by Teva's inducement. The Federal Circuit recognizes that these are separate questions. *See Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc.*, 1 F. App'x 879, 883-84 (Fed. Cir. 2001). Thus, neither the 17% figure (for direct infringement) nor the 43% figure (for sales GSK otherwise would have made), even if credited as accurate, provides any support for the unfounded assumption of 100% inducement.

[5] At a minimum, the Court should grant Teva a new trial on damages. For the same reason noted in note 3, such a trial would, however, prove futile.

evidence that Teva intended or knew it was inducing infringement during this time period.

A. No Jury Could Reasonably Conclude that Teva's Skinny Label Constituted an Affirmative Act that Encouraged Direct Infringement

GSK was required to prove that Teva took affirmative acts after January 8, 2008 to encourage direct infringement. (*See* D.I. 440 § 4.2.2.) To rely on Teva's Skinny Label as an affirmative act, it was GSK's burden to prove that Teva's label "encourage[d], recommend[ed], or promote[d] infringement." *Takeda*, 785 F.3d at 630; *see AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010) ("*AstraZeneca 2010*"). The Court warned GSK at summary judgment: "[i]f GSK wants the jury to find that Teva's label 'would inevitably lead some [third parties] to practice the claimed method,' GSK is going to have to prove that—not merely assert it." (D.I. 411 ¶ 5(citation omitted).) As set forth below, GSK did not prove it.

1. Under *Warner-Lambert*, Teva's Skinny Label Could Not Instruct Doctors to Prescribe Carvedilol to Decrease Mortality Caused by CHF

During claim construction, GSK argued successfully that direct infringement required a doctor to administer carvedilol for the intentional purpose of "decreasing mortality caused by CHF," and not for the purpose of treating some other condition. Thus, the inducement inquiry necessarily turns (in part) on whether Teva's label instructed doctors to administer the drug for the intentional purpose of treating CHF—in particular, to "decrease mortality ***caused by*** CHF."

It was agreed at trial that Teva's Skinny Label omitted substantial information concerning the use of carvedilol in the treatment of CHF. For example, unlike the COREG label, Teva's "Indications and Usage" section did not identify "mild to severe chronic heart failure" as one of the conditions Teva's drug was "indicated for the treatment of." (*See* Tr. at 1191:3-5 (Zusman); PTX-1080.0001.) Teva's Skinny Label also did not contain instructions for administering carvedilol for purposes of treating CHF in the "Dosage and Administration" section. (Tr. at 1191:6-8 (Zusman).) Teva's Skinny Label omitted the entire discussion of the CHF clinical

trials (Tr. at 1191:19-22 (Zusman)), and also did not include information about treating CHF with carvedilol in the "warnings and precautions," "adverse reactions," and "special populations" sections. (Tr. at 1191:9-18 (Zusman).) The regulatory impact of these changes was undisputed. Both FDA experts testified that during this period, Teva's carvedilol was not approved by FDA for use in the treatment of CHF. (Tr. at 584:4-6 (Lietzan) ("Q. And in 2007, was Teva's label approved for congestive heart failure? A. No, it was not."); *see also* Tr. at 1027:20-23 (Karst).)

In view of this evidence, this case falls squarely within Federal Circuit precedent that a label for a drug can only instruct those uses for which the drug has received FDA approval—and, by extension, cannot instruct unapproved or "off label" uses. *See, e.g.*, *Warner-Lambert*, 316 F.3d at 1364-65; *Allergan*, 324 F.3d at 1334; *Bayer*, 676 F.3d at 1321-23. Because Teva's carvedilol was not approved for use in the treatment of CHF, its label could not, as a matter of law, instruct that off-label use. Although *Warner-Lambert* and its progeny arose in the pre-launch context, the same principle concerning what *the label* encourages necessarily applies post-launch. While other conduct, post-launch, may be considered, what a label encourages is the same before or after launch. If a carved-out label does not amount to an affirmative instruction of direct infringement pre-launch, the label itself cannot amount to an affirmative instruction of direct infringement post-launch under § 271(b). *See Caraco Pharm. Labs. v. Novo Nordisk A/S*, 566 U.S. 399, 406 (2012) (upon approval of a carve-out label, the generic company may "place its drug on the market, (assuming the [applicant] meets other requirements), but only for a subset of approved uses—*i.e.*, those not covered by the brand's patents ").

