No. 18-1976, -2023

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

GLAXOSMITHKLINE LLC and SMITHKLINE BEECHAM (CORK) LIMITED,

Plaintiffs-Appellants,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Cross-Appellant.

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

REPLY BRIEF OF DEFENDANT-CROSS-APPELLANT TEVA PHARMACEUTICALS USA, INC.

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March 5, 2019

CERTIFICATE OF INTEREST

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

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

Teva Pharmaceuticals USA, Inc.

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

N/A

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

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

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

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

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

/s/ William M. Jay
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TABLE OF ABBREVIATIONS

the ’000 patent	U.S. Patent No. RE40,000 (Appx31-45)
ACC	American College of Cardiology
AHA	American Heart Association
CHF	Congestive heart failure (Appx128-130)
GSK	Appellants GlaxoSmithKline LLC and SmithKline Beecham (Cork) Limited
JMOL	Judgment as a matter of law
Post-MI LVD	Left ventricular dysfunction following myocardial infarction
Teva	Defendant-Cross-Appellant Teva Pharmaceuticals USA, Inc.

INTRODUCTION

If the Court reaches the conditional cross-appeal, it should reject GSK's lost-profits argument. GSK is claiming that even if Teva (and each of the other generic carvedilol manufacturers that GSK did not sue) had sold generic carvedilol without inducing anyone to practice the claimed method, GSK would have experienced the same loss of profits because physicians would have directly infringed *without any inducement*. Set aside for a moment the glaring inconsistency with GSK's inducement argument in the main appeal, which asks the Court to infer that Teva's inducement caused *all* of the direct infringement—*i.e.*, that not a single doctor would have infringed absent inducement *by Teva*. Even on its own terms, GSK's infringement-anyway argument highlights why lost profits are not available: inducement is the sole allegation against Teva, yet GSK's theory is that inducement was not the but-for cause of its lost profits. GSK cannot recover $234 million from Teva if inducement by Teva did not cause GSK $234 million in injury. Lost profits are *compensatory* damages, not a penalty or a windfall.

GSK also ignores entirely this Court's holding in *Grain Processing Corp. v. American Maize-Products Co.* that if an infringement defendant could have taken "alternative action" to avoid infringing and made the same sales, then only a reasonable royalty award is warranted. 185 F.3d 1341, 1350-1351 (Fed. Cir. 1999). GSK does not dispute that Teva could have avoided infringement by, for

example, launching its product with only the hypertension indication on the label. Had Teva done so, the undisputed facts show that GSK would have lost just as many sales. These are precisely the circumstances that, under *Grain Processing*, defeat but-for causation and lost profits.

At best, GSK invokes not a but-for world, but an imaginary one—one in which generic drug manufacturers are prohibited from launching with a skinny label, or pharmacies are prohibited from substituting generic drug products for branded ones irrespective of why the doctor prescribes them. This turns upside-down the hypothetical market-reconstruction inquiry, which is supposed to be grounded in "sound economic and factual predicates." *Riles v. Shell Exploration & Prod. Co.*, 298 F.3d 1302, 1311 (Fed. Cir. 2002).

But even if this Court were to agree with GSK with respect to JMOL *and* lost profits, it could not simply reinstate the jury verdict. GSK does not dispute that the district court failed to rule on Teva's motion in the alternative for a new trial, as Federal Rule of Civil Procedure 50(c)(1) requires. Instead GSK asks this Court to rule, in the first instance, that Teva is not entitled to a new trial. That is neither necessary nor appropriate to remedy the district court's noncompliance with Rule 50(c)(1): the new-trial motion included issues not before this Court, and the district court has first-line discretion to decide whether to grant it. If it does not affirm, the Court should simply remand the new-trial issue for a decision.

ARGUMENT

I. The District Court Refused To Consider The Key Fact: Teva's Sales Would Have Gone Not To GSK, But To Other Non-Infringing Generic Carvedilol Manufacturers.

