IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

PLAINTIFFS' MOTION FOR ENHANCED DAMAGES, ATTORNEY FEES, AND INTEREST

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I. INTRODUCTION

Despite the record adduced at trial, in its post-trial letter to the Court, Teva characterizes GSK's infringement theory as attacking a legitimate "skinny label" allowed under Hatch-Waxman. The trial record showed this not a true "skinny label" case. As an initial matter, Teva's partial label was never "skinny" because it included Post-MI LVD, which is heart failure. Heart failure is a disease that exists on a continuum. At its mildest, the patient has a reduced ejection fraction because of left ventricular dysfunction and no symptoms; at its most severe, the patient is bedridden and on death's door. Coreg®'s label describes the full continuum from asymptomatic post-MI LVD through severe congestive heart failure. GSK's patent covers nearly that entire continuum; specifically, all those patients who have symptomatic reduced ejection fraction heart failure regardless of the origin. The jury rejected Teva's "skinny label" arguments, and the Court should do the same.

Moreover, this is not the first time that a section viii carve out label allowed by FDA has been a basis for induced infringement. In *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010), the Federal Circuit affirmed a preliminary injunction based on the district court's finding that a section viii carve out label would induce infringement.

Teva's "skinny label" mantra is really an attempt to distract from its pattern of conduct that began with a clear intent to capture the market for GSK's patented use and concluded with Teva leaving no doubt about this intent by blatantly copying GSK's full label without any good-faith belief in non-infringement or invalidity. GSK presented overwhelming evidence of Teva's intent, which started as early as 2002 when it told GSK and FDA it would launch its generic carvedilol with a full label. But after the Patent Office reviewed GSK's patent a second time and indicated that it would be re-issued over prior art Teva identified, Teva opted for a partial label and a marketing effort for all indications that would achieve the same result. That continued for a few years until

Teva dropped the charade and changed its label to include all the instructions relating to the full continuum of heart failure (and did so without providing notice to GSK as required by the Hatch-Waxman Act). It's difficult to think of a more intentional, willful example of copying a method of use in the pharmaceutical world. The jury heard the whole story, and after careful consideration, deemed Teva's infringement willful.

Teva's course of conduct was neither innocent nor ordinary. This is not a case where a generic manufacturer played by the rules and directed its activities at non-infringing uses. Teva could have removed all instructions for the patented use from its label. Teva could have also challenged GSK's patent through the legal system or waited to launch until the patent expired. But Teva did none of those things. *Halo* and the cases that follow demonstrate that Teva's actions warrant enhancement under § 284. GSK recognizes that enhancement (including the appropriate amount) is up to the Court's sound discretion. Respectfully, GSK believes that a small, but meaningful enhancement sends the appropriate message that generic manufacturers must not game the system set up by Hatch-Waxman.

Courts have found that egregious conduct like Teva's can, on its own, support an award of attorney fees under § 285. But the case for attorney fees here is even more compelling because of the unreasonable way that Teva litigated the case. For example, Teva argued throughout trial that doctors do not read generic drug labels, knowing that it previously argued the opposite to FDA. Teva also took other positions relating to its alleged lack of communication with doctors that were flatly contradicted by its own documents and website. Teva even argued at trial that its actions were justified by a non-existent "gap" in GSK's patent protection—a position that is contrary to law and that Teva had to abandon by the end of trial.

Finally, GSK also seeks an award of pre-judgment interest calculated at prime rate and post-judgment interest at the statutory rate in 28 U.S.C. § 1961. The facts here do not warrant departure

from the Court's usual practice and an award of interest at the prime rate will ensure that GSK is fully compensated for Teva's infringement.

II. NATURE AND STAGE OF PROCEEDINGS

After a seven-day trial from June 12-20, 2017, the jury returned a verdict finding that Teva willfully infringed GSK's Patent No. RE40,000 (the '000 patent) and that the patent was valid. The jury also awarded GSK $235,510,000 in lost profits and reasonable royalty damages. (D.I. 448.) The briefing on post-trial motions is set to close on October 6, 2017. (D.I. 456.) The Court will hear argument on post-trial motions on October 26, 2017. (*Id.*) The Court has not yet set a date for the bench trial to address Teva's remaining invalidity and equitable estoppel defenses. (*Id.*)

III. FACTUAL BACKGROUND

Having heard all the evidence on infringement and validity, the jury found that Teva infringed GSK's '000 patent from the time it issued in early 2008 until its expiration in 2015, and also rejected Teva's validity defenses. (D.I. 448.) The jury also found that Teva's infringement was willful through the entire timeframe—*i.e.*, during both the "partial" and "full" label periods. (D.I. 448 at 4.) The jury must thus have determined, in accordance with the Court's instructions, that it "consider[ed] all of the facts" and determined that Teva's conduct "was reckless, willful, wanton, malicious, committed in bad faith, deliberate, consciously wrongful, flagrant, or as it may be described – 'characteristic of a pirate.'" (D.I. 440 at 32.) The jury showed care in its deliberations. They asked for a magnifying glass, (D.I. at 1937:23-1938:1), and asked the Court to direct them to Teva's partial and full labels. (*Id.* at 1939:24-1940:3.)

Although the jury may have needed a magnifying glass to read the print on the product labels, they did not need to look that hard to find evidence of Teva's willful disregard of GSK's patent rights. After seeing the success of Coreg® (carvedilol) in the marketplace for the treatment of heart failure, Teva—the world's largest generic company—was determined to capture the heart

failure market when it launched its generic carvedilol. Teva's egregious behavior culminated with a product label that was basically a replica of GSK's label—and included ***all*** of the information relating to the GSK's patented congestive heart failure indication. Teva offered no good-faith justification for its deliberate copying of GSK's label or the pattern of infringing conduct leading up to it. Teva's behavior in this case was unique and deserving of the jury's willful infringement verdict.

A. GSK Defies the Conventional Wisdom to Introduce the First Beta-Blocker for Heart Failure Patients that Reduces Their Risk of Death.

The '000 patent claims a breakthrough in the treatment of congestive heart failure that was as important as it was unexpected. Heart failure stems from the left ventricle's inability to pump enough blood to the body's organs. (*See* D.I. 458 at 359:7-360:21 (Lukas); D.I. 459 at 601:7-604:22 (McCullough); D.I. 462 at 1519:8-24 (Shusterman).) It causes a range of symptoms, including fatigue, shortness of breath, and, eventually, the inability to exert oneself in any kind of physical movement. (D.I. 458 at 359:7-360:21 (Lukas); D.I. 459 at 601:7-604:22 (McCullough); D.I. 462 at 1519:8-24 (Shusterman).) Patients are "not able to basically live their lives the way they have been because their muscles, their tissues are not getting adequate support from the heart and adequate oxygen." (D.I. 458 at 360:11-14 (Lukas).) Prior treatments, although they sometimes improved patients' symptoms, did not do enough to extend patients' lives, making heart failure "a death sentence" with "more grave mortality than most cancers." (D.I. 458 at 361:25-362:20 (Lukas).) Half of heart failure patients died within five years of their diagnosis, (*id.*), which left a "clear need for additional pharmacotherapy to improve quality of life and life expectancy." (PTX-784.0002.)