2. The Skinny Label Does Not "Inevitably" Instruct Direct Infringement

While GSK has repeatedly relied upon *AstraZeneca 2010*, the trial record here conclusively established that this is not a case where a "skinny" label would "inevitably lead" a doctor to practice the claimed method. *See AstraZeneca 2010*, 633 F.3d at 1060. Dr. Zusman

explained that a doctor would not understand that the Skinny Label was instructing the use of carvedilol for the purposes of decreasing mortality caused by CHF. (Tr. at 1191:23-1192:11.) Dr. McCullough testified that he would expect a drug's label to identify the "indications for which the drug is to be used" and the "corresponding safety information for those indications." (Tr. at 614:5-12.) But that is exactly the "important information" (*see* Tr. at 1652:3-1653:2 (McCullough)) that Teva carved-out from the Skinny Label. Thus, by GSK's rebuttal case, Dr. McCullough expressly confirmed that the Skinny Label did ***not*** encourage an infringing use as he testified that, had he read Teva's Skinny Label in 2007, he would not have prescribed Teva's carvedilol "[b]ecause even though the drug is the same, the difference is the package insert and the label ***which is missing too much information***." (*See* Tr. at 1660:18-1661:2 (emphasis added).) There is no way to reconcile Dr. McCullough's admission with GSK's theory that Teva's Skinny Label instructed administering carvedilol for the purpose of decreasing mortality caused by CHF.

Indeed, GSK did not even attempt to show how Teva's Skinny Label "inevitably lead" a doctor to write an infringing prescription. (*See* D.I. 411 ¶ 5.) Dr. McCullough merely conducted a cursory "march" through Teva's Skinny Label, where he pointed to various isolated statements that he contended "meet" or "mention" words in the various limitations of the claims. (Tr. at 623:15-17, 624:24-625:3, 625:24-626:8, 626:23-627:1, 629:15-18, 631:12-15.) For the limitations that required the doctor to write the prescription with a specific intent to "decrease mortality caused by congestive heart failure," Dr. McCullough pointed to only a sentence in the "Indications" section that reflected that Teva's carvedilol had received FDA approval for a ***different*** condition (i.e., not congestive heart failure)—treatment of left ventricular dysfunction following myocardial infarction ("Post-MI LVD")—and another sentence in the "Warnings"

section of Teva's label. (*See* PDX-4.17, PDX-4.34; Tr. at 623:6-17, PDX-4.18; Tr. at 623:18-23.) To carry its burden, however, GSK had to do more than "march" through the Skinny Label and find words and pictures that corresponded to or "mentioned" "heart failure," "mortality," and "ACE inhibitors."[6] It was required to show that Teva's Skinny Label recommended to physicians that they administer carvedilol as required by the claims—with the other medications and ***for purposes*** of decreasing mortality caused by CHF. At no point did Dr. McCullough offer any explanation of how or why any doctor would "inevitably" put together these isolated sentences (and graphs) from disparate sections in Teva's label in a manner that instructed an infringing use. *See Otsuka Pharm. Co., Ltd. v. Torrent Pharm. Ltd., Inc.*, 99 F. Supp. 3d 461, 493 (D.N.J. 2015) ("[I]f a patentee must engage in a 'scholarly scavenger hunt' through the label to identify statements that may inferentially but not inevitably tie a physician's thoughts or acts, the inducement theory necessarily fails." (citations omitted)). It is unreasonable to think the jury pieced these parts together in a way that was not supported by Dr. McCullough's testimony.

The Indications section recommends only treatment of different conditions—Post-MI LVD and hypertension. GSK was able to survive summary judgment on an argument that Post-MI LVD bore a close relation to CHF, but the trial record made clear that administering carvedilol for the purposes of treating Post-MI LVD is different from an instruction to administer carvedilol to decrease mortality "caused by CHF." *See Allergan,* 324 F.3d at 1324; *Bayer*, 676 F.3d at 1321. Even if some patients may have both conditions, the two conditions reflect

[6] For the limitation that required the administration of carvedilol "in combination with" other drugs, Dr. McCullough pointed to a sentence in the summary of the CAPRICORN study in the "Clinical Studies" portion of Teva's Skinny Label that stated "that the background treatment in these studies included ACE inhibitors or angiotensin receptor blockers" (which are not claimed) "in 97 percent of patients" and, he explained, "ACE inhibitors and diuretics are certainly mentioned there." (Tr. at 625:8-19.) For the limitation "said maintenance period is greater than six months," Dr. McCullough did not even direct the jury to a passage, instead pointing to a graph in the "Clinical Studies" portion of Teva's Skinny Label. (Tr. at 627:9-21; PDX-4.30.)