A. The "Controlling Question" Is What The Patentee Would Have Earned In Profit But For The Defendant's Wrongful Conduct.

As GSK acknowledges (at 32), GSK is entitled to "compensation" for any profits lost *because of Teva's* infringement. *See* 35 U.S.C. § 284 ("damages adequate to compensate for the infringement"). It is not entitled to more than that. As a result, "to determine the damages that may be recovered from [Teva] here," the controlling question is how much GSK would have earned in profit *if Teva* had not infringed by inducement. *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 507 (1964) ("[W]e must ask how much CTR suffered *by Aro's infringement*—how much it would have made *if Aro* had not infringed." (emphases added)); *Water Techs. Corp. v. Calco, Ltd.*, 850 F.2d 660, 671 (Fed. Cir. 1998) ("Our precedent is in agreement that a lost profits award is appropriate only if WTC/WPCS proved that it would have made sales of its water purifier product 'but for' *Calco's and Gartner's infringement*, i.e., that causation existed." (emphasis added)).

This inquiry, which requires proof grounded in "sound economic and factual predicates" to "reconstruct[]" what the market would have looked like if the defendant had not infringed using proof," *Riles v. Shell Exploration & Prod. Co.*,

298 F.3d 1302, 1311 (Fed. Cir. 2002), allows patentees to show "all of the ways in which they would have been better off in the 'but for world.'" *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1350 (Fed. Cir. 1999). In this case, that means asking what additional sales (if any) GSK would have made if neither Teva nor any other generic defendant had infringed the '000 patent. And answering that question requires recognition that manufacturers and pharmacies could sell the same generic carvedilol, under the same generic-substitution regime, without infringing the '000 patent.

GSK's brief sidesteps the question entirely. Instead, GSK's entire argument is founded on a premise that if it can satisfy the four-factor test articulated in *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152 (6th Cir. 1978), that is the end of the story. GSK simply ignores the well-established principle (collected in Teva's principal brief at 69-70) that the "prerequisite for lost profits" is "but-for causation," not the *Panduit* factors. *BIC Leisure Prods., Inc. v. Windsurfing Int'l, Inc.*, 1 F.3d 1214, 1218 (Fed. Cir. 1993). *Panduit* itself involved a very different fact pattern having nothing to do with inducement, and this Court has long recognized that while *Panduit* can be useful in some contexts, "other fact situations may require different means of evaluation." *Id*. The ultimate test is but-for causation. Where, as here, *Panduit* is not suited to analyze whether the but-for standard has been satisfied, GSK's simplistic reliance on it is misplaced.

The *Panduit* factors best fit the "easy case": where "there are only two suppliers in the market, the infringer and the patent owner," *Water Techs.*, 850 F.2d at 672, and therefore it is "reasonable to assume, provided the patent owner has the manufacturing and marketing capabilities, that it would have made the infringer's sales," Robert Patrick Merges, *Patent Law and Policy* 1063 (2d ed. 1997).[1] The factors do not apply in every case, and they are a particularly poor fit in complicated cases, like this one, with many non-infringing suppliers of a product. *BIC*, 1 F.3d at 1218 (reversing and remanding because the district court "erred by failing to apply the 'but for' test" and instead applied the *Panduit* factors, where were "not appropriate in th[at] case").[2]

This is not the "easy case." As GSK told the district court repeatedly, "this case is a very fact specific case that Your Honor may not have ever seen before and may not ever see again." Appx12162, Appx12179, Appx12220. GSK does

[1] *See also* John C. Jarosz & Erin M. Page, *The* Panduit *Lost Profits Test After* BIC Leisure v. Windsurfing, 3 Fed. Cir. B.J. 311, 315 (1993) ("A limitation of the straight Panduit test is that, at best, it may be applicable only in very specific circumstances—when the infringer's and the patent owner's products at issue are the only ones in the relevant 'market.'"); Liane M. Peterson, Grain Processing *and* Crystal Semiconductor*: Use of Economic Methods in Damage Calculations Will Accurately Compensate for Patent Infringement*, 13 Fed. Cir. B.J. 41, 61 (2003) ("[T]he original *Panduit* test is simple to apply and works well in a two-supplier market, because it is reasonable to assume that the patent holder would have made all of the infringing sales if the infringement had not occurred." (footnote omitted)).

[2] In multiple-supplier markets, for example, this Court has applied a "market share" test rather than a straight application of the *Panduit* factors. *See, e.g.*, *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1578 (Fed. Cir. 1989).

not dispute that this case does not involve an infringing product (the carvedilol molecule was not patent-protected); that numerous generic carvedilol suppliers sold generic carvedilol without committing any act of infringement (inducement or otherwise); and that even if Teva's product were removed from the market, pharmacies would have substituted those other generic products (sold and prescribed without inducement) for GSK's Coreg.[3] Instead, GSK contended that the court could simply ignore these facts and that Teva should be precluded from presenting them. But these undisputed facts show that GSK would have lost exactly the same profits to non-infringing generic competitors in the absence of Teva's alleged infringement (and even in the absence of Teva from the market altogether).