GSK's inventors defied the conventional wisdom by administering carvedilol, and, by doing so, created a treatment method that has prolonged many thousands of lives. This is precisely the type of invention that the patent system is meant to protect and incentivize. When GSK's inventors began work, the conventional wisdom was not to give a beta-blocker like carvedilol to a heart failure patient. (D.I. 458 at 357:6-358:8, 362:21-364:21 (Lukas); D.I. 461 at 1267:14-21, 1279:9-25

(Ruffolo); PTX-1302.016; PTX-920.0003; D.I. 461 at 1393:8-1395:7 (Rosendorff).) They were "contraindicated" because everyone was worried that administering "a standard dose" would decrease heart rate and worsen the heart's pumping function, exacerbating the very problem from which heart failure patients suffer. (*Id.*; *see also* D.I. 462 at 1519:8-24 (Shusterman).) GSK's inventors fought to convince their colleagues to even attempt a clinical trial, and, when the trial was eventually set, no one was sure how it would unfold. (*See* D.I. 462 at 1280:3-7, 1286:22-1287:18 (Ruffolo), D.I. 458 at 436:8-438:3 (Lukas).) Faced with this skepticism and uncertainty, GSK established a Data Safety and Monitoring Board (DSMB) to keep a close eye on how patients were progressing—a departure from the usual practice of blinding everyone to which patients were taking the drug (vs. placebo) until after the trial was complete. (D.I. 458 at 371:1-372:9, 438:5-8 (Lukas); PTX-1.0014 (Col. 6:15-35); PTX-78.0002.) When inventor Robert Ruffolo got a call that DSMB had halted the trial, he feared the worst, thinking "oh my God, it killed people, just like everybody said, and it's my fault." (D.I. 461 at 1282:2-3.)

But to Dr. Ruffolo's great relief, and to the great benefit of many heart failure patients and their loved ones, the DSMB hadn't stopped the trial because anyone died. (D.I. 461 at 1282:4-18; *see also* D.I. 458 at 372:10-373:18 (Lukas).) The DSMB took this extraordinary step because carvedilol was so effective in reducing the risk of death "that it was no longer ethical" to continue administering placebo and denying some patients the benefit of the treatment. (*Id.*) Patients would die without the treatment, not with it. Indeed, as a subsequent *New England Journal of Medicine* article reported, treating heart failure patients with the inventors' method of administering carvedilol resulted in a "reduction in risk" of death of "65 percent." (PTX-78.) The inventors were "really shocked" by their own success, and, "to have this effect be as large as it was, was completely unexpected." (D.I. 458 at 374:8-19 (Lukas).) These results, the culmination of over 10 years' work, led the FDA to approve carvedilol—the first ever beta blocker approved for heart failure patients,

and were, in Dr. Lukas's words, "my life achievement." (*Id.* at 379:4-18.) The inventors' work changed the standard of care for heart failure: a drug that once had been "contraindicated" was now the exception to the rule that beta-blockers may have "unfavorable effects." (PTX-1303.0034; D.I. 458 at 383:8-385:9 (Lukas).) GSK launched Coreg® (carvedilol) in 1997 after its heart failure trials and the subsequent approval by the FDA. (D.I. 458 at 376:4-17 (Lukas); PTX-323; D.I. 459 at 795:9-10, 797:22-798:4 (Maness).) GSK's first patent on the use of Coreg® to treat heart failure (U.S. Patent 5,760,069) issued in June 1998. (DTX-2003.)

B. GSK Continued Researching the Use of Carvedilol to Treat Heart Failure in Post-MI LVD Patients.

GSK's research efforts didn't stop after Coreg®'s initial approval and launch. Heart failure is a broad disease that includes a wide spectrum of patients—some in the early stages of the disease and some in the later stages with severe problems. (D.I. 458 at 378:10-383:2 (Lukas).) GSK ran additional clinical trials to address both ends of the spectrum. For example, the COPERNICUS trial, run from 1997 to 2000, showed that Coreg® reduced the risk of death by 35% in patients with severe heart failure. (*Id.* at 381:1-18.) Likewise, GSK's CAPRICORN trial, run from 1997 to 2002, focused on the earlier end of the spectrum: patients who had recently suffered a heart attack (*i.e.*, "myocardial infarction" (MI)) and whose hearts had trouble pumping blood (*i.e.*, "left ventricular dysfunction" (LVD) because the ejection fraction was 40% or below). (*Id.* at 381:22-382:20 (Lukas); Flanagan Decl., Ex. A at GSK01006656.) Some of these "post-MI LVD" patients already have the symptoms of heart failure, while others don't have them yet. (D.I. 458 at 381:22-382:20 (Lukas); D.I. 459 at 602:23-603:8, 605:22-25, 673:21-674:1 (McCullough); D.I. 462 at 1520:8-21 (Shusterman).) But they have, in either case, "an early form of heart failure," because "the left ventricle cannot pump out and keep a normal ejection fraction." (D.I. 459 at 603:5-8 (McCullough).)

GSK stressed the significant overlap between left ventricular dysfunction and heart failure

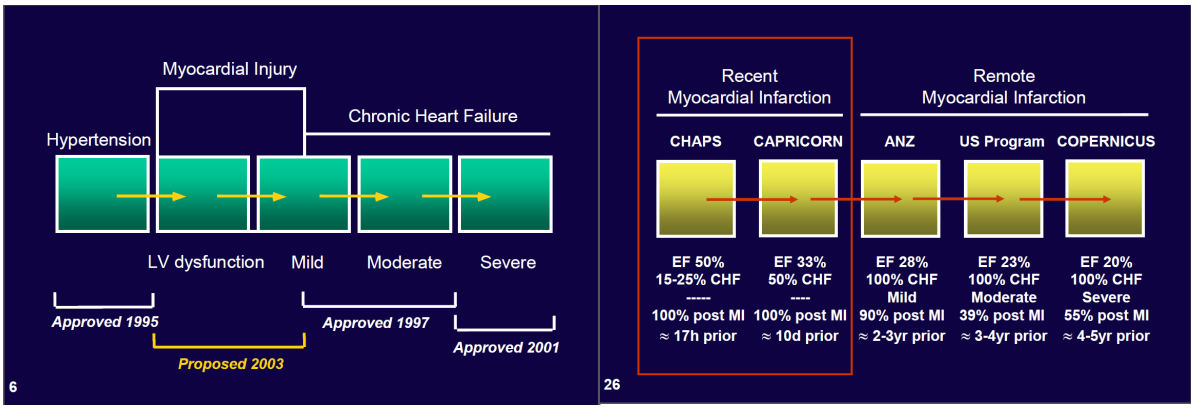
when obtaining FDA approval for the "post-MI LVD" indication in 2003. For example, Dr. Lukas testified before the FDA's Cardiovascular and Renal Drug Advisory Committee that about half of the LVD patients in the CAPRICORN (post-MI LVD) trial also had congestive heart failure:

> The CAPRICORN trial evaluated patients who had survived an acute MI an average of 10 days earlier, all of whom had left ventricular dysfunction, **but about half of whom had heart failure**. The mean ejection fraction in this trial was higher than those in the trials that were conducted in patients with chronic heart failure.

