IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER INTELLECTUAL PROPERTY GMBH and BAYER PHARMA AG, Plaintiffs, v. WARNER CHILCOTT COMPANY, LLC, WARNER CHILCOTT (US), LLC, and WARNER CHILCOTT PLC, Defendants.	)	Civil Action No. 12-1032-GMS

MEMORANDUM

I. INTRODUCTION

The plaintiffs Bayer Intellectual Property GmbH and Bayer Pharma AG (collectively, "Bayer") filed this patent infringement lawsuit against defendants Warner Chilcott Company, LLC, Warner Chilcott (US), LLC, and Warner Chilcott plc (collectively, "Warner Chilcott") on August 13, 2012. (D.I. 1.) Bayer alleges infringement of U.S. Patent No. 5,980,940 ("the '940 Patent").[1] Presently before the court is Warner Chilcott's motion for summary judgment on the grounds that the '940 Patent is indefinite and therefore invalid. (D.I. 131.) For the reasons that follow, the court will grant Warner Chilcott's motion for summary judgment.

II. BACKGROUND

The '940 Patent claims an oral contraception regimen in which two hormones are taken at set time points throughout the dosing schedule. *See, e.g.*, '940 Patent, claim 1. Bayer alleges that Warner Chilcott's product Lo Loestrin infringes the '940 Patent's claims.

[1] Bayer also alleges that Warner Chilcott's patent—U.S. Patent No. 7,704,984 ("the '984 Patent")—interferes with the '940 Patent by claiming the same subject matter. (D.I. 5.)

The parties sought construction of the claim term: "high contraceptive reliability, low incidence of follicular development, and satisfactory cycle control, with reliable avoidance of intracyclic menstrual bleeding and undesirable side-effects" (the "disputed term"). '940 Patent, claims 1, 8 & 10. In its October 9, 2014, Claim Construction Order, the court found that it was "unable to construe the disputed phrase." (D.I. 120 at 3.) In particular, the court found that the words of degree—*i.e.*, "high," "low," "satisfactory," and "reliable"—had no standards against which to draw comparisons, and the patent offered no suggestions for how to measure these criteria. (*Id.* at 7–8.) "The court is left at an impasse and is unable to discern the meets and bounds of the asserted claims." (*Id.* at 8.) As a result, the court indicated that summary judgment would be the proper avenue to address an indefiniteness challenge. (*Id.*)

III. STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 56(c), summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *See also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The moving party bears the burden of proving that no genuine issue of material fact exists. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 585 n.10 (1986). A fact is material if it "could affect the outcome" of the proceeding. *Lamont v. New Jersey*, 637 F.3d 177, 181 (3d Cir. 2011). There is a genuine issue "if the evidence is sufficient to permit a reasonable jury to return a verdict for the non-moving party." *Id.* When determining whether a genuine issue of material fact exists, the district court must view the evidence in a light most favorable to the nonmoving party and draw inferences in that party's favor. *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007). If the moving party is able to demonstrate an absence of disputed

material facts, the nonmoving party must then "come forward with 'specific facts showing that there is a genuine issue for trial.'" *Matsushita*, 475 U.S. at 587 (citing Fed. R. Civ. P. 56(e)).

Patent invalidity on indefiniteness grounds requires proof by clear and convincing evidence. *See* 35 U.S.C. § 282 ("A patent shall be presumed valid."); *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238 (2011) ("We consider whether § 282 requires an invalidity defense to be proved by clear and convincing evidence. We hold that it does.").

IV. DISCUSSION

The law of patent definiteness has its roots in 35 U.S.C. § 112: "The specification shall conclude with one or more claims *particularly pointing out and distinctly claiming* the subject matter which the inventor or a joint inventor regards as the invention." § 112 (emphasis added). In light of this statutory mandate, "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, *with reasonable certainty*, those skilled in the art about the scope of the invention." *See Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014) (emphasis added). Claims may be found invalid as indefinite when they fail to specify clear, definite boundaries or standards. *See Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014) ("The claims, when read in light of the specification and the prosecution history, must provide objective boundaries for those of skill in the art.").

The court has already explained in its Claim Construction Order that the intrinsic record fails to assign meaning to the words of degree in the disputed term. (D.I. 120 at 3–8.) Bayer did not seek reconsideration of this ruling, and the court need not revisit its reasoning. Nonetheless, Bayer contends that the disputed term is not indefinite because one skilled in the art would understand—with reasonable certainty—its meaning, as demonstrated by extrinsic evidence.

Bayer provides dozens of pieces of extrinsic evidence, as well as a supplemental declaration from Dr. Lee Shulman, in support of a new argument that the disputed term and the words of degree simply indicate that the claimed invention performs *comparably* to other oral contraceptives on the market.[2] (*See, e.g.*, D.I. 135.)

As an initial matter, the court takes issue with Bayer's procedure in making its arguments. As even Bayer highlights in its brief, the court gave counsel an opportunity during the *Markman* hearing to explain why extrinsic evidence was necessary to construe the terms—Bayer conceded that the evidence was merely for "context." (D.I. 134 at 3; D.I. 84 at 17 ("Our position is the meaning is clear from the text of the claim itself, and that it will be understood by a person of skill in the art. . . . It [extrinsic evidence] is simply meant to provide the context . . . .").) At this stage, however, Bayer contends that extrinsic evidence and expert testimony is indeed required to understand the disputed term for the purposes of an indefiniteness inquiry. Notwithstanding the fact that Bayer knew about Warner Chilcott's indefiniteness defense at the time of the *Markman* hearing, the court fails to understand Bayer's argument that different analyses apply, depending on whether the court is construing terms versus assessing definiteness—they are two sides of the same coin. *See Noah Sys., Inc. v. Intuit Inc.*, 675 F.3d 1302, 1311 (Fed. Cir. 2012) ("Whether a claim complies with the definiteness requirement of 35 U.S.C. § 112 ¶ 2 is a matter of claim construction . . . .").