The "determinative question" is whether "but for" causation is established, *Grain Processing*, 185 F.3d at 1350, not whether the *Panduit* factors are satisfied, *BIC*, 1 F.3d at 1218. Because the *Panduit* factors cannot answer the but-for causation question in this case, GSK's reliance on *Panduit* is unavailing.[4]

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[3] In response to the substantial evidence that Teva's sales would not have been made by GSK but rather by the other non-infringing generic drug manufacturers, *see* Appx12528-12531, Appx12532; Appx12548-12557, GSK submitted *no* contrary evidence. Indeed, GSK's expert, Dr. Maness, assumed away the other generic manufacturers as part of the market in the but-for world. Teva Principal Br. 66-67; Appx12303; Appx10840-10841.

[4] Even if *Panduit* applied without modification, the district court still erred. The second *Panduit* factor required GSK to prove "an absence of acceptable noninfringing substitutes." 575 F.2d at 1156. As discussed in the text, generic

B. GSK's "But For World" Is An Economic Fiction.

Assessing the "but for world" is "by definition a hypothetical enterprise," but as noted above, it must be grounded in "sound economic and factual predicates." *Riles*, 298 F.3d at 1311. GSK has never disputed that, as a matter of economic reality, sales made by Teva would have been made by other generic drug manufacturers that did not engage in any inducement. Those other non-infringing generic manufacturers had already taken most of GSK's market before June 2008, when the damages period began, and they would have taken the share captured by Teva too had Teva not been on the market. Indeed, the record demonstrates why this has never been a question. Shortly after generic launch, Teva had just over 20% of the carvedilol market, and GSK had almost none. Appx6769. Teva increased its market share by diverting sales *from other generics that were never accused of inducement*, including Apotex, Dr. Reddy's, and, later, Mylan. *See* Appx6769-6771. When Teva's market share later dropped to just under 15% in October 2015), those sales went *to other generics*, including Aurobindo, not to GSK. *See* Appx6771-6772.

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carvedilol sold by companies that did not induce infringement, and that could have been sold by Teva itself without inducement, is a non-infringing substitute in this context. That product was made by companies that engaged in no form of infringement, and the product itself is non-infringing. That *doctors* may infringe a use patent based on how *they* prescribe those products does not make the products themselves infringing, nor does it make the manufacturers and pharmacies that sell those products infringers.

Despite this economic reality, GSK argues (at 33) that "GSK absolutely would have made 'additional sale[s] of Coreg'" because the but-for world must *assume* that no generic drug company's carvedilol product—not even generic carvedilol from *non-infringing* manufacturers—would have been dispensed for indications not listed on the label. But that construct is fantasy. Such a but-for world could exist only if GSK had a much broader patent, or if the statutory and regulatory frameworks regarding pharmaceutical entry and substitution were dramatically changed—if generic drug companies could not launch at all with skinny labels, or if pharmacies were prohibited from substituting therapeutically equivalent generic drugs for branded alternatives. That is not the real world, and it is also not the world that would exist "but for" Teva's alleged infringement.

Thus, GSK's assertion (at 35) that "[t]he economic reality is that Teva's inducement has taken hundreds of millions in revenue from GSK" relies on a complete fiction. Any alleged inducement by Teva diverted revenue *from other non-infringing generics lawfully on the market* whose products would have been dispensed pursuant to state law for uses claimed by the '000 patent anyway, not from GSK. In fact, the trial evidence shows that GSK had already lost *95*% of its market share to generic drug manufacturers by June 2008, when the damages period began—and more than two-thirds had gone to Apotex, Dr. Reddy's, and Mylan, which GSK has never accused of inducing infringement. Appx6768.

GSK understandably does not like the statutory and regulatory framework that allows for carve-outs and generic substitution, but GSK is not entitled to construct a but-for world that ignores economic reality.

