UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WARNER CHILCOTT COMPANY LLC Plaintiff, v. MYLAN INC., et al. Defendants.	Civil Action No. 11-3262 (JAP) **OPINION**

PISANO, District Judge.

Plaintiff Warner Chilcott Company, LLC ("Warner" or "Plaintiff") brings this patent infringement action against Defendants Mylan Inc., Mylan Pharmaceuticals Inc., and Famy Care Ltd. (collectively, "Mylan" or "Defendants") alleging infringement of U.S. Patent No. 5,552,394 (the " '394 patent"). Plaintiff's action is founded upon Mylan's filing with the U.S. Food and Drug Administration ("FDA") an Abbreviated New Drug Application ("ANDA") seeking approval to market a generic version of Plaintiff's product Loestrin 24 Fe, an oral contraceptive for women. Presently before the Court is the parties' request for claim construction. A *Markman* hearing was held on February 28, 2013.

I. BACKGROUND

As set forth in the complaint, Warner is the holder of New Drug Application No. 21-871 for Loestrin 24 Fe, an oral contraceptive product containing the active ingredients norethindrone acetate and ethinyl estradiol. Loestrin 24 Fe is sold as a 28-day oral

contraceptive regimen that includes 24 active tablets comprising 1 mg norethindrone acetate and 0.02 mg ethinyl estradiol, followed by 4 ferrous fumarate tablets, which act as a placebo. According to Plaintiffs, the use of Loestrin 24 Fe is covered by the '394 patent, which is entitled "Low Dose Oral Contraceptives with Less Breakthrough Bleeding and Sustained Efficacy." The '394 patent relates to a method of female contraception, which comprises, *inter alia*, monophasicly administering a combination comprising 0.02 mg of ethinyl estradiol and 1 mg of norethindrone acetate for 24 days of a 28 day cycle.

Claim 1 of the '394 patent contains the single term that is the subject of the instant dispute. This claim reads as follows (disputed term in bold):

> A method of female contraception **which is characterized by a reduced incidence of breakthrough bleeding** after the first cycle which comprises monophasicly administering a combination of estrogen and progestin for 23-25 consecutive days of a 28 day cycle in which the daily amounts of estrogen and progestin are equivalent to about 1-35 mcg of ethinyl estradiol and about 0.025 to 10 mg of norethindrone acetate, respectively, and in which the weight ratio of estrogen to progestin is at least 1:45 calculated as ethinyl estradiol to norethindrone acetate.

'394 patent, col. 8, lines 2-12 (emphasis added). The parties disagreement over the term "which is characterized by a reduced incidence of breakthrough bleeding" is two-fold. The threshold issue is whether the term, which the parties do not dispute is part of the preamble to claim 1, is a claim limitation. Defendants contend that it is, while Plaintiffs contend it is not.

The second issue arises in the event the Court finds this preamble language to be limiting. If the Court so finds, the parties disagree as to how the term should be construed. Plaintiffs contend that the term means as follows: "which has as one characteristic a statistically significant decreasing trend after the first cycle in the number of days of untimely flow or spotting." Defendants, on the other hand, assert that the disputed term should be

construed to mean "which has the distinguishing feature, as compared to combination oral contraceptive regimens that comprise daily administration of estrogen and progestin for 21 days followed by a hormone-free period of 7 days, of a statistically significant reduction in the occurrence of breakthrough bleeding following the first cycle of administration of a combination oral contraceptive regimen."

II. LEGAL STANDARD

In order to prevail in a patent infringement suit, a plaintiff must establish that the patent claim "covers the alleged infringer's product or process." *Markman v. Westview Instrs., Inc.*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotations omitted) (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("we look to the words of the claims themselves ... to define the scope of the patented invention"). Consequently, the first step in an infringement analysis involves determining the meaning and the scope of the claims of the patent. *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 988 (Fed. Cir. 1995). Claim construction is a matter of law, *Markman v. Westview Instrs., Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) *aff'd* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996), therefore, it is "[t]he duty of the trial judge ... to determine the meaning of the claims at issue," *Exxon Chem. Patents, Inc. v. Lubrizoil Corp.*, 64 F.3d 1553, 1555 (Fed. Cir. 1995).

Generally, the words of a claim are given their "ordinary and customary meaning," which is defined as "the meaning that the term would have to a person of ordinary skill in the

art in question at the time of the invention." *Phillips*, 415 F.3d at 1312–13 (citations omitted). In this regard, the Federal Circuit has noted that

> It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning and usage in the field. The inventor's words that are used to describe the invention—the inventor's lexicography—must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology. Thus the court starts the decisionmaking process by reviewing the same resources as would that person, viz., the patent specification and the prosecution history.

Id. (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998)).