(*See* Flanagan Decl., Ex. A at GSK01006661 (emphasis added).) Likewise, Dr. Milton Packer, the lead author on the *New England Journal of Medicine* article reporting the surprising results of the initial heart failure trial, explained that LVD and heart failure "are part of a single disease continuum with patients moving from one phase of the disease to the next over a period of weeks, months or years." (*Id.* at GSK01006681.) Dr. Claire Kahn, GSK's Vice President of Regulatory Affairs, echoed this description, explaining that the "post-MI LVD" indication addressed "the beginning of the heart failure continuum," whereas the earlier studies focused on more severe forms of the disease:

> Carvedilol was first approved for the treatment of hypertension in 1995 and in 1997, the drug was approved in patients with mild to moderate chronic heart failure. In 2001, the indications for carvedilol were expanded towards the end of the heart failure continuum to include the treatment of patients with severe chronic heart failure and to include prolongation of survival.
>
> Today, we are proposing that the current labeling for carvedilol be modified to ***include experience towards the beginning of the heart failure continuum, specifically the treatment of patients who have recently survived a myocardial infarction and who have left ventricular dysfunction***.

(*Id.* at GSK01006658.) Dr. Kahn also presented the heart failure continuum graphically in a presentation that FDA continues to maintain on its web site. (*See* Flanagan Decl., Ex. B at GSK01005826, GSK01005846.)



This information was public as of January 2003, and thus told the world that GSK's post-MI LVD indication did, in fact, involve a significant class of symptomatic heart failure patients. (*See Id.*) Teva's expert, Dr. Zusman, reinforced this understanding, testifying that "a patient who has a left ventricular ejection fraction of less than or equal to 40 percent with symptomatic heart failure would [be] diagnosed as suffering from congestive heart failure." (D.I. 461 at 1226:14-19 (Zusman).) Thus, by the time FDA approved GSK's post-MI LVD indication in 2003 (DTX2311.7), GSK had made it well known, and clinicians understood, that all post-MI LVD patients have heart failure, and a subset of them are symptomatic. It is that subset that meets the patient group criteria of the '000 patent's method claims.

GSK invested heavily in these new treatments for heart failure patients of all types. GSK spent over $350 million in developing Coreg® and Coreg® CR, (PTX-917; D.I. 458 at 501:23-505:21 (Vojir)), and even more on other potential treatments that ultimately failed. (*Id.* at 349:9-350:19 (Lukas).) For example, one such failure involved 10 years of testing, at least two full-blown clinical trials, hundreds of researchers, and a "very, very large investment." (*Id.*) When those types of failures are included, the total cost to find any given treatment is much higher—about $2.6 billion on average. (D.I. 459 at 791:14-793:9 (Maness); Flanagan Decl., Ex. C at PTX-1417.) That's why GSK's annual research and development expenditures in that timeframe were over $6.4 billion. (PTX-982.0016; D.I. 458 at 504:16-505:21 (Vojir).) GSK pays for this development by reinvesting

its profits from successful drugs like Coreg®, (*id.* at 504:8-13), and, in turn, relies on patents to protect its inventions and sell those drugs at a price that enables GSK to recoup those costs and invest in finding more new treatments.

C. Teva Intentionally Infringed GSK's Patent While Attempting to Disguise Its Misconduct.

After seeing Coreg®'s commercial success for heart failure, in March 2002, Teva filed an Abbreviated New Drug Application (ANDA) seeking approval to sell generic carvedilol for all its potential uses, including heart failure. (PTX-1063A; D.I. 458 at 443:3-7 (Pastore).) Teva told the FDA that it would not launch its product before separate patents on the carvedilol molecule expired in September 2007. But it made a paragraph IV certification on the '069 patent (GSK's original patent), alleging it was invalid based on a variety of prior art, including the Kelly reference. (PTX-106.0003-0005; PTX-1063A.0036; D.I. 458 at 529:10-530:14 (Lietzan); D.I. 460 at 890:25-891:25 (Pastore).) Teva's paragraph IV letter did not, however, include ***any*** non-infringement arguments.

GSK received Teva's invalidity arguments and, in 2003, put the '069 patent into reissue proceedings, where it added more details to claim 1 that better captured the invention. (*See generally* PTX-2; 532:15-18 (Lietzan).) It also added claims 8 and 9. GSK gave the Patent Office Teva's paragraph IV letter and all the prior art it cited (including Kelly), and the examiner considered that material when deciding whether to grant a reissue patent. (D.I. 461 at 1377:4-1380:5 (Rosendorff), D.I. 462 at 1666:8-1667:13 (McCullough), PTX-1 (references cited section listing the paragraph IV letter and all cited art); Flanagan Decl., Ex. D at PTX-2.9133, 2.9138.) In 2006, the Patent Office issued a Notice of Allowability, indicating that the revised claims were patentable despite the prior art and the arguments in Teva's paragraph IV letter. (*Id.* at PTX 2.9123; DTX-2227; D.I. 458 420:20-421:23, 427:3-11 (Lukas).) A second Notice of Allowability issued on January 8, 2007, again confirming the revised claims were patentable. (Flanagan Decl., Ex. D at PTX-2.9588.) Teva nevertheless launched its generic product on September 6, 2007. (PTX-1301; 35 U.S.C. § 252.) The

Patent Office issued the '000 patent on January 8, 2008, and Teva became aware of it that day. (PTX-1051.0006.)

From 2002 until a couple weeks before its generic carvedilol was approved, Teva had included all references to heart failure on its proposed product labeling. (D.I. 458 at 456:4-457:11, D.I. 460 at 968:11-969:2 (Pastore).) But in August 2007, Teva's strategy abruptly changed. (*Id.* at 970:16-25 (Pastore), D.I. 458 at 534:17-537:1 (Lietzan); PTX-1192.) Teva was the first generic company to seek approval of generic carvedilol while making a paragraph IV certification, which would have entitled it to market its product 180 days before any other generics who made paragraph IV certifications. (*See* 21 U.S.C. § 355(j)(5)(B)(iv); D.I. 458 at 476:20-477:14 (King).) But Teva learned that other generics, including a company it had acquired, Ivax, had chosen to pursue a section viii statement instead of a paragraph IV certification. (DTX-2765.1.) As a result, Teva wouldn't be getting any 180-day exclusivity from maintaining its paragraph IV. (*See* PTX-1190.0001.) And, Teva knew that there was "a forthcoming patent certification change or [] an exclusivity [Teva] knew was listed that [they] needed to address." (D.I. 458 at 449:11-14 (Pastore).) So Teva adopted the same approach as its competitors, and removed some, but not all, references to heart failure from its label. (PTX-1078; PTX-1080.)