GSK also makes no attempt to address *In re Gabapentin*. As described at length in Teva's principal brief (at 69), *Gabapentin* held that generic drugs that a brand-name manufacturer allowed to stay on the market must be factored into the lost-profits inquiry because they "may alter the marketplace in a way that is relevant to lost profits." No. CA 00-CV-2931 (FSH), 2011 WL 1807448, at *6 (D.N.J. May 12, 2011). That analysis falls squarely in line with this Court's and the Supreme Court's lost-profits jurisprudence. The but-for world is supposed to reflect economic reality, and economic reality should consider not only the infringer's actions, but also the patentee's.

C. GSK's Focus On Physicians Is Misplaced.

GSK argues that Teva should be subject to a $234 million damages award because *physicians*' use of other suppliers' carvedilol, which would have been available from non-infringing drug manufacturers and would have been lawfully (and automatically) substituted by pharmacies, "would still directly infringe GSK's patent." GSK Response/Reply Br. 33. This argument is irreconcilable with this Court's lost-profits jurisprudence, which consistently instructs that the damages analysis must focus on the "nature and extent" *of the defendant's* wrongdoing

(here, alleged inducement), 7 *Chisum on Patents* § 20.01 (2018), and on what would have occurred *absent that misconduct*. *See* p. 3, *supra* (citing *Water Techs.*, 850 F.2d at 671; *Aro Mfg*, 377 U.S. at 507). Teva did not directly infringe, so questions about direct infringement by doctors are not relevant to the but-for causation inquiry, which asks whether GSK would have made any additional profits in the absence of the challenged inducement.

This principle is not unique to the patent context. As the Supreme Court has explained, compensatory damages "are intended to redress the concrete loss that the plaintiff has suffered *by reason of the defendant's wrongful conduct*." *Cooper Indus., Inc. v. Leatherman Tool Grp., Inc.*, 532 U.S. 424, 432 (2001) (emphasis added). "And compensatory damages under the patent statute, which calls for damages adequate to compensate the plaintiff for its loss due to the defendant's infringement, should be treated no differently than the compensatory damages in other fields of law." *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1284 (Fed. Cir. 2017). Thus, "[i]n patent cases, as in other commercial torts, damages are measured by inquiring: had *the tortfeasor not committed the wrong*, what would have been the financial position of the person wronged?" *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1579 (Fed. Cir. 1992) (emphasis added); *accord Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359, 1366-1367 (Fed. Cir. 2008). In contrast, GSK seeks a windfall for sales that it would

have lost no matter what Teva did, because of the many generic competitors that have never been accused of committing any wrong.

Aside from criticizing Teva (at 34) for not citing any Federal Circuit cases with facts identical to this one,[5] GSK nowhere explains why this Court should depart from its well-established damages jurisprudence and impose hundreds of millions of dollars in lost profits that GSK would have lost even if Teva had not induced, solely because *doctors* would have still infringed in the same numbers. *See* GSK Response/Reply Br. 33.[6] Ironically, this argument demonstrates why physicians' infringement was *not* caused by Teva's infringement, and therefore

[5] Of course, GSK cites no cases that are on all fours with the facts here either. Instead, it cites only cases involving either (1) defendants that directly infringe or (2) *products* that are inherently infringing and therefore could not lawfully be on the market. Moreover, GSK's four-page argument fails to provide any response to most of the relevant authorities Teva cites.

[6] GSK argues that this distinction is irrelevant because in the but-for world it could have gone to court seeking to enjoin any and every individual doctor in the United States from prescribing carvedilol to decrease mortality in CHF patients despite the lack of inducement by drug manufacturers. This completely misses the point: if Teva is responsible for infringing by inducement, it should not be held liable for damages that would have taken place in the absence of *that infringement*. Such an outcome would be irreconcilable with the fundamental purpose of patent damages—to compensate a plaintiff for the infringement caused by a defendant's wrongful acts, not to *punish* a defendant for infringing in a way that caused no loss of profits. And even putting aside the absurd practical impossibility of enjoining every doctor in the United States, it is *pharmacies*, not doctors, that substitute generic drugs for brand-name versions, even where the doctors write the brand-name version on their prescription pads. Under the laws of many states, they are *required* to do so, and GSK does not contend it could enjoin pharmacies from following state law. Teva Principal Br. 14, 66.

why GSK's inducement argument fails on the merits. But even setting that to one side, drug manufacturers do not control who uses their products, or how they use them. The but-for world therefore should not consider the use an ultimate consumer might make of a product, if the product is not itself infringing and the seller does not induce or contribute to infringement. GSK's argument does nothing to establish "the concrete loss that the plaintiff has suffered *by reason of the defendant's wrongful conduct*." *Cooper Indus.*, 532 U.S. at 432 (emphasis added).