different patient populations, defined by separate clinical studies.[7] Dr. Zusman explained that doctors have different goals in mind when treating the two, separately defined conditions: "post-MI LVD patients, heart attack survivors, refer to a patient population who very recently suffered their heart attack. So it's usually within the first two weeks or maybe in the first three weeks. And when we treat those patients, we are treating them to help them survive their heart attack." (Tr. at 1183:2-22; *see also id*. at 1183:23-1184:8 ("We are treating survivors of a heart attack with a different goal in mind."); *accord* Tr. 605:17-606:8 (McCullough).) Although GSK had the burden on this issue, Dr. McCullough provided no testimony to the contrary,[8] and Dr. Zusman's testimony was fully corroborated by Dr. Neil Shusterman, a named inventor of the '000 patent and the GSK employee responsible for overseeing the U.S. Carvedilol (CHF) and CAPRICORN (Post-MI LVD) trials, who testified that the two studies involved "[f]undamentally different patient group[s]" with a "[f]undamentally different physiology going on in those two periods of time." (Tr. at 1522:2-1523:7; *see also* Tr. at 1183:2-22 (Zusman).) GSK confirmed the distinction between CHF and Post-MI LVD, when it swore in the patent information provided to FDA that the Post-MI LVD indication was ***not*** related to the '000 patent. (*See* Tr. at 1042:16-1044:18 (Karst); DTX-2190.9.) There was no evidence at trial that just because a doctor was treating a patient with both Post-MI LVD and CHF, she was inevitably intending to treat CHF. In fact, the only evidence in the record is that carvedilol was ***not effective*** in treating the subset of patients that suffered from both conditions. (Tr. at 1185:18-

[7] GSK obtained the Post-MI LVD indication by conducting a clinical trial (CAPRICORN) that specifically ***included*** the patient population excluded in the U.S. Carvedilol (CHF) trials. (Tr. at 1513:4-14, 1515:13-17 (Lukas, 30(b)(6) testimony.) Dr. Lukas, GSK's Rule 30(b)(6) witness on the conception and reduction to practice of the '000 patent, confirmed that Post-MI LVD patients were "not the basis of the ['000] patent. (*See* Tr. at 1516:5-14.)

[8] Dr. McCullough admitted that Post-MI LVD was broader than CHF—as not all Post-MI LVD patients suffer from CHF (i.e., the "without … symptomatic heart failure" in Teva's label)—and narrower than CHF—as not all CHF patients had a previous heart attack. (Tr. at 682:1-18.)

1187:5 (Zusman, explaining that Teva's Skinny Label for carvedilol showed no statistically significant benefit for patients with both Post-MI LVD and CHF).) The Skinny Label does not encourage infringement.

B. No Jury Could Reasonably Conclude that Teva's Actions Outside the Skinny Label Constituted an Affirmative Act that Encouraged Direct Infringement

Without Teva's Skinny Label as evidence of an affirmative act to encourage infringement—which was the foundation on which GSK built its argument to survive Teva's motions to dismiss and for summary judgment—GSK is left without legally sufficient evidence to support the jury's verdict during the Skinny Label Period. Indeed, until Dr. McCullough's rebuttal testimony, GSK had always relied on Teva's Skinny Label as key evidence in support of its claim. The additional evidence presented by GSK at trial is insufficient to prove inducement.

Turning to the evidence, the only alleged affirmative act by Teva during the Skinny Label Period (January 2008-May 2011) that GSK presented the jury was Teva's spring 2008 Product Guide (PTX-1208.8) that listed Teva's carvedilol as "AB rated" to COREG. All of the other alleged "affirmative acts" relied on by GSK and Dr. McCullough did not occur during the Skinny Label Period and thus cannot constitute affirmative acts of inducement during that period as a matter of law and logic.[9] As discussed below, that 2008 Product Guide (and arguments about what else it should have said) was legally insufficient to sustain the jury's verdict.