The information that remained on Teva's partial label satisfies every element of GSK's '000 patent claims 1-3, (D.I. 459 at 623:5-631:21, 647:6-656:14 (McCullough); PTX-1080), as the jury concluded when finding infringement. (D.I. 448.) For example, Teva's partial label still included explicit instructions telling doctors to use the product to reduce the risk of death for a class of symptomatic heart failure patients—those in the early stages of the disease that already had post-MI LVD:

> Carvedilol tablets are indicated to reduce cardiovascular mortality in clinically stable patients who have survived the acute phase of myocardial infarction and have left ventricular ejection fraction of 40% with or without symptomatic heart failure.

(PTX-1080.0003; D.I. 459 at 623:10-17, 602:23-603:8, 605:22-24, 673:21-674:1, 682:9-18 (McCullough).) As referenced above and consistent with the label's plain language, GSK had publicly told the FDA in 2003 that left ventricular dysfunction is "the beginning of the heart failure continuum," and noted that 50% of the left ventricular dysfunction patients in the clinical trials had heart failure. (*See* Flanagan Decl., Ex. A at GSK01006658.) Yet Teva opted to launch with that language on the label. Another section of Teva's partial label noted that "worsening heart failure" might occur during the titration period, which also encouraged using the drug for heart failure patients. (PTX-1080.0005; D.I. 459 at 623:18-23.) The partial label also encouraged the use with heart failure patients by providing the specifics of treating heart failure patients with left ventricular dysfunction, referring to specific dosages of carvedilol, co-administration with an ACEI or diuretic, a desired daily maintenance dosage of 25 mg, and administration for greater than 6 months. (*Id.* at 624:12-628:14, 629:15-631:21 (McCullough).) Because of this language, Teva's label was not in fact "skinny."

Moreover, Teva encouraged doctors to use generic Coreg® to treat heart failure after its partial-label launch. Teva laid the groundwork for that persuasion in 2004, with a press release touting the tentative approval of its product and explaining that its "Carvedilol Tablets are the AB-rated generic equivalent of GlaxoSmithKline's Coreg® Tablets and are indicated for treatment of heart failure," and that Coreg®'s annual sales, including those for heart failure, were $670 million. (PTX-1297.0002.) After its partial-label launch, Teva still told the world its product should be used for heart failure by selling it as fully-substitutable for all Coreg® indications. Teva's 2007 press release, for example, said it was selling a "Generic version of GlaxoSmithKline's cardiovascular agent Coreg®," (PTX-1301), which doctors would interpret to mean that the drug could be used for heart failure. (D.I. 462 at 1659:11-1660:13 (McCullough).) Moreover, Teva's product catalogs repeatedly stated that generic carvedilol was AB-rated and juxtaposed it next to Coreg®, as shown in

the example below:

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	

(PTX-1208.0008; *see also* PTX-1212.0009; PTX-1165.0019; PTX-860.0001; D.I. 458 at 543:12-545:8 (Lietzan).) Teva's website said the same thing from when it first launched the product in 2007. (D.I. 460 at 991:16-992:6 (Collier).) When a generic manufacturer directly compares its product to the branded product in this case, FDA's position is that the generic product can be used for anything the branded product is used for. (D.I. 458 at 544:16-545:14, 582:21-583:14 (Lietzan).) And Teva never told doctors or patients that they shouldn't use Teva's generic carvedilol for heart failure in a manner that infringes GSK's patent, even though it easily could have done so. (*See id.* at 547:11-548:17 (Lietzan).)

Teva actions were not innocent. They were a deliberate attempt to capture the patented heart failure market. For example, Teva's 2007 press release announcing the approval of its generic product referred to the entire revenue for generated by Coreg® ($1.7 billion), which, of course, includes the sales for heart failure. (PTX-1301; *see also* PTX-1187; D.I. 460 at 974:1-6 (Pastore).) That was no accident. Indeed, Teva's regulatory professional, Jill Pastore questioned whether Teva should include that entire revenue now that it was going to launch with a partial label. (*Id.* at 971:4-9, 972:14-975:4; PTX-1186.) Teva nevertheless decided to reference all Coreg® revenue because, as the jury reasonably concluded, Teva knew it would capture GSK's entire market (including all its heart failure sales) through its course of conduct. Teva's Jennifer King admitted as much:

> Q. So is it the expectation of Teva that when you carve out a particular indication, that Teva will still get sales of that drug for that indication once it's launched its product?
>
> A. It's a legal strategy, not a commercial strategy.

Q. But as a commercial person, ***is it your expectation that Teva will get sales for the carved out indication?***

A. Yes.

***

Q. ***Teva was aware in 2007*** that its drug was being prescribed by physicians, its ***carvedilol*** generic, was being ***prescribed by physicians for treatment of congestive heart failure***?

A. Okay, ***yes***.

(D.I. 458 at 488:2-11; 491:5-9 (King).) Teva's Jill Pastore made the same admissions. (*Id.* at 452:25-453:18; 458:17-459:2 (Pastore).)

In 2011, Teva gave up the pretense of a partial label and added back everything about the heart failure indication. (*Id.* at 461:22-462:3 (Pastore); 484:20-485:16 (King); D.I. 459 at 568:3-569:9 (Lietzan).) Not only did Teva double down on its infringement, but it also failed to notify GSK that it had copied all of the heart failure indication language back onto its label, in violation of the FDA rules. (PTX-1089; PTX-1088; D.I. 459 at 569:1-9, 571:6-572:10 (Lietzan); D.I. 460 at 976:7-12 (Pastore).) Teva's own regulatory expert admitted at trial that the FDA's policy requires generic applicants to provide a patent certification where, as here, the applicant is seeking approval to add more information in the form of an additional indication—here, the separate heart failure indication—to its label. (*Id.* at 1049:9-1050:10 (Karst).)

D. The Jury Found that Teva Willfully Infringed GSK's Patent, Despite Teva's Myriad Defenses.

GSK filed this suit in July 2014 to address Teva's years of willful infringement. (D.I. 1.) Teva responded with a kitchen-sink set of defenses that, as far as the record reveals, were almost all developed post-suit and there is no evidence that any of them were relied upon pre-suit by anyone at the company. For example, Teva never argued non-infringement at any point before this case.

What's worse, the non-infringement defenses Teva raised in this case contradict what it

advocated in the past. Teva's lawyers and experts claimed here that doctors never read generic labels. (D.I. 461 at 1151:11-13; 1259:14-17 (Zusman); *Id.* at 1296:17-22 (Rosendorff); D.I. 463 at 1901:19-23 (Closing).) But Teva told the FDA in 2002 that it should "presume that doctors will follow the generic drug's labeling" and argued against the "false spectre" of presuming "that doctors will ignore or disregard a generic drug's labeling." (Flanagan Decl., Ex. E at 5.)

Teva's opening statement repeatedly sought to justify its actions by arguing it started selling generic carvedilol during a "gap in [GSK's] patent protection where they had no patent to enforce against the sales." (*See, e.g.*, D.I. 458 at 324:14-25; 325:4-20; 327:3-17; 343:1-18.) But as the Court eventually instructed the jury, GSK's '069 patent was in force at the time, and there was no gap in patent protection whatsoever. (D.I. 440 at 24 ("When a patent owner submits a patent to the United States Patent Office for reissue, the surrender of the original patent takes effect at the moment when the reissue patent is granted.").)