D. GSK Ignores That Teva Could Have Avoided Infringing And Made The Same Sales.

GSK's flawed analysis overlooks not just what Teva's generic competitors could have done, but what Teva *itself* could have done to market the same product without infringing GSK's narrow method patent. GSK has no answer to this Court's explicit instruction in *Grain Processing* that a lost-profits analysis *must* consider actions that the defendant infringer could have taken to avoid infringing. As this Court explained, "The competitor in the 'but for' marketplace is hardly likely to surrender its complete market share when faced with a patent, if it can compete in some other lawful manner." 185 F.3d at 1351. Thus, "a fair and accurate reconstruction of the 'but for' market also must take into account, where relevant, alternative actions the infringer foreseeably would have undertaken had he not infringed." *Id.* at 1350-1351. And if a competitor could have taken action to avoid infringing and still made the same sales, then the only damages available

are a reasonable royalty—not an award of lost profits. *Id.* at 1351. That is this case: Teva's product would still have been AB-rated even if Teva did not tout that fact, and it would still have been substituted at the pharmacy even if it had different labeling.

Courts have recognized this principle time and time again. In one such case, infringement began when St. Jude Medical acquired a competitor that had been selling the accused devices lawfully, pursuant to a license. The license expired with the change of corporate control, and St. Jude Medical failed to successfully acquire a comparable license. *Cardiac Pacemarkers, Inc. v. St. Jude Med., Inc.*, 418 F. Supp. 2d 1021, 1037 (S.D. Ind. 2006), *aff'd in part, rev'd in part, and remanded, all on unrelated grounds*, 576 F.3d 1348 (Fed. Cir. 2009). The court concluded that *Grain Processing* required any lost-profits analysis to consider whether the defendant could have avoided infringing by deciding *not* to merge with its market competitor; without the merger, the same devices would have been sold without infringing. *Id.* at 1037-1039.

Another relevant case involved a defendant that "refurbished" and sold patented disposable cameras. *Fuji Photo Film Co. v. Jazz Photo Corp.*, 249 F. Supp. 2d 434, 438 (D.N.J. 2003), *aff'd*, 394 F.3d 1368 (Fed. Cir. 2005). The patentee sued, alleging that the defendant infringed by impermissibly "reconstruct[ing]" the patented cameras, rather than permissibly "repairing" them.

Id. at 439. The jury and court agreed. Nevertheless, the district court granted judgment as a matter of law with respect to lost profits, because the infringer could have taken the alternative action of "permissibly repairing cameras out of shells first sold in the United States," which "would have had all of the appearances of the cameras [the defendant] actually sold." *Id.* at 455. Had the defendant done so, it would have diverted the patentee's profits but done so without infringing. *See also DSU Med. Corp. v. JMS Co.*, 296 F. Supp. 2d 1140, 1156-1157 (N.D. Cal. 2003) (excluding expert lost-profits testimony that failed to account for foreseeable steps the defendant could have taken to avoid infringement), *aff'd*, 471 F.3d 1293 (Fed. Cir. 2006).

These cases make perfect sense. "Patent doctrine allows the aggrieved patentee to be quite creative about what would have happened in the absence of the infringement . . . . By the same token, it would seem self-evident that courts should invite evidence of second order responses *by infringers* under the (increasingly ornate) hypothetical scenarios being spun by patentees." Merges, *supra*, at 1080, *cited in Grain Processing*, 185 F.3d at 1351; *see id.* ("[T]he infringer should have a chance to argue what he or she might have done in the absence of infringement."). A contrary approach would result in "systematically over-reward[ing] patented inventions." John W. Schlichter, *Patent Law: Legal and*

Economic Principles § 9:59 (2d ed. 1997), *quoted in Grain Processing*, 185 F.3d at 1351.

