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July 10, 2017

The Honorable Leonard P. Stark
United States District Court for the
District of Delaware
844 N. King Street
Wilmington, DE 19801

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Principal
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Re: *GlaxoSmithKline v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 14-878-LPS-CJB

Dear Chief Judge Stark:

Pursuant to the Court's June 30, 2017 Order (D.I. 454), the parties submit this letter identifying the issues on which each will seek post-trial relief.

GSK's Post-trial Motions:

GSK's intends to file post-trial motions pursuant to 35 U.S. C. § 284 seeking (a) an award of pre- and post-judgment interest on damages, *Ateliers de la Haute-Garonne v. Broetje Automation-USA Inc.*, 85 F. Supp. 3d 768, 783-84 (D. Del. 2015) ("prejudgment interest on a damages award based on patent infringement 'is the rule' under 35 U.S.C. § 284. … The Court will also amend the judgment to award [plaintiff] post-judgment interest, which is mandatory for all damages awarded."), (b) costs,[1] and (c) enhancement of the damages award pursuant to 35 U.S.C. § 284 based on the jury's willfulness finding, including the extensive evidence that Teva always intended to capture sales for heart failure.

GSK also intends to file a post-trial motion for attorneys' fees pursuant to 35 U.S.C. § 285 on the same basis for which it seeks enhanced damages for Teva's willful infringement.

Teva's Post-trial Motions:

Consistent with its oral motion for judgment as a matter of law after GSK closed its case-in-chief, Teva intends to file post-trial motions pursuant to Fed. R. Civ. P 50(a) and 59(a) seeking judgment as a matter of law or in the alternative a new trial on the following subjects:

1. Teva will seek judgment as a matter of law of no inducement or a new trial because GSK based its inducement case on a theory that physicians "as a class" had been induced to infringe the '000 patent, and no jury could reasonably conclude that 100% of physicians were actually induced by Teva's actions – as opposed to other factors such as the ACC/AHA guidelines, the FDA's 2007 press release, the Orange Book, state law substitution practices, doctor's past prescribing habits, and ten years' worth of GSK's own promotional efforts – to administer Teva's

[1] GSK intends to request its costs now, and will supplement that request at a time consistent with Local Rule 54.1(a)(1).

carvedilol to patients in a manner that infringed the '000 patent. *See, e.g., Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1354 (Fed Cir. 2007).

2. Teva will seek judgment as a matter of law of no inducement or a new trial because no jury could reasonably conclude based on the evidence that the Teva documents identified by GSK (*e.g.*, Teva's labels, product guides, monthly prescribing references and/or press releases), as opposed to other factors such as those identified above in Teva's Issue No. 1 above, actually caused any physician to administer Teva's carvedilol to a patient for use in an infringing manner. *See* Final Jury Instruction § 4.2.4.

3. Teva will seek judgment as a matter of law of no inducement or a new trial because GSK's ultimate argument, as presented in the rebuttal testimony of Dr. McCullough and in closing, was improperly based upon Teva's having failed to affirmatively state to physicians that Teva's carvedilol was not approved for treatment of CHF when it made statements that Teva's generic carvedilol product was AB-rated to Coreg or was a "generic version of Coreg" in press releases or in product materials, and the alleged failure by Teva to make such an additional disclosure does not constitute an affirmative act of inducement, or make Teva's statements about its AB-rated product an inducement, as a matter of law. *See* Final Jury Instruction 4.2.2; D.I. 191 at 20; D.I. 328 (adopting D.I. 191).

4. Teva will seek judgment as a matter of law of no lost profits, and remittitur of the jury's award of lost profits damages, or a new trial, because GSK failed to "prov[e] the amount of any direct infringement that was caused by Teva's inducement with reasonable certainty" (*see* Final Jury Instruction § 6.3.5) as GSK's experts admitted on cross examination that they had not attempted to quantify the amount of the infringement caused by Teva's alleged inducement; instead, GSK's damages expert assumed that 100% of GSK's alleged lost sales were induced by Teva, without regard to the undisputed other factors separate from any inducement by Teva that influenced doctor's prescribing habits or that resulted in the substitution of Teva's product by the pharmacies, and therefore the jury was left with no evidentiary basis from which it could find that GSK met its burden of proving it was entitled to any lost profit damages.

In addition to the primary issues listed above, Teva anticipates seeking post-trial relief under Fed. R. Civ. P. 50(a) and 59(a) on the following issues:

5. Teva will seek judgment as a matter of law or a new trial because no reasonable jury could conclude that Teva's Skinny Label constituted affirmative acts that encouraged direct infringement because GSK did not introduce any evidence that the language that instructed the treatment of Post-MI LVD either did in fact, or would "inevitably," lead physicians to prescribe carvedilol with the specific intent to decrease mortality caused by congestive heart failure as required by the claims.

6. Teva will seek judgment as a matter of law or a new trial that no reasonable jury could conclude that Teva intended to induce infringement because (i) intent to induce infringement cannot be inferred given the substantial non-infringing uses of carvedilol, (ii) the mere knowledge of

potential direct infringement is not evidence of intent to induce infringement, and (iii) the only evidence probative of Teva's intent was the undisputed testimony that Teva's labeling decisions were based on FDA requirements, not to induce patent infringement.

7. Teva will seek judgment as a matter of law or a new trial on the question of anticipation by the Kelly reference because the evidence, including admissions on cross examination by Dr. McCullough, establish that the cause and measurements of heart failure described in the reference would mean the study would include patients with reduced ejection fraction and thus "congestive heart failure"; that "follow up" (the exact language in the Kelly paper) established six months of treatment "for certain" for purposes of infringement and the same meaning should apply for validity; and that the Garg reference established that the study described in Kelly was not theoretical.

Finally, Teva expects to reserve space in its post-trial briefing to raise certain additional issues to the extent necessary in order to preserve any appellate rights, including (i) GSK's failure to present evidence that any doctor actually directly infringed the '000 patent (as opposed to "the label" being the direct infringement), (ii) that GSK's evidence of secondary considerations is insufficient to rebut Teva's strong obviousness case that a person of ordinary skill in the art would have been motivated to combine Kelly and Garg and would have had a reasonable expectation of success; (iii) GSK's failure to address, let alone rebut, Teva's evidence that claim 8 is invalid for failing to meet the written description requirement; and (iv) GSK's failure to introduce evidence of inducement of claims 6 (specifying one of three ACE inhibitors) and 7 (specifying one of two diuretics) and apportion damages for dependent claims 3, 6, and 7-8, as well as appropriate grounds for a new trial under Fed. R. Civ. P. 59.

Respectfully submitted,

/s/ Elizabeth M. Flanagan

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cc: Counsel of Record – via e-mail