Teva has yet another post-suit defense that the Court has yet to hear—equitable estoppel. Teva now says that it relied on the "use codes" that GSK included in the FDA's Orange Book and was misled into thinking that it wouldn't infringe if it left the post-MI LVD indication and information on its partial label. (D.I. 356, Ex. 3 at ¶ 23.) There are a multitude of problems with this theory, as the Court will hear when it fully considers the defense. For example, one problem is that the FDA has told generics that the use codes "are not meant to substitute for the applicant's review of the patent and the approved labeling," meaning that they are not to be relied on. (PTX-1407.0009.) Another problem is that Teva deliberately added the full heart failure indication onto its label in 2011, so it was either never really relying on the carve-out to avoid infringement or it simply lost interest in avoiding infringement in 2011, which makes its actions even more egregious. Either way, the point for present purposes is that Teva hasn't identified any contemporaneous documents showing it actually believed in non-infringement or relied upon the use codes at the time.

IV. SUMMARY OF THE ARGUMENT

1. Teva's willful infringement warrants the imposition of enhanced damages. From the start, Teva intended to capture the market for GSK's patented treatment of congestive heart failure, engaged in an egregious pattern of conduct to achieve that goal, and ultimately copied GSK's full label without any good-faith believe in non-infringement or validity. After hearing all of the evidence, the jury correctly found Teva's infringement willful. This is not an ordinary case where a generic manufacturer complied with the law and directed its activities at non-infringing uses through use of a true "skinny" label. Teva deliberately targeted GSK's patented congestive heart failure indication through its product labels and its marketing efforts. Teva had several alternative paths it could have chosen, but elected to disregard GSK's patent rights for its own profit. Teva's conduct is precisely the type of intentional infringement that § 284 is meant to deter and punish.

2. Teva's willful infringement and its unreasonable defenses support an award of attorney fees under § 285. Teva, for example, argued here that doctors do not read generic drug labels to suit its defenses here, but previously argued the opposite to the FDA. GSK was also forced to spend significant trial time refuting Teva's arguments about its alleged lack of communication with doctors that conflicted with its own documents and website. Likewise, GSK was forced to address Teva's argument that its actions were justified due to a "gap" in GSK's patent protection that did not exist and was contrary to law.

3. GSK respectfully requests that the Court adopt its common practice in this case and award pre-judgment interest at the prime rate compounded quarterly, which is appropriate here given that GSK has borrowed in excess of the damages award throughout the relevant period. GSK also seeks post-judgment interest at the statutory rate in 28 U.S.C. § 1961.

V. ARGUMENT

A. This Court Should Award Enhanced Damages to Punish Teva's Misconduct and Deter Similar Willful Infringement in the Future.

1. Legal Standard for Enhanced Damages

GSK respectfully submits that the unique, and unusual, facts of this case warrant enhanced damages. "[T]he court may increase the damages up to three times the amount found or assessed." 35 U.S.C. § 284. "The subjective willfulness of a patent infringer, intentional or knowing, may warrant enhanced damages, without regard to whether his infringement was objectively reckless." *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923, 1933 (2016). The Court must focus on the defendant's behavior "at the time of the challenged conduct," *i.e.*, when the infringement began, and not later-developed litigation defenses that the defendant didn't rely upon at the time it infringed. *Id.* Although enhanced damages are "punitive" and "not to be meted out in a typical infringement case," they are appropriate where the defendant's conduct is "willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant, or—indeed—characteristic of a pirate." *Id.* at 1932. The jury found that Teva's conduct meets that standard. (D.I. 448 at 4.)

The appellate courts have not yet elucidated all the factors the Court may consider in assessing enhancement after *Halo*, but the Supreme Court's decision drew heavily on history. *See Halo*, 136 S. Ct. at 1928-30, 1932-33. The Federal Circuit previously collected the factors that courts have historically examined when deciding whether to enhance, giving each factor whatever weight was appropriate in the circumstances of a particular case:

> (1) whether the infringer deliberately copied the ideas or design of another;
>
> (2) whether the infringer, when he knew of the other's patent protection, investigated the scope of the patent and formed a good-faith belief that it was invalid or that it was not infringed;
>
> (3) the infringer's behavior as a party to the litigation;

(4) defendant's size and financial condition;

(5) closeness of the case;

(6) duration of defendant's misconduct;

(7) remedial action by the defendant;

(8) defendant's motivation for harm; and

(9) whether defendant attempted to conceal its misconduct.

Read Corp. v. Portec, Inc., 970 F.2d 816, 827 (Fed. Cir. 1992).

District court decisions that have enhanced damages after *Halo* have used these factors—called "the *Read* factors"—and they are helpful to guide the analysis here. *See, e.g.*, *Stryker Corp. v. Zimmer, Inc.*, No. 10-cv-01223-RJJ, D.I. 608 (W.D. Mich. July 12, 2017); *SRI Int'l, Inc. v. Cisco Sys., Inc.*, __ F. Supp. 3d __, 2017 WL 2385604, at *31-33 (D. Del. June 1, 2017); *Innovention Toys, LLC v. MGA Entm't, Inc.*, No. 07-cv-6510, D.I. 761 (E.D. La. Mar. 8, 2017); *Polara Eng'g, Inc. v. Campbell Co.*, 237 F. Supp. 3d 956, 991-94 (C.D. Cal. 2017); *PPC Broadband, Inc. v. Corning Optical Commc'ns RF, LLC*, 2016 WL 6537977, at *5-6 (N.D.N.Y. Nov. 3, 2016); *Dominion Res. Inc. v. Alstom Grid, Inc.*, 2016 WL 5674713, at *18-24 (E.D. Pa. Oct. 3, 2016); *Imperium IP Holdings (Cayman), Ltd. v. Samsung Elecs. Co., Ltd.*, 203 F. Supp. 3d 755, 761-64 (E.D. Tex. 2016); *Arctic Cat Inc. v. Bombardier Rec. Prods., Inc.*, 198 F. Supp. 3d 1343, 1350-54 (S.D. Fla. 2016).

2. Teva Copied GSK's Patent Method to Take Market Share and Attempted to Conceal Its Infringement, Even as Its Conduct Grew More Blatant over Time. (*Read* Factors 1, 4, 6-9)

The *Read* factors demonstrate that this is the type of case where enhanced damages are needed to deter and punish willful misconduct. Teva copied GSK's patented method pure and simple: it sold carvedilol for the exact use described in GSK's patent (reducing the risk of mortality from symptomatic heart failure by administering the drug in combination therapy for over 6 months). Copying of this sort imposes significant harm on both GSK and society as a whole. GSK

invested significantly over the course of several years to gain approval for the patented treatment that reduced the risk of death from heart failure. (*See* pp. 8-9 above.)