Thus, this Court's *Grain Processing* rule "ensure[s] a more accurate representation" of the reconstructed but-for market. Peterson, *supra*, at 64. And "if the defendant is not permitted to present evidence of this ilk"—which is precisely what occurred in this case when the district court excluded Teva's evidence—"the analysis is quite skewed: only the patentee's 'best case' scenario is presented, rather than a more realistic scenario." *Grain Processing*, 185 F.3d at 1351 (quoting Merges, *supra*, at 1080).

Teva discussed the *Grain Processing* rule at length (Teva Principal Br. 68, 70, 71), but GSK has no answer to it and instead simply ignores it. That rule is dispositive here. This case presents just the scenario that *Grain Processing* described as one that would forbid a lost-profits award: "where an infringer demonstrates that it could have chosen to market a noninfringing alternative and that it would have done so had it known that it was infringing . . . the sales that it made of the infringing products were not sales that the patentee would otherwise have made." 185 F.3d at 1351 (quoting Martin J. Adelman, *Patent Perspectives* § 5.2[2] (2d ed. 1998)).[7]

[7] *Cf. BASF Corp. v. Aristo, Inc.*, No. 2:07 CV 222 PPS, 2012 WL 2159252, at *3-*4 (N.D. Ind. June 12, 2012) ("[I]f, instead of licensing the product, the infringer could spend some money to change its manufacturing process such that its product

Teva could readily have made the sales without doing what GSK calls inducement, and thus without exposure to any form of infringement patent liability. That is so even under GSK's new and extreme labeling theory (which argues that notwithstanding what GSK told the FDA, even *the post-MI LVD* indication was claimed by the '000 patent, *see* Teva Principal Br. 50-54). All Teva would have had to do was launch its product with only the hypertension indication and omit any (accurate) mention of carvedilol being the "AB-rated" "equivalent" to Coreg—information that would have been communicated by FDA in any event, Teva Principal Br. 58. It would have cost Teva nothing to take this alternative action, and doing so would have resulted in precisely the same sales, as GSK does not dispute that pharmacies would still have automatically substituted generic carvedilol for Coreg. Teva Principal Br. 68. And given Teva's willingness to carve out the CHF indication before launch to avoid being sued for infringement, there can be no doubt that Teva would have carved out the post-MI LVD indication too, if GSK had ever identified that indication as covered by the claimed method. Because GSK's profit losses would have been exactly the same whether or not Teva's infringement occurred, then Teva's actions could not have caused them.

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would be basically identical but would no longer be infringing," then the damages calculation should "be the cost of changing the process rather than the cost of licensing." (citing *Grain Processing*, 185 F.3d at 1350-1351)).

E. The Lost-Profits Verdict Cannot Stand Because The Jury Was Not Allowed To Consider Whether Teva Took Sales From *GSK* Rather Than From The Other Generics That Did Not Infringe.

GSK asserts (at 35) that the jury has already "rejected" Teva's lost-profits argument.[8] But the jury never considered it—and was not *allowed* to consider it. Indeed, the district court concluded that there was a triable issue on lost profits only because it concluded (1) that GSK could ignore the impact of other generic drug manufacturers that had lawfully launched generic carvedilol without inducing infringement on GSK's profits, and (2) that Teva *could not present any evidence* that other generic drug manufacturers would have lawfully captured Teva's sales. Appx221-223.

Thus, even if this Court were to vacate the district court's JMOL, the jury's lost-profits award cannot stand. At the very least, this Court should vacate the lost-profits award and remand it for reconsideration *that takes into account* Teva's ability to avoid infringement and the impact of non-infringing generic carvedilol manufacturers lawfully on the market during the relevant time period.

[8] GSK's implicit suggestion is that the infringement and lost-profits inquiries are the same. GSK Response/Reply Br. 35. But the whole point of this Court's lost-profits jurisprudence is that sometimes infringement does not cause the patentee a loss in profits. *See, e.g.*, *Grain Processing*, 185 F.3d at 1351. In that case, only a reasonable royalty is available. *See id.*; 35 U.S.C. § 284.

II. GSK Effectively Concedes The District Court's Error In Failing To Conditionally Rule On Teva's Motion For A New Trial.

GSK does not dispute that, under Federal Rule of Civil Procedure 50(c)(1), a district court that grants a renewed JMOL motion after trial "must also conditionally rule on any motion for a new trial." Nor does GSK dispute that the district court erroneously failed to make such a conditional ruling here.

