IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXOSMITHKLINE LLC and SMITHKLINE BEECHAM (CORK) LIMITED, Plaintiffs, v. GLENMARK PHARMACEUTICALS INC., USA, Defendant.	:	C.A. No. 14-877-LPS-CJB
GLAXOSMITHKLINE LLC and SMITHKLINE BEECHAM (CORK) LIMITED, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	:	C.A. No. 14-878-LPS-CJB

MEMORANDUM ORDER

WHEREAS, Magistrate Judge Burke issued a 47-page Report and Recommendation (the "Report") (D.I. 346)[1], dated May 2, 2017, recommending that the Court deny the invalidity portions of Defendants Teva Pharmaceuticals USA, Inc. and Glenmark Pharmaceuticals Inc., USA's (collectively, "Defendants" or "Defs") motion for summary judgment (D.I. 248)[2];

[1]All references to the docket index (D.I.) are to the *Teva* action, C.A. No. 14-878.

[2]Defendants filed a "Combined Motion for Summary Judgment and to Exclude Certain Expert Testimony" (D.I. 248), in which they, *inter alia*, moved for summary judgment on multiple issues. The Report – and, accordingly, this Order – solely relates to the portions of Defendants' motion raising invalidity arguments.

WHEREAS, on May 12, 2017, Plaintiffs GlaxoSmithKline LLC and SmithKline Beecham (Cork) Limited (collectively, "GSK") as well as Defendants objected to the Report (D.I. 353 ("Defendants Objections" or "Defs Objs"); D.I. 355 ("GSK Objections" or "GSK Objs"));

WHEREAS, on May 22, 2017, both sides responded to the opposing Objections (D.I. 366 ("GSK Response" or "GSK Resp"); D.I. 367 ("Defendants Response" or "Defs Resp"));

WHEREAS, the Court has considered the parties' objections and responses *de novo*, *see St. Clair Intellectual Prop. Consultants, Inc. v. Matsushita Elec. Indus. Co., Ltd.*, 691 F. Supp. 2d 538, 541-42 (D. Del. 2010); 28 U.S.C. § 636(b)(l); Fed. R. Civ. P. 72(b)(3);

NOW THEREFORE, IT IS HEREBY ORDERED that:

1. Defendants' Objections (D.I. 353) are OVERRULED, GSK's Objections (D.I. 355) are OVERRULED, Judge Burke's Report (D.I. 346) is ADOPTED to the extent and as explained below, and Defendants' Motion for Summary Judgment as related to invalidity (D.I. 248) is DENIED.

2. Defendants object to the Report's conclusion that the record reveals a genuine dispute of material fact with regard to whether prior art reference Kelly expressly discloses treatment with carvedilol for more than six months. (Defs Objs at 1-2) The Court agrees with the Report. While Kelly discloses a "long-term study" with "6 and 18 months of follow-up," the Report correctly observed that "Kelly never expressly states that the patient is to actually receive carvedilol for all of that time." (Report at 16, 17) Defendants point to the first sentence of the Kelly abstract, which mentions "[s]ustained oral treatment;" however, as GSK notes, "sustained" may be viewed in that sentence as not referring to the protocol for the study but, rather, as

referring to other studies that had already occurred. (GSK Response at 4) Thus, at trial, both sides will be given the opportunity to present evidence on the disputed factual issue of whether Kelly discloses treatment for more than six months (which is an element of the asserted claims of the patent-in-suit).[3]

3. GSK objects to the Report's findings on inherent anticipation, arguing that the Report misstates the law by (1) incorrectly concluding that whether the asserted claims constitute an unpatentable newly discovered result of a known process, rather than a patentable new use of a known process, depends on whether there is a manipulative difference in the steps of the methods in the prior art and the method claimed in the patent, and (2) disregarding the "intent" limitation in the asserted claims. (GSK Objs at 6-9)

Regarding the first issue, the Report thoroughly examined the existing caselaw on inherent anticipation, concluding that the proper test for determining whether a use is patentably "new" is to compare "the methods disclosed in the prior art" to those disclosed in the patent to determine if "they teach the same physical steps" or whether there is a "manipulative difference" in the disclosed steps. (Report at 23, 29) The Report properly considered and rejected GSK's proposed alternative test – that a claimed method is patentable even if it is the same as the method of the prior art, so long as "the use is different and not present in the prior art." (*Id.* at

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[3]Defendants also argue that GSK's expert, Dr. McCullough, only first disputed the length of treatment in the Kelly study during his deposition, having failed to raise this issue in his expert report. (Defs Objs at 3) While Defendants are correct that Dr. McCullough's expert report does not explicitly raise this issue, Defendants are not entitled to any relief. Defendants did not raise a concern about the timing of Dr. McCullough's length of treatment opinion in the summary judgment briefing or oral argument. (*See* GSK Resp at 7) Nor have Defendants attempted to show that they have been unfairly prejudiced by GSK's actions or that such prejudice could not be cured by consequences short of striking Dr. McCullough's opinion on this issue.