By contrast, the cost of copying GSK's treatment is low because Teva didn't have to run its own clinical trials, and can thus drastically undercut GSK's pricing when it enters the market. Like other innovators, GSK relies on patent protection to enable the enormous investment in successful drugs like Coreg®, as well as all the other failed efforts that never led to an approved product. (*See, e.g.*, Flanagan Decl., Ex. F at 4 2003 ("By preventing rival firms from free riding on the innovating firms' discoveries, patents can enable pharmaceutical firms to cover their fixed costs and regain the capital they invest in R&D efforts.").) Without strong remedies for willful infringement of a patent like GSK's, which discloses a treatment that has extended countless lives, the public will ultimately suffer because pharmaceutical companies couldn't afford the investment needed to bring new drugs to market. (*See, e.g.*, *Id.*, Ex. G at 512- 13 ("[P]atents appear to be a prerequisite for the vast majority of pharmaceutical innovation."); *id.*, Ex. H (explaining that "pharmaceuticals are the poster child for the patent system," because "the invention of a new drug tends to be extremely costly," and "if copying were permitted, drug companies that had not incurred the cost of invention and testing could undercut the price charged by the inventing company yet make a tidy profit, and so the inventing company would never recover its costs.").

This isn't a case where Teva made any contribution (intellectual or otherwise) to the new treatment. Everything Teva needed was spelled out in GSK's labeling, clinical trials, and patent. Teva's copying in this case warrants enhanced damages because Teva strayed well outside the bargain contemplated by the Hatch-Waxman Act. The Act contemplates that the generic, in certain situations and under certain conditions, can rely on the innovator company's clinical trials to obtain approval and bring cheaper generic drugs to market. But that privilege is secondary to innovator patent rights. When a treatment is covered by a patent, the generic company must certify that either

(1) the generic will not launch its product until the patent expires, (2) the generic will send the innovator a "paragraph IV" letter that allows it to obtain a stay of generic approval while a court resolves any patent infringement claims, or (3) the generic will do a "section viii" carve-out to completely remove the patented use from its label and sell its product only for non-infringing uses with that "skinny label." *See AstraZeneca*, 633 F.3d at 1045-46. This statutory balance allows innovators to enforce the patent rights that make investment in drug research possible.

One reason this is not a run-of-the-mill case of infringement is because Teva circumvented the rules that facilitate the statutory balance of the patent laws and Hatch-Waxman Act. From the start, Teva wanted to capture the congestive heart failure market and notified GSK of that intent with a paragraph IV certification. (PTX-106.0003-0005; PTX-1063A.0036; D.I. 458 at 529:13-530:18 (Lietzan); D.I. 460 at 890:15-24 (Pastore).) But when its invalidity defense disappeared at the Patent Office during the reissue of GSK's patent, Teva could not get what it wanted and continue to play by the rules. Its egregious pattern of infringing conduct began with section viii carve-out with an infringing partial label. As the jury found, Teva failed to remove all the inducing information off the label. (D.I. 448 at 2.) Like in *AstraZeneca*, where both the district court and the Federal Circuit found that the section viii label would lead some consumers to practice the claimed method, Teva's section viii label contained sufficient information regarding heart failure that induced doctors to infringe the method of the '000 patent. *See AstraZeneca*, 633 F.3d at 1060. Moreover, Teva continued to promote its product for heart failure by advertising it as equivalent to Coreg®, describing it as a "cardiovascular agent," and taking no steps to discourage its use for heart failure, even though it told the FDA that it was carving the patented use off the label. *See MGM Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 934-37 (2005). Teva knew exactly what it was doing—a press release at launch referenced Coreg®'s entire sales even after a Teva employee pointed out that was inconsistent with the carve out. (D.I. 460 at 971:4-9, 972:14-975:4 (Pastore); PTX-1186.)

Eventually, Teva abandoned any pretense that it carved the treatment of congestive heart failure out of its label by adding back everything to create a "full label," knowing full well of the '000 patent's existence and Orange Book listing. And despite the obligation under Hatch-Waxman to notify GSK of the change in its label through a paragraph IV letter (or otherwise), Teva said nothing in a further attempt to conceal its willful infringement.

Teva's conduct here was neither innocent nor accidental. As the jury understood when finding Teva a willful infringer, Teva's motive from the start was to sell generic carvedilol for every potential use, including the patented heart failure use. ((D.I. 458 at 488:2-11; 491:5-9 (King); *id.* at 452:25-453:18; 458:17-459:2 (Pastore).) Hatch-Waxman provides several legitimate options for a generic manufacturer to address innovator patent rights and market products. Teva chose not to follow any of those options. It withdrew its paragraph IV certification at the last minute in favor of a section viii carveout that didn't actually carve out the patented treatment, and thus did not result in a "skinny label." Teva also marketed its product through several different channels in a manner inconsistent with the alleged carveout. A few years later, Teva just blatantly copied GSK's label and completed ignored Hatch-Waxman's requirements by failing to provide any type of patent certification to GSK. (PTX-1089; PTX-1088; D.I. 459 at 569:1-9, 571:6-572:10 (Lietzan); D.I. 460 at 1049:9-1050:10 (Karst); *id.* at 976:7-12 (Pastore).)

Enhanced damages are appropriate here because Teva's behavior is of the sort that could be deterred through punishment. They would prevent Teva from flouting the Hatch-Waxman rules in future cases by making willful infringement as unpalatable as possible. *See, e.g.*, *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 762 F. Supp. 2d 710, 724 (D. Del. 2011) ("[E]vidence of motivation to harm becomes greater when the patentee and infringer are in direct competition, and the accused infringer's actions are specifically intended to take business away from the patent owner.").

3. Teva Lacked Any Good Faith Belief in Non-Infringement or Invalidity at the Relevant Time, Which Outweighs the Importance of Any of Its Unsuccessful Litigation Defenses. (*Read* Factors 2, 3, and 5.)

Enhancement is also appropriate because Teva lacked any good faith belief in non-infringement or invalidity during the relevant period (*i.e.*, from the '000 patent's issuance in January 2008 until this suit was filed in 2014). Teva did not present any testimony or other evidence at trial that it had a belief in non-infringement or invalidity before this suit began. Teva identified no non-infringement position when it submitted its paragraph IV letter, it identified no non-infringement position at any point leading up to the final approval of its generic carvedilol, and it identified no non-infringement position when it went full label in 2011. Indeed, at trial, Teva's primary defenses to non-infringement were that doctors don't read labels—which is contrary to Teva's prior statement to the FDA (*see* Flanagan Decl., Ex. E at 5)—or that the FDA told Teva to add heart failure back to its label. As the jury found, neither of these are reasonable, much less viable, defenses. And, after considering Teva's paragraph IV letter including the Kelly reference (as well as many others), the Patent Office reissued the claims adding, among other things, "… daily maintenance dosages for a maintenance period … said maintenance period is greater than six months." Teva has not presented any pre-suit evidence that it believed the reissued claims of the '000 patent are invalid or not infringed. If anything, the fact that Teva did not send a paragraph IV letter regarding the '000 patent when it amended its label in 2011 supports a conclusion that Teva had no such belief. Teva is thus left with no good faith defense during the time period that the Supreme Court held was most relevant to the enhancement inquiry. *See Halo*, 136 S. Ct. at 1933 ("[C]ulpability is generally measured against the knowledge of the actor at the time of the challenged conduct.").