Instead, GSK only asks this Court to rule, in the first instance, that no new trial is warranted. That is not the question on appeal. A new-trial motion is ruled on by the district court in the first instance, given that court's greater familiarity with the trial record and the evidence. And once the district court rules, its decision is reviewed only for abuse of discretion,[9] meaning that this Court does not need to decide what it would have done if it were the district court—the question GSK wants the Court to ask. This Court should follow the ordinary procedure: where a district court fails to conditionally rule on a new-trial motion as required by Rule 50(c)(1), if a ruling on the new-trial motion becomes necessary, the proper remedy is to remand for the district court to issue one. *See, e.g.*, *Rhone Poulenc Rorer Pharm. Inc. v. Newman Glass Works*, 112 F.3d 695, 699 (3d Cir. 1997); *McGinnis v. Am. Home Mortg. Servicing, Inc.*, 817 F.3d 1241, 1264 (11th Cir. 2016); *accord Olefins Trading, Inc. v. Han Yang Chem Corp.*, 9 F.3d 282, 290 (3d

[9] *See, e.g.*, *City Select Auto Sales Inc. v. David Randall Assocs., Inc.*, 885 F.3d 154, 163 (3d Cir. 2018); *Whitserve, LLC v. Computer Packages, Inc.*, 694 F.3d 10, 26 (Fed. Cir. 2012) (following the standard of review of the regional circuit).

Cir. 1993); *Jones v. Iowa Cent. Cmty. Coll.*, 972 F.2d 354 (8th Cir. 1992); *Isaksen v. Vt. Castings, Inc.*, 825 F.2d 1158 (7th Cir. 1987). That is doubly sensible here, where any reversal on JMOL would require a remand anyway because other issues would remain to be decided in the district court. *See* Appx30.

GSK does not cite even one appellate case taking the approach it advocates—*i.e.*, deciding in the first instance that a new trial would be impermissible. Instead, GSK cites *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292 (Fed. Cir. 2011), in which this Court reviewed a district court's order *conditionally granting* the defendant's motion for a new trial—the ruling that the district court in this case erroneously failed to make. That illustrates why Rule 50(c)(1) requires conditional rulings; it does not suggest that this Court should proceed to rule in the *absence* of a conditional ruling and become a court of first view, rather than a court of review.

Trying to camouflage its request that the Court be the first to rule on the issues, GSK argues (at 36-37) that this Court should "affirm the denial of a new trial" (a denial that never occurred) because "there is no separate basis for one other than the erroneous JMOL argument." That is wrong on the facts and on the law. First, Teva's alternative motion for a new trial in fact included issues that the district court did not reach in its decision, including Teva's argument that GSK failed to quantify the amount of lost profits caused by Teva's inducement.

Appx12462-12464 & n.5. Those arguments are not presented on this appeal, precisely because they would not be ripe for appeal until the district court decided them.

Second, GSK is simply incorrect that granting a new trial would be improper if this Court were to vacate or reverse the district court's order granting JMOL on inducement. As the district court recognized in another portion of its decision, the two motions are decided under a different legal standard, and "the standard for granting a new trial is less rigorous than the standard for granting judgment as a matter of law." Appx10; *accord Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 585 F. Supp. 2d 568, 581 (D. Del. 2008); *Cudone v. Gehret*, 828 F. Supp. 267, 269-270 (D. Del. 1993). In considering a new-trial motion, the district court "need not view the evidence in the light most favorable to the verdict winner," Appx10, "but instead exercises its own judgment in assessing the evidence," *Leader Techs., Inc. v. Facebook, Inc.*, 678 F.3d 1300, 1305 (Fed. Cir. 2012) (quoting *Marra v. Phila. Hous. Auth.*, 497 F.3d 286, 309 n.18 (3d Cir. 2007)).

Because a trial court exercises its own independent judgment and weighs the evidence it viewed first-hand, that court has discretion to grant a new trial even where it may not grant a JMOL. Indeed, the case GSK cites—*Uniloc*—makes clear that there are cases in which "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." 632 F.3d at 1310. The district court in *Uniloc* did not exercise that discretion, because it "did not present any analysis apart from its [JMOL] analysis." *Id.* Here, of course, the district court has not yet passed on the issue.