Moreover, during the October 31, 2014, teleconference, the court explained that additional extrinsic evidence would not be considered at this stage:

> I am certainly not going to prevent or prohibit Bayer from making an argument regarding indefiniteness that they didn't get a chance

[2] This construction based on "comparable" performance differs from that asserted during the original claim construction arguments. Indeed, Dr. Shulman—Bayer's expert—previously provided a declaration supporting Bayer's claim construction proposal. (D.I. 68.) There was no mention of comparing the claimed invention with existing oral contraceptives in that declaration.

> to make at the Markman proceeding. But I don't see the need for any further testimony or discovery of an opinion type in this case.
>
> . . . .
>
> I think I have made it pretty clear in my order that in spite of having the benefit of the thoughts of those of skill that I have been unable to construe certain of the terms in the patent.

(D.I. 126 at 3.) Nonetheless, Bayer has flooded the court with never-before-seen evidence and expert testimony, supporting a new, "clearly established" meaning of the disputed term. Bayer's efforts to reargue claim construction with entirely new evidence at this time is improper.

As the court stated in its Claim Construction Order, "[t]he difficulty the court has encountered in construing the terms may unavoidably present an indefinite[ness] issue that will need to be addressed at summary judgment." (D.I. 120 at 8.) Being unable to construe the disputed term, the court finds, by clear and convincing evidence, that the '940 Patent does not "inform those skilled in the art about the scope of the invention with reasonable certainty"; the '940 Patent is therefore indefinite and invalid under § 112.

Indeed, the court would reach the same result, even if it were to accept the additional extrinsic evidence and allow Bayer to assert a new construction. First, the proposed construction (and the underlying extrinsic evidence) conflicts with the intrinsic record of the '940 Patent, violating a basic tenet of claim construction. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1318 (Fed. Cir. 2005) ("[A] court should discount any [extrinsic evidence] 'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history . . . .'" (quoting *Key Pharms. v. Hercon Labs. Corp.*, 161 F.3d 709, 716 (Fed. Cir. 1998))). Whereas Bayer pushes for a construction that essentially replaces all of the words of degree in the disputed term with "comparable," the specification and prosecution history state repeatedly that the patented invention performed superior to prior art products on the market.

In addition, the conflicting interpretations of the disputed term offered by Dr. Shulman in his two declarations underscore the fact that the patent "fails to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *See Interval Licensing*, 766 F.3d at 1369–70 (quoting *Nautilus*, 134 S. Ct. at 2124). Bayer contends that Dr. Shulman's supplemental declaration and the extrinsic evidence demonstrate a "known industry standard" or an "established meaning in the art." (D.I. 134 at 8–9.) But Bayer's change of course shows this argument to be specious. As Warner Chilcott states, if there were actually an "established meaning in the art," Dr. Shulman would have identified it in his original declaration. (D.I 138 at 7–8.)

Finally, even if it were to accept Bayer's new construction—"comparable to other marketed oral contraceptives"—the court still would find the '940 Patent to be indefinite. "The claims, when read *in light of the specification and the prosecution history*, must provide objective boundaries for those of skill in the art." *See Interval Licensing*, 766 F.3d at 1371 (emphasis added). Bayer's proposed construction cannot stand by itself. By definition, "comparable" requires a frame of reference, *e.g.*, data from other marketed products. The intrinsic record fails to provide this requisite information. Moreover, the word "comparable" is itself subjective, without defined boundaries. Bayer gives no indication of *how* comparable the performance of the claimed invention versus the analogous products should be. "[A] patent must be precise enough to afford clear notice of what is claimed, thereby apprising the public of what is still open to them. Otherwise there would be a zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims." *Nautilus*, 134 S. Ct. at 2129 (internal citations, footnote, and quotation marks omitted). Thus, even Bayer's new proposal, "on its face, provides little guidance to one of skill in the art." *See Interval Licensing*, 766 F.3d at 1371.

For these reasons, the court finds that the '940 Patent is indefinite. The court will grant Warner Chilcott's motion for summary judgment.[3]

V. CONCLUSION

The court grant's Warner Chilcott's motion for summary judgment. (D.I. 131.) The '940 Patent is invalid as indefinite, pursuant to 35 U.S.C. § 112.

Dated: April 21, 2015

UNITED STATES DISTRICT JUDGE

[3] Warner Chilcott notes that a finding of indefiniteness necessarily eliminates Bayer's interference allegations. (D.I. 132 at 14–16.) Bayer did not respond to this portion of Warner Chilcott's motion. The court agrees that, having found the '940 Patent to be indefinite, there would be no way of effectively comparing it with the '984 Patent, for the purposes of conducting an interference analysis. *See Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1332 (Fed. Cir. 2010) ("Without a discernable claim construction, an anticipation analysis cannot be performed.").

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ORDER

For the reasons stated in the court's Memorandum of this same date, IT IS HEREBY ORDERED that:

Warner Chilcott's Motion for Summary Judgment Based on Indefiniteness (D.I. 131) is GRANTED.

Dated: April 21, 2015

UNITED STATES DISTRICT COURT