24) The Court agrees with the Report's conclusions of law on inherent anticipation, including that there is not "an exception for the later discovery of life-saving inherent results of a known method." (*Id.* at 34)

With regard to the second inherent anticipation issue raised in GSK's Objections, the Report correctly concluded that a patentee may not circumvent the doctrine of inherent anticipation simply by adding an "intent" limitation to a claim. (*See* Report at 36) That is, if the only distinction between the prior art and the asserted claim is an express intent limitation in the asserted claim – and there is no manipulative difference in the physical steps in the asserted claims as compared to those in the prior art – then the asserted claim is anticipated. *See Rapoport v. Dement*, 254 F.3d 1053, 1061 (Fed. Cir. 2001) (finding no inherent anticipation where intent for administering buspirone as part of asserted claims – to treat sleep apnea – resulted in manipulative difference from method disclosed in prior art – which was to treat anxiety; dosing regime for anxiety was three times daily while regime for sleep apnea was larger dose once a day at time of sleep); *see also Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1371, 1378 n.* (Fed. Cir. 2005) (affirming district court's finding of inherent anticipation, even when preamble reciting purpose of claimed method was construed as limiting, because prior art reference disclosed same steps as those in claims, and reversing district court's finding of anticipation where claimed method differed from prior art).[4]

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[4]GSK also argues that the Report is, in part, an improper advisory opinion because it reaches the parties' arguments on inherency and enablement after finding a genuine dispute of material fact with regard to whether Kelly contains all elements of the claims, in particular the six-month maintenance period. (GSK Objs at 1-2) The Court disagrees. Moreover, even if GSK were correct, it would mean, at most, that the Report constitutes slightly premature assistance to the Court in deciding a legal dispute that will have to be addressed no later than when the jury is instructed. The Court has discretion to decide this legal issue now and to allow its

4. Finally, Defendants object to the Report's conclusion that the record reveals a genuine dispute of material fact as to whether the study disclosed in Kelly – a planned but not yet initiated trial – is enabling of the asserted claims. (Defs Objs at 5-6) Defendants assert that there is no legal or factual basis for this conclusion because: (1) the study in Kelly is not "too theoretical" to be enabling, and (2) enablement under 35 U.S.C. § 102 does not require a clinical trial to be underway. (*Id.* at 6-7)

Neither party identified much pertinent caselaw, so the Report turned to *In re Montgomery*, 677 F.3d 1375 (Fed. Cir. 2012), and found by analogy that here a factual dispute exists as to whether the disclosure in Kelly is "too theoretical" to be enabling (Report at 43). Dicta in *Montgomery* differentiated between a mere "invitation to investigate" or "abstract theory," both of which may not be sufficiently enabling for anticipation, and the reference at issue in *Montgomery,* which disclosed "an advanced stage of testing designed to secure regulatory approval." 677 F.3d at 1382. Similarly here, the Report found the fact that the Kelly trial had not yet started was not dispositive, but the fact that the trial was not so far along as to be designed to secure regulatory approval supported the conclusion that a material dispute of fact underlies the legal issue of enablement. (Report at 44-45) ("On the one hand, the disclosure in Kelly can be seen as being more concrete than the exemplary 'invitation to investigate' set out by the *Montgomery* Court, in that the planned multicentre trial in Kelly was focused on the use of particular drugs . . . , in particular dosage levels . . . , to treat particular symptoms . . . of patients who have a particular condition. . . . Yet on the other hand, the disclosure in Kelly regards a planned but not yet started trial, and so in that sense, can be seen as more 'abstract' than [the

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determinations to guide both its jury instructions and its evidentiary decisions at trial.

disclosure in *Montgomery*].")

A reasonable jury, taking the evidence in the light most favorable to Teva, might find that Kelly meets the standard for enablement under § 102, as that standard does not require actual performance or advanced studies, but only requires that the prior art reference "describe[] the claimed invention sufficiently to enable a person of ordinary skill in the art to carry out the invention." *Impax Labs., Inc. v. Aventis Pharm., Inc.*, 468 F.3d 1366, 1383 (Fed. Cir. 2006); *see Novo Nordisk Pharm., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1355 (Fed. Cir. 2005). Alternatively, a reasonable jury, taking the evidence in the light most favorable to GSK, might instead find that Kelly does not meet the standard for enablement under § 102, for reasons including Kelly's brevity and that the study had not yet even begun.

5. The Court will address the implications of its adoption of the Report, including what issues relating to anticipation will be tried before the jury, during the pretrial conference to be held tomorrow.

May 25, 2017
Wilmington, Delaware

HON. LEONARD P. STARK
UNITED STATES DISTRICT JUDGE