Teva's 2008 Product Guide simply reported that Teva's carvedilol product was AB-rated to COREG. As this Court has already observed, listing a product as AB-rated alone will not support a finding of inducement, and for good reason. Absent other evidence of affirmative,

[9] The exhibits relied on by Dr. McCullough that pre-date January 2008, such as Teva's September 2007 press release (*see.* Tr. at 642:24-644:7; PTX-1251), cannot be affirmative acts under the Court's jury instruction and *Nat'l Presto Indus., Inc. v. West Bend Co.*, 76 F.3d 1185, 1196 (Fed. Cir. 1996). The other exhibits all ***post-date*** the May 2011 label change. (*See* Tr. at 635:9-636:6 (Teva's 2015 website, PTX-860); 636:7-639:12 (the 2013 "MPR", PTX-1205); 639:13-640:22 (Teva's July 2011 Product Guide, PTX-1202).)

inducing acts (and, as set forth above, the Skinny Label is insufficient), "[a] finding in this context that the promotion of an 'AB rating' could amount to a plausible induced infringement claim would go too far. It would rely too heavily on the mindset or misconception of *third parties* in an attempt to ascribe wrongful intent to the alleged inducer." (*See* D.I. 191 at 20.)

In this case, there is no evidence that Teva's references to AB-rating in its product guide amount to "statements or actions directed to promoting infringement." *AstraZeneca 2010*, 633 F.3d at 1059. To begin, Dr. McCullough could not even say whether the Product Guide was ***seen***, let alone relied on, by doctors. (Tr. at 686:3-8 ("I don't know that. I think it's possible.").) Putting that aide, however, it does not instruct, teach, encourage, or promote any particular use, let alone the claimed method of use. In fact, the Product Guide does not even mention CHF. It does not instruct to administer Teva's carvedilol "in combination with" the other claimed drugs. There is no reference to any dosing schedule, let alone the use of a "maintenance dosage" for a "maintenance period" that is "greater than six months." In the context of a label, the Federal Circuit has held that "[g]iven the statutory scheme explained above,"—i.e., the Hatch-Waxman Act that expressly authorized, if not encouraged, carve-outs—"vague label language cannot be combined with speculation about how physicians may act to find inducement." *Takeda*, 785 F.3d at 632. Here, GSK's reliance on a product guide is even further removed from the label in *Takeda*, and is not inducement to use a drug in a particular manner. *See Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 937 (2005) (inducement requires "purposeful, culpable expression and conduct," not "ordinary acts incident to product distribution").

Indeed, the undisputed evidence at trial was that an AB-rating does not mean approved for all indications. (Tr. at 534:10-16 (Lietzan); Tr. at 1033:15-18 (Karst); DTX-2171.7.) FDA granted Teva an AB-rating in 2007, even though it had not been approved for the CHF

indication. (Tr. at 1077:25-1078:10 (Kinsey).) The FDA's own 2007 press release announcing approval of multiple generic carvedilol products stated all those products "work [in] the same way" as (i.e., are therapeutically equivalent to) the brand, while also noting that their labels may contain carve-outs. (DTX-2287.) GSK's regulatory expert, Professor Lietzan, confirmed that an "AB-rating" is "shorthand for therapeutically equivalent" which means "if the generic drug is used ***in accordance with its label***, you would expect it to have the same clinical effect in a person as if that person had taken the brand drug." (Tr. at 533:24-534:16; *accord* Tr. at 1035:5-24 (Karst).) And, she testified that Teva's statement that its product was AB-rated to COREG ***was accurate*** during the Skinny Label Period. (Tr. at 542:8-10; *accord* Tr. at 1030:21-25 (Karst).) There is no dispute, therefore, that Teva's statements about its AB-rating did not actually teach any particular use of its carvedilol, and a jury could not reasonably find otherwise.

GSK nevertheless suggests that Teva somehow crossed the line to inducement when it went beyond saying "AB-rated" and instead said that its product was "AB rated and bioequivalent ***to COREG***." But there is no difference between saying "AB-rated" without reference to COREG and saying "AB-rated" with a reference to COREG, either legally or factually, and neither teaches any particular use for the product. An AB-rating is a "therapeutic equivalence" rating. (Tr. at 533:24-534:9 (Lietzan).) FDA gives A ratings (including AB ratings), in its own words, to "drug products that FDA considers to be therapeutically equivalent to other pharmaceutically equivalent products." (DTX-2171.13 (emphasis altered).) In other words, any AB rating is ***necessarily a comparison*** to the brand product. For example, FDA's approval letter to Teva stated that Teva's product was "therapeutically equivalent to … Coreg." (PTX-1093.2.) The Orange Book is structured on this premise: all carvedilol products are listed together, with COREG designated as the "reference" drug to which the other carvedilol products,

including Teva's, are identified as AB-rated. (Tr. 1034:21-1035:20 (Karst); DTX-2171.)