It will be no answer for Teva to point to its equitable estoppel defense and argue that it was somehow relying on GSK's use codes as the basis for non-infringement of its partial label. For one

thing, the FDA's regulations say that generics shouldn't rely on the use code for anything more than an identification of the patent and should instead review the patent themselves to assess the risk of infringement. (PTX-1407.0009.) For another, GSK had publicly stated in 2003 that the left ventricular dysfunction indication (which Teva left on its partial label) is the "the beginning of the heart failure continuum," and that 50% of the left ventricular dysfunction patients in the clinical studies had symptomatic heart failure. (*See* Flanagan Decl., Ex. A at GSK01006658.) So Teva could not have been surprised that leaving the post-MI LVD language on its label covers symptomatic chronic heart failure patients and infringed GSK's patent. And, in any event, Teva added the separate heart failure indication and all its associated language back to its label in 2011. It could not have been relying on the use codes at that point, and its inclusion of the heart failure language undermines its unsubstantiated claim that it was ever relying on them. Indeed, Teva produced no witness, document, or other evidence that it relied on GSK's use code.

It will also be no answer for Teva to point to the alleged closeness of the case as a basis to deny enhancement. Although objective reckless remains a factor that the Court can consider, *see WesternGeco L.L.C. v. Ion Geophysical Corp.*, 837 F.3d 1358, 1361-63 (Fed. Cir. 2016), the Supreme Court made clear that subjective bad faith alone is sufficient to justify enhancement. *See Halo*, 136 S. Ct. at 1933 ("The subjective willfulness of a patent infringer, intentional or knowing, may warrant enhanced damages, without regard to whether his infringement was objectively reckless."). The Federal Circuit has affirmed enhancement where the district court determines that bad faith copying and infringement outweigh the objective strength of any litigation-inspired defense. *See WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1340-41 (Fed. Cir. 2016) ("Kohler cannot insulate itself from liability for enhanced damages by creating an (ultimately unsuccessful) invalidity defense for trial after engaging in the culpable conduct of copying, or 'plundering,' WBIP's patented technology.").

Teva's trial defenses deserve especially little weight here because, in many cases, they contradict what Teva said before this litigation. In fact, that Teva has staked out such litigation positions is a further reason to enhance under *Read* factor 3. Teva's central defense at trial was that doctors don't read generic labels, as the quotes below from its lawyers and experts illustrate:

- D.I. 461 at 1151:11-13 (Zusman) ("Q. And until this case, had you ever even read a generic drug label? A. No, I had not.")
- *Id.* at 1259:14-17 (Zusman) ("[D]octors don't rely on Teva's product label in making decisions about the proper treatment of a patient with heart failure or any other disease for whom he or she might be responsible.")
- *Id.* at 1296:17-22 (Rosendorff) ("Q. In your practice, do you rely on generic labels in prescribing carvedilol? A. Never. Q. Have you ever reviewed a generic product label in your practice? A. Not that I can recall.")
- D.I. 463 at 1901:19-23 (Closing) (arguing that Dr. Zusman "knows what he is talking about" and that "he relied on other things and didn't rely on generic drug labels. I mean he just didn't")

These arguments contradict Teva's own statements to physicians introduced at trial. Teva directs physicians to its *Monthly Prescribing Reference Health Systems Pharmacy Drug Reference*, which states that "[i]f any questions arise" the "***clinician should verify it against labeling*** or by contacting the company marketing the drug." (PTX-1203.0001, .0003; PTX-1205.0003, .0005 (emphasis added).)

Moreover, Teva's litigation arguments contradict its pre-litigation statements to the FDA, where it emphatically argued that physicians read generic drug labels. (Flanagan Decl., Ex. E at 5.) In particular, when trying to defend the safety of its products in 2002, Teva called "the presumption that doctors will ignore or disregard a generic drug's labeling" a "scare tactic[]," and argued that "FDA should presume that doctors *will* follow the generic drug's labeling"—exactly the opposite what it is saying in this case. (*Id.*) Teva then invoked a district court decision rejecting the proposition that "health care providers would either fail to read or ignore clear warnings" on the label. *Id.*; *see also Zeneca Inc. v. Shalala*, 1999 U.S. Dist. Lexis 12327, at *30 (D. Md. Aug. 11, 1999).

Teva's litigation defenses are thus entitled to little weight in the enhancement analysis, while its tactical decision to try and escape liability here by contradicting what it has said in the past warrants punishment.

B. This Is an Exceptional Case That Supports an Award of Attorney Fees.

The "court in exceptional cases may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285. "[A]n 'exceptional' case is simply one that stands out from others with respect to the substantive strength of a party's litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated." *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749, 1756 (2014).

Willful infringement alone can provide a basis to award attorney fees. *See, e.g.*, *Golight, Inc. v. Wal-Mart Stores, Inc.*, 355 F.3d 1327, 1340 (Fed. Cir. 2004) ("Based on a finding of willful infringement, it is within the district court's discretion whether to award attorney fees under § 285."); *Avia Grp. Int'l, Inc. v. L.A. Gear California, Inc.*, 853 F.2d 1557, 1567 (Fed. Cir. 1988) (holding that "the willfulness of the infringement provided a sufficient basis for a section 285 fee award to the prevailing patent owner"). For example, the Federal Circuit remarked that "[d]istrict courts have tended to award attorney fees when willful infringement has been proven, and this court has uniformly upheld such awards." *S.C. Johnson & Son, Inc. v. Carter–Wallace, Inc.*, 781 F.2d 198, 200 (Fed. Cir. 1986). One court after *Halo* noted that the jury's willfulness finding "alone is a 'compelling' indication that this is an exceptional case." *See Georgetown Rail Equip. Co. v. Holland L.P.*, 2016 WL 3346084, at *22 (E.D. Tex. June 16, 2016). District courts have wide authority to award fees based on "the need in particular circumstances to advance considerations of compensation and deterrence." *Octane Fitness*, 134 S. Ct. at 1756 n.6.

Teva's willful infringement supports a finding that this case is "exceptional" under § 285 and stands out from others sufficiently to warrant attorney fees. The considerations discussed previously in support of enhanced damages also demonstrate that fees are appropriate.

Several of Teva's post-suit defenses were also unreasonable, which further supports an award of attorney fees. For example, Teva argued throughout trial that doctors do not read generic labels, despite having made the opposite representations in its own promotional materials and before the FDA. Teva also took other positions relating to its alleged lack of communication with doctors that were flatly contradicted at trial by its own documents and website. Teva's argument about a non-existent "gap" in GSK's patent protection was contrary to law and resulted in a jury instruction to set the record straight for the jury. Moreover, Teva's theory about carve-outs and the use of carvedilol for congestive heart failure was also contradicted by Teva's allegations in other cases where it sued other generics for infringement over the manufacture of carvedilol. (*See, e.g.,* D.I. 460 at 879:18-880:21 (Berlanska); DTX-2156; *Teva Pharm. Indus. Ltd. v. Dr. Reddy's Labs., Ltd.*, Case No. 07-cv-02894-GEB-JJH (D.N.J.); *Teva Pharm. Indus. Ltd. v. Mylan Pharms., Inc.*, Case No. 07-cv-5915 (S.D.N.Y.); *Teva Pharm. Indus. Ltd. v. Glenmark Generics Inc., USA*, Case No. 08-cv-04355-GEB-DEA (D.N.J.).) In those cases, Teva stressed that carvedilol is a "heart failure" drug, underscoring its knowledge that all it was taking sales of the patented use away from GSK despite its purported carve-outs. (*See* Flanagan Decl., Ex. I at GSK00444902) ("Teva holds patents relating generally to methods of manufacturing the drug product carvedilol, which is a beta-blocker used in the treatment of congestive heart failure.").)