Thus, even if the record did not justify JMOL, the district court could still grant the lesser remedy of a new trial. Under the different standard, the district court could examine *all* the evidence presented at trial; draw the inferences it thinks are correct; and exercise its discretion that the jury's decision was "against the clear weight of the evidence." *Uniloc*, 632 F.3d at 1310 (citation omitted). For example, in determining whether the jury's verdict was against the clear weight of the evidence with respect to causation, the district court could consider the *general* testimony from GSK's expert (Dr. McCullough) that GSK relies on—testimony that doctors "get product catalog information, and we get pointed to it through a variety of means," GSK Response/Reply Br. 15—alongside Dr. McCullough's *specific* testimony that he had no idea whether any of *Teva's product guides* were "actually given to doctors" and his testimony that *Teva's product guides* were "communication[s] from Teva directly to patients," not to physicians. Appx10686, Appx10688-10689.

The district court could also consider the two press releases that preceded the issuance of the '000 patent and the launch of generic carvedilol—in one instance, by nearly five years—that GSK emphasizes (at 3, 11, 12-14 of its Response and Reply Brief) alongside the fact that not one cardiologist who testified at trial said that generic drug manufacturers' press releases affect prescribing decisions—not even GSK's expert, Dr. McCullough, who testified only that press releases are relevant to him because they inform him "when drugs are going generic." Appx11655. The district court could also consider that while GSK now repeatedly trumpets that Teva's press releases were archived on its website—which was *not* in the trial record or argued to the jury or the district court—with hundreds of other press releases Teva has issued in the past 15 years, not one cardiologist testified that he even viewed Teva's website before prescribing carvedilol. Indeed, GSK's own expert testified only about viewing a screenshot of Teva's website taken in 2015, that he did not know what was on Teva's website during the partial label period, and that he "d[id]n't know" whether he was "trying to suggest to the jury here that this website had anything to do with the . . . skinny label period." Appx10686-10688.

Furthermore, the district court could compare the lack of any evidence that doctors as a class were influenced by Teva's label or marketing materials with the "vast amount" of *direct* evidence that GSK largely ignores: among other things,

(i) uncontroverted direct evidence showing "that doctors' decisions to prescribe carvedilol during the relevant periods were influenced by multiple non-Teva factors" both before and after the launch of generic carvedilol, Appx20, including ACC and AHA guidelines, physicians' knowledge and experience, research published about carvedilol in medical journals, Appx20, Appx10668, Appx10676-10677, Appx11151-11152, Appx11296-11297; and (ii) uncontroverted direct evidence that the doctors' prescribing practices were exactly the same pre- and post-generic launch—the only difference in the two time periods was that pharmacies "automatically" substituted generic carvedilol for the same Coreg or carvedilol prescriptions that physicians had been writing for years. Appx10675; Appx11175-11176. And considering the mountains of direct evidence that Teva did *not* induce doctors to infringe, the district court could certainly decide that the inference of causation that GSK seeks was against the great weight of the evidence presented at trial.

Thus, the district court plainly could grant a new trial. This fact-intensive determination about the merits of Teva's new-trial motion is one that the district court should make in the first instance, given its "unique opportunity to consider the evidence in the living courtroom context." *Gasperini v. Ctr. for Humanities, Inc.*, 518 U.S. 415, 438 (1996) (citation omitted). That is why such a decision is reviewed only for abuse of discretion.

Finally, GSK's argument (at 36) that granting a new trial could violate the Seventh Amendment is contrary to Supreme Court precedent, *see Gasperini*, 518 U.S. at 433; unaccompanied by citation to any authority; and, for good measure, forfeited, because GSK never made it in the district court. *See, e.g.*, *Monsanto Co. v. Bayer Bioscience N.V.*, 363 F.3d 1235, 1243 n.1 (Fed. Cir. 2004).

CONCLUSION

If this Court reaches the conditional cross-appeal, it should vacate the jury's lost-profits award and remand for the district court to award a reasonable royalty. At the very least, pursuant to Rule 50(c)(1), it should remand for the district court to consider Teva's new-trial motion in the first instance.

Respectfully submitted.

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Dated: March 5, 2019

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I hereby certify that this brief complies with the type-volume limitation of Federal Circuit Rule 32(a). The brief contains 5,991 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b).

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March 5, 2019

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CERTIFICATE OF SERVICE

I, William M. Jay, hereby certify that I served a copy of the foregoing document on counsel of record on March 5, 2019 by Electronic Means via the CM/ECF system.

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