Perhaps recognizing that the product guide did not instruct infringement on its face, GSK sought to impose upon Teva an obligation not found in the law in rebuttal and closing—i.e., that Teva was required to inform doctors that Teva's product was not approved for all indications. As GSK argued in closing (with demonstratives PDX-7.3, PDX-7.4 for context):

> So what could Teva have done to let doctors know that it had not been approved for the treatment of congestive heart failure at least up until 2011? What could they have done? This is their 2007 press release. They deliberately put in the whole market, including heart failure right here. They deliberately call it GlaxoSmithKline's cardiovascular agent Coreg and that they are the generic version of it. All they had to do is that. ***If they had done that, we would not be here today.*** Now, they didn't even have to do it in red. They could save ink and do it in black. ***They could even do it in fine print if they want[ed] to and then put the onus on the doctor to read it more carefully***. They could have done it. They didn't do it.

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

* * *

> Their product catalog, what could they have done? Right there. That's it. Simple. Asterisk. We don't want to mislead you. Not approved for the treatment of congestive heart failure, because this is in 2008, so it had not been approved at that point.

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	93/51	AB*	0093-0051-01	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

(Tr. at 1859:20-1860:21.)[10]

[10] That GSK would make this argument to the jury was surprising in view of GSK's prior admission to the Court that such an argument would be "hyperbol[e] ." (*See* Tr. at 943:4-18.)

The Court should squarely reject GSK's theory that Teva was required to include disclaimers or "fine print" in its product catalogues because it is wrong as a matter of law.[11] "The addition of the adverb 'actively' [to § 271(b)] suggests that the inducement must involve the taking of affirmative steps to bring about the desired result." *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 760 (2011). As a result, the Federal Circuit has already rejected the very argument GSK advanced here, that generic drug companies need to affirmatively disclaim carved-out uses of a drug, which it concluded would "turn[] the legal test [of inducement] on its head." *See Takeda*, 785 F.3d at 632 n.4 ("Takeda need[ed] to show that Hikma took affirmative steps to induce, not affirmative steps to make sure others avoid infringement."); *Tegal Corp. v. Tokyo Electron Co., Ltd.*, 248 F.3d 1376, 1378 (Fed. Cir. 2001) ("[E]vidence of mere inaction [does] not constitute inducement."). Indeed, if the Court were to impose a duty to disclaim on companies, the well-trodden rule that "intent to induce infringement cannot be inferred even when the defendant has actual knowledge that some users of its product may be infringing the patent" would be rendered illusory. *See Warner-Lambert*, 316 F.3d at 1365.

There is no evidence by which a reasonable jury could find Teva actively encouraged infringement during the Skinny Label period. JMOL of no infringement should be granted.

[11] By endorsing this legal theory, the Court would create a new rule that would dramatically upset the delicate balance struck by the Hatch-Waxman Act. Generic drug companies have been relying on the brand company's patent information, carving-out indications, and obtaining "AB-ratings" since the mid-1980s. For that entire time, neither Professor Lietzan nor Mr. Karst had ever heard of a generic company inserting GSK's disclaimer. (Tr. at 578:4-12 (Lietzan); Tr. at 1030:9-14 (Karst).) Moreover, by carving-out the CHF indication, ***Teva did communicate*** that its product was not approved for CHF. (Tr. at 584:4-6 (Lietzan); Tr. at 1027:20-23 (Karst).) Dr. McCullough's admission that Teva's Skinny Label "was missing too much information" (Tr. at 1660:18-1661:2) to be relied on should end the inquiry. *See AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1380 (Fed. Cir. 2012) (when a label "explicitly and undisputably carve[s] out all patented indications," a plaintiff may not rely on the fact that "pharmacists ***and doctors*** will nonetheless substitute the generic for all indications….") (emphasis added).

C. No Jury Could Reasonably Conclude that Teva Knowingly Intended to Induce Infringement of the '000 Patent During the Skinny Label Period

1. There is No Evidence Teva *Intended* to Induce Infringement

GSK presented no evidence that Teva intended any of its conduct to induce doctors to infringe. To the contrary, the evidence demonstrated that Teva attempted to carve out of its label the entire indication—treatment of CHF—covered by GSK's patent. *See Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1329 (Fed. Cir. 2009) (finding no specific intent when instructions were amended evidencing "intent to discourage infringement"); *Otsuka*, 99 F. Supp. 3d at 485-86 ("[T]his affirmative action [of removing the indication] would seem to negate any reasonable inference of an active intent to induce infringement.").