Teva's infringing conduct and unreasonable arguments in this case stand out from the norm. And they have harmed GSK's business and forced GSK to address numerous unnecessary arguments throughout the case. Attorney fees are appropriate to ensure GSK is fully compensated for the harm inflicted by Teva's willful misconduct. *See, e.g.*, *Stryker Corp. v. Zimmer, Inc.*, No. 10-cv-

01223-RJJ, D.I. 608 (W.D. Mich. July 12, 2017); *SRI Int'l, Inc. v. Cisco Sys., Inc.*, __ F. Supp. 3d __, 2017 WL 2385604, at *31-33 (D. Del. June 1, 2017); *Arctic Cat Inc. v. Bombardier Rec. Prods., Inc.*, 198 F. Supp. 3d 1343, 1350-54 (S.D. Fla. 2016).

C. The Court Should Award Pre- and Post-Judgment Interest.

GSK requests that the Court award pre- and post-judgment interest on the jury's damages award, as contemplated by 35 U.S.C. § 284. ("[T]he court shall award the claimant damages . . . together with interest and costs as fixed by the court."). "As a general matter, prejudgment interest should ordinarily be awarded in patent cases to provide patent owners with complete compensation." *LG Display Co. v. AU Optronics Corp.*, 722 F. Supp. 2d 466, 475 (D. Del. 2010); *see also General Motors Corp. v. Devex Corp.*, 461 U.S. 648, 655 (1983). The Court has broad discretion to select the applicable prejudgment interest rate. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 939 F.2d 1540, 1545 (Fed. Cir. 1991).

GSK respectfully requests that the Court apply its common practice of using the prime rate, compounded quarterly, to determine pre-judgment interest.[1] The Federal Circuit has approved using the prime rate. *Uniroyal,* 939 F.2d at 1545. "Courts have recognized that the prime rate best

[1] *See, e.g., Comcast IP Holdings I, LLC v. Sprint Commc'ns Co. L.P.*, 2015 WL 4730899, at *10 (D. Del. Aug. 10, 2015); *Ateliers de la Haute-Garonne v. Broetje Automation-USA Inc.*, 85 F. Supp. 3d 768, 783 (D. Del. 2015); *Dow Chem. Co. v. Nova Chems. Corp.*, 2014 WL 1285508, at *11 (D. Del. Mar. 28, 2014); *DePuy Synthes Prods., LLC v. Globus Med., Inc.*, 2014 U.S. Dist. LEXIS 61450, at *25-28 (D. Del. Mar. 25, 2014); *XpertUniverse, Inc. v. Cisco Sys., Inc.*, 2013 WL 6118447, at *11 (D. Del. Nov. 20, 2013); *LG Elecs. U.S.A., Inc. v. Whirlpool Corp.*, 798 F. Supp. 2d 541, 561-62 (D. Del. 2011); *Edwards Lifesciences AG v. CoreValve, Inc.*, 2011 WL 446203, at *13 (D. Del. Feb. 7, 2011); *Energy Transp. Grp., Inc. v. Sonic Innovations, Inc.*, 2011 WL 2222066, at *22 (D. Del. June 7, 2011); *LG Display*, 722 F. Supp. 2d at 475; *Telcordia Techs, Inc. v. Cisco Sys, Inc.*, 592 F. Supp. 2d 727, 749 (D. Del. 2009); *St. Clair Intellectual Prop. Consultants, Inc. v. Fuji Photo Film Co., Ltd.*, 674 F. Supp. 2d 555, 561 (D. Del. 2009); *Finjan Software, Ltd. v. Secure Computing Corp.*, 2009 WL 2524495, at *14 (D. Del. Aug. 18, 2009); *Siemens Med. Sols. USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, 615 F. Supp. 2d 304, 319 (D. Del. 2009); *TruePosition Inc. v. Andrew Corp.*, 611 F. Supp. 2d 400, 414 (D. Del. 2009); *Becton Dickinson & Co. v. Tyco Healthcare Grp. LP*, 2008 WL 4745882, at *3 (D. Del. Oct. 29, 2008); *Cordis Corp. v. Medtronic Vascular, Inc.*, 576 F. Supp. 2d 645, 652 (D. Del. 2008); *TruePosition Inc. v. Andrew Corp.*, 568 F. Supp. 2d 500, 534 (D. Del. 2008); *IMX, Inc. v. LendingTree, LLC*, 469 F. Supp. 2d 203, 228 (D. Del. 2007); *Tristrata Tech., Inc. v. Mary Kay, Inc.*, 423 F. Supp. 2d 456, 472 (D. Del. 2006).

compensate[s] a patentee for lost revenues during the period of infringement because the prime rate represents the cost of borrowing money, which is a better measure of the harm suffered as a result of the loss of the use of money over time." *IMX, Inc. v. LendingTree, LLC*, 469 F. Supp. 2d 203, 227 (D. Del. 2007). Here, GSK borrowed amounts that exceed the damages award consistently throughout the relevant period (2008-present). (Vojir Decl. at ¶¶ 2-3.) Using the prime rate, compounded quarterly, GSK's expert, Dr. Maness, calculated $41,853,822 in pre-judgment interest as of today. (*See* Maness Decl. at ¶ 3.) Pre-judgment interest will continue to accrue at the same rate until judgment is entered. With respect to post-judgment interest, GSK asks that it be awarded at the statutory rate set by 28 U.S.C. § 1961.

D. GSK Will Seek an Award of Costs After the Conclusion of Any Appeal Consistent with Local Rule 54.1.

Finally, GSK seeks its costs under 35 U.S.C. § 284 and 28 U.S.C. § 1920. "Unless otherwise ordered by the Court, the prevailing party shall be entitled to costs." *See* D. DEL. LR 54.1(a)(1). An award of costs is appropriate here—GSK is the prevailing party and incurred significant costs to recover its damages due to Teva's willful infringement. This Court's Local Rules defer the deadline for filing a bill of costs until after an appeal is concluded. *See id.* ("The party shall, within 14 days after the time for appeal has expired or within 14 days after the issuance of the mandate of the appellate court, file a bill of costs."). GSK will thus defer filing a bill of costs until after the conclusion of any appeal, but wanted to ensure that it has preserved its right to do so by noting now that it intends to seek costs should it ultimately prevail.

VI. CONCLUSION

For the reasons above, GSK respectfully requests that the Court award enhanced damages, attorney fees, and interest, and that the Court award costs after any appeal in this case is complete.

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