Moreover, the relevant regulatory and factual record relating to Teva's labeling amendments was undisputed at trial. Federal law imposed on GSK a duty to disclose to FDA and, by extension the generic pharmaceutical industry, those portions of its label that it believed were covered by the '000 patent. (Tr. at 1002:13-1004:2 (Karst); *see also* Tr. at 521:6-9 (Lietzan).) GSK admitted that it never identified the Post-MI LVD indication to FDA or any language associated with the Post-MI LVD indication, despite the requirements of the FDA to separately identify each indication. (Tr. at 1066:13-1067:3 (Kinzig); DTX-2192.7; DTX-2190.9-.10.) Teva thereafter relied on GSK's sworn description of its patent coverage and followed FDA's instructions as to what language to carve-out from its label. (Tr. at 906:10-908:20 (Pastore); DTX-2203.) Teva then certified to FDA that it believed it had successfully and appropriately carved-out the language covered by GSK's patent. (Tr. at 904:17-905:15 (Pastore); PTX-1192.1; DTX-2286.1.) GSK never communicated to Teva that it believed Teva was inducing infringement through the Skinny Label prior to filing this case in 2014.

In view of this undisputed record, GSK sought to have the jury infer a wrongful intent based on the fact that Teva ***knew*** its product would be substituted at the pharmacy level for virtually all COREG prescriptions and Teva "never stopped it." (Tr. at 1848:7-22 (GSK closing).) While GSK may have succeeded in villainizing Teva's witnesses, its theory of specific intent was contrary to law. Teva's actual knowledge of direct infringement is "legally irrelevant" to the question of intent and it was wrong for GSK to have the jury infer wrongful intent based on Teva's knowledge alone. *See Warner-Lambert*, 316 F.3d at 1364-65. There was no other evidence that Teva intended to induce doctors to infringe.

2. There Is No Evidence that Teva *Knew* It Was Inducing Infringement

With respect to the Skinny Label, even if some doctor would cobble together the isolated portions of Teva's Skinny Label in the manner alleged by Dr. McCullough and even if that resulted in an act of direct infringement, there is no evidence that Teva ***knew*** its label was causing a doctor to behave in that manner. In other words, there is no evidence that Teva believed anything other than it had successfully carved-out the '000 patent from its label.

The same conclusion must be reached with respect to Teva's reference to its product as AB-rated. Particularly given the evidence recited above, there is no evidence from which a jury could reasonably conclude that Teva knew that listing a product as AB-rated in its product guide was causing doctors to write infringing prescriptions. *See Global-Tech*, 563 U.S. at 765-66. The only evidence is that Teva was aware of substitution laws and may have known that its carvedilol would be substituted for CHF prescriptions ***by pharmacists*** (who are not direct infringers). But there is no evidence that Teva knew it was inducing ***doctors*** to write infringing prescriptions.

D. GSK Is Not Entitled to Lost Profits if the Court Enters JMOL in Teva's Favor During the Skinny Label Period

If the Court grants Teva's motion for JMOL during the Skinny Label Period, then the

Court should enter JMOL of no lost profits during the later Amended Label period because GSK introduced no evidence to show how much, if any, inducement during the Amended Label period was caused by Teva's Amended Label. Under that scenario, the lost profits question becomes: how many additional sales did GSK lose with the indication added back to the label beyond what it already had been losing during the Skinny Label period? Even though GSK agreed that liability should be separately adjudicated during the Skinny and Amended Label Periods, GSK offered no evidence of an appropriate lost profits award in the Amended Label Period-only scenario.[12] Instead, the only record evidence is Dr. McCullough's testimony that he (wrongly) *always* assumed Teva's label was the same as GSK's COREG and that doctors generally are unaware that generic companies can even omit indications from their label. (Tr. at 1661:15-22; 1662:25-1663:5.) Further, Dr. McCullough testified that his prescribing habits did not change when Teva amended its label in 2011. (Tr. at 699:6-10.) And, the undisputed evidence was that changes to the label—even adding an indication—have no market impact because substitution takes place ***independent*** of the labeled indications. (*See* Tr. at 1038:2-24 (Karst); Tr. at 1085:7-1087:10 (Kinsey).) Thus, there is no evidentiary basis, let alone substantial evidence, from which a jury could conclude that Teva's May 2011 Amended Label ***caused*** GSK to lose any additional sales that would be required to establish lost profits.[13] Moreover, the Skinny Label could not induce all CHF treatment as Dr. McCullough admitted that not all CHF patients previously suffered a heart attack (i.e., were Post-MI). (*See* Tr. at 682:12-18.) GSK put forth no estimate to quantify that subset of total CHF patients for purposes of assessing damages.

[12] Dr. Maness's testimony about the amount of claimed lost profits per year (Tr. at 814:20-816:3; *see* PTX-1489, PTX-1490, PDX-6.31) does not cure this fatal deficiency. This evidence was merely chronological; it did nothing to isolate the incremental amount of lost profits (if any) caused by adding the CHF indication back to Teva's label.

[13] In this scenario, lost profits are also not available because the Skinny Label constitutes a non-infringing alternative under *Grain Processing*.

III. THE COURT SHOULD ENTER JMOL OF NO WILLFUL INFRINGEMENT

There is not substantial evidence to support the jury's finding that Teva willfully infringed GSK's patent. Teva raised invalidity defenses in a detailed statement in 2002, and presented similar defenses—based on Kelly (DTX-2124)—at trial. (PTX-106.) Teva's invalidity position was reasonable then and it was reasonable today. Indeed, the Court agreed with Teva on the primary legal dispute concerning the test for inherency. (D.I. 380 at 3-4.) With respect to inducement, as set forth above, Teva tried to avoid inducing infringement. Jill Pastore and the team responsible for labeling relied on the patent information that GSK provided and FDA's instructions in determining what to carve-out (just like ten other generic companies did). (Tr. at 911:25-913:11.) When FDA asked Teva to put the material back in the label in 2011, Teva did so to comply with FDA's request. (Tr. at 465:7-10, 925:9-926:7 (Pastore); PTX-1089.1; PTX-1088.1.) Even if that decision was ultimately wrong, it was certainly not willful.

IV. THE COURT SHOULD ENTER JMOL OF INVALIDITY

A. The Court Should Enter JMOL that Kelly Anticipates the Asserted Claims

Teva renews its motion for JMOL or seeks a new trial that Kelly (DTX-2124)—which describes the same Australia / New Zealand ("ANZ") carvedilol trial described in the Amended Label—anticipates the asserted claims. At trial, GSK contested only three issues: (1) whether Kelly disclosed treating "congestive heart failure"; (2) whether Kelly disclosed administering carvedilol for more than six months; and (3) whether Kelly was enabled.

With respect to the question of enablement, the sole factual question for the jury was whether Kelly was "too theoretical" to be considered enabling. (D. I. 417 ¶ 5.) Dr. McCullough testified that "[u]ntil the research study is done, it is theoretical, it is not proven, and that it would require undue experimentation, meaning that one would actually need to do the study in order" for it to be enabling. (Tr. at 1679:6-19.) Not only was Dr. McCullough's testimony contrary to

the Court's order precluding GSK from arguing that Kelly was not enabling because it did not contain data on efficacy (D.I. 417 ¶ 5), it misstated the law of enablement of prior art references. *See Novo/Nordisk Pharm. Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1355 (Fed. Cir. 2005); *accord In re Montgomery*, 677 F.3d 1375, 1382 (Fed. Cir. 2012). It was also contrary to the evidence. He admitted on cross examination—referring to a 1993 publication by Garg (DTX-2288)—that the prior art taught that the AZN study was underway prior to the filing date of the patent. (Tr. at 1710:6-1712:4 (admitting that the ANZ trial was "not theoretical anymore.").)

Dr. McCullough testified that the statement in Kelly that patients will be compared to baseline "after 6 and 18 months of ***follow-up***" was too ambiguous to tell whether the patients actually received the drug for a "maintenance period … greater than six months." (Tr. at 1673:11-18.) In his infringement presentation for that same six-month limitation, however, Dr. McCullough pointed to that same phrase in Teva's Amended Label—"follow up"—for the same ANZ trial as evidence that he was "certain" that the patients received the drug for more than six months. (Tr. at 629:5-14.) When confronted with this inconsistency, he flatly admitted he simply interpreted the same phrase differently for purposes of infringement and invalidity. (Tr. at 1717:10-1718:9.) In view of his testimony on direct examination, the admission on cross, and the explanation provided by Dr. Rosendorff (Tr. at 1312:25-1313:25), no jury could reasonably conclude that "follow up" meant anything other than more than six months of treatment.

Third, with respect to whether Kelly discloses administering the drug to treat ***congestive*** heart failure, Dr. McCullough testified as follows: "[T]his is a very brief description so it doesn't disclose a range of symptoms [] patients would have, and it doesn't disclose the ejection fraction, which is a very important number in cardiology." (Tr. at 1673:2-7.) Dr. McCullough's analysis amounted to a conclusory assertion that he did not see certain words in Kelly, *see*

Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 716 (Fed. Cir. 1984), while he ignored the ***other*** information that was disclosed in Kelly that Dr. Rosendorff explained taught Kelly was directed toward "congestive heart failure." (Tr. at 1401:12-1402:25.) GSK presented no contrary evidence. No reasonable jury could fail to find that Kelly anticipates the '000 patent.

B. The Court Should Find the Asserted Claims Obvious

There is no genuine dispute that all of the limitations of the '000 patent were disclosed in the prior art. As noted above, GSK disputed only that Kelly disclosed (1) treating "congestive heart failure" and (2) administering carvedilol for longer than six months. But another reference concerning the same trial, Garg (DTX-2288), explicitly disclosed these details. Garg confirmed that Kelly was directed towards patients that suffered from CHF as construed by the Court. (*See* Tr. at 1681:1-1682:3, 1712:20-1713:5 (McCullough).) Dr. McCullough did not address, let alone rebut, the multiple prior art references that discussed the beneficial effects of long-term (i.e., greater than six months') treatment with beta blockers generally and carvedilol in particular in heart failure patients. (*See, e.g.*, Tr. at 1343:3-10 (Rosendorff).)

GSK focused its validity rebuttal on its contention that there was not a reasonable expectation of success that carvedilol would "decrease mortality caused by CHF." (*See* Tr. at 1684:4-9 (McCullough).) The inquiry is not whether a POSA would ***know*** that an inherent characteristic of a claimed treatment method would work, but whether the claimed result was unexpected. *See Honeywell Int'l Inc. v. Mexichem Amanco Holding S.A. DE C.V.*, __ F.3d __, 2017 WL 3254943, at *4 (Fed. Cir. Aug. 1, 2017). Dr. McCullough did not address the prior art that expressly predicted that beta blockers, like carvedilol, would improve survival. (Tr. at 1336:15-1337:6 (Rosendorff).) And, he admitted that the prior art taught (and provided supporting data) that carvedilol improved "cardiac function"—in other words, carvedilol

improved the health of an otherwise failing heart. (Tr. at 1708:7-1709:8.) As Dr. Rosendorff explained, "[i]f the heart gets better, patients live longer." (Tr. at 1357:14-1358:6.)

Finally, the rest of GSK's rebuttal case involved a march through various secondary considerations, each of which suffered problems. (*See* Tr. at 1529:14-1537:20 (Hoffman) (blocking patent of commercial success); Tr. at 1705:8-1707:15 (McCullough) (praise for prior artists); Tr. at 1708:8-1709:8 (McCullough) (failure of others).) This evidence was insufficient for a reasonable jury to fail to conclude that the claims were obvious.

C. The Court Should Grant a New Trial on Invalidity

At a minimum, Teva respectfully requests a new trial on the questions of invalidity. Even if none of the issues raised above would justify judgment as a matter of law, the jury's finding of validity of all claims is contrary to the clear weight of the evidence.

V. THE COURT SHOULD ENTER JMOL OF NO INDUCEMENT OF CLAIMS 6 AND 7 DURING THE AMENDED LABEL PERIOD

Although the jury correctly concluded that Teva did not induce infringement of claims 6 and 7 during the Skinny Label Period, it found that Teva induced infringement of those claims during the Amended Label Period. (D.I. 448 at 3.) But GSK offered only a single theory of infringement for both time periods—that Teva induced these dependent limitations because of information in *third-party guidelines* about available ACE inhibitors and diuretics. (Tr. at 649:9-651:4 (McCullough).) Dr. McCullough admitted that nothing in Teva's label instructed the use of the specific ACE inhibitors and diuretics claimed. (Tr. at 658:14-659:9.) Thus, JMOL of no inducement for claims 6 and 7 during the Amended Label period is warranted.

CONCLUSION

For the foregoing reasons, Teva respectfully requests the Court enter judgment as a matter of law of non-infringement, invalidity, and no lost profits.

/s/ David M. Fry

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
David M. Fry (No. 5486)
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
dfry@shawkeller.com
Attorneys for Defendant Teva Pharmaceuticals USA, Inc.

OF COUNSEL:
Ira J. Levy
Andrew E. Riley
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018
(212) 813-8800

Daryl L. Wiesen
J. Anthony Downs
Christopher T. Holding
Elaine Herrmann Blais
Lana S. Shiferman
Robert Frederickson, III
Alexandra Lu
GOODWIN PROCTER LLP
100 Northern Avenue
Boston, MA 02110
(617) 570-1000

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