In order to determine the meaning of a claim as understood by a person skilled in the art, a court may look to various sources from which the proper meaning may be discerned. These sources include intrinsic evidence, which consists of "the words of the claims themselves, the remainder of the specification, [and] the prosecution history," *id.* at 1314, and extrinsic evidence "concerning relevant scientific principles, the meaning of technical terms, and the state of the art," *id.*

When considering the intrinsic evidence, the court's focus must begin and remain on the language of the claims, "for it is that language that the patentee chose to 'particularly point[ ] out and distinctly claim[ ] the subject matter which the patentee regards as his invention.' " *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed.Cir.2001) (quoting 35 U.S.C. § 112, ¶ 2). The specification is often the best guide to the meaning of a disputed term. *Honeywell Int'l v. ITT Indus.*, 452 F.3d 1312, 1318 (Fed.Cir.2006). It is improper, however, to import limitations from the specification into the claims. *Seachange Int'l v. C–COR Inc.*, 413 F.3d 1361, 1377 (Fed. Cir. 2005). The court may

also consider as intrinsic evidence a patent's prosecution history, which is evidence of "how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1317.

While a court is permitted to turn to extrinsic evidence, such evidence is generally of less significance and less value in the claim construction process. *Id.* at 1317. Extrinsic evidence is evidence that is outside the patent and prosecution history, and may include expert testimony, dictionaries, and treatises. *Id.* The Federal Circuit has noted that caution must be exercised in the use of extrinsic evidence, as this type of evidence may suffer from inherent flaws affecting its reliability in the claim construction analysis. *Id.* at 1319 ("We have viewed extrinsic evidence in general as less reliable than the patent and its prosecution history in determining how to read claim terms."). While "extrinsic evidence may be useful to the court, ... it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." Extrinsic evidence may never be used to contradict intrinsic evidence. *Id.* at 1322–23.

III. CONSTRUCTION OF THE DISPUTED CLAIM TERM

The threshold issue to be addressed by the Court is whether the preamble to claim 1 is a limitation. There is no litmus test to determine whether a claim's preamble is limiting , although the Federal Circuit has set forth "general principles to guide that inquiry." *American Medical Systems, Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1358 (Fed. Cir. 2010). Whether to treat a term in the preamble as a claim limitation is "determined on the facts of each case in light of the claim as a whole and the invention described in the patent." *Id.* (quoting *Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 831 (Fed. Cir. 2003)).

Generally, a claim's preamble is not limiting "when the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002). Nor is a preamble limiting if it "merely gives a descriptive name to the set of limitations in the body of the claim that completely set forth the invention." *IMS Tech., Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1434–35 (Fed. Cir. 2000). However, a claim's preamble may limit the claim when the drafter uses the preamble to define the subject matter of the claim. *Allen Eng'g Corp. v. Bartell Indus.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002). A preamble will be construed as limiting when it is " 'necessary to give life, meaning and vitality' " to the claim based on the facts of the case at hand and in view of the claim as a whole. *Allen Eng'g Corp. v. Bartell Indus.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002) (quoting *Kropa v. Robie*, 187 F.2d 150, 152 (1951)). Where a claim depends on its preamble "for antecedent basis, or when [the preamble] is essential to understand limitations or terms in the claim body," the preamble will be construed as a limitation. *C.W. Zumbiel Co., Inc. v. Kappos*, 702 F.3d 1371, 1385 (Fed. Cir. 2012). Statements of intended use, features or benefits in a preamble may only be limiting if an "applicant clearly and unmistakably relied on those uses or benefits to distinguish prior art." *Catalina*, 289 F.3d at 809. In sum, only in "rare instances" will a claim's preamble constitute a limitation. *Id.*

This is not one of those rare instances. As an initial matter, given the requirement to examine the issue based "on the facts of each case in light of the claim as a whole and the invention described in the patent," *American Med.*, 618 F.3d at 1358, the Court rejects Mylan's argument that the mere use of the term "characterized by" in the preamble directs a finding that the disputed preamble language constitutes a limitation. Further, examining all of

the relevant facts and the claim as a whole, the Court finds that the disputed language is not necessary to give "life, meaning and vitality" to the claim, nor does it provide an antecedent basis for the claim. The disputed language is not essential to the understanding of the limitations or terms in that appear in the claim body. Indeed, the claim body itself describes a complete invention; deletion of the preamble term in no way affects the steps of the claimed invention. Even in the absence of the disputed term, claim 1 completely describes the claimed contraception method:

> A method of female contraception … which comprises
>
> [1] monophasicly administering a combination of estrogen and progestin for 23-25 consecutive days of a 28 day cycle
>
> [2] in which the daily amounts of estrogen and progestin are equivalent to about 1-35 mcg of ethinyl estradiol and about 0.025 to 10 mg of norethindrone acetate, respectively, and
>
> [3] in which the weight ratio of estrogen to progestin is at least 1:45 calculated as ethinyl estradiol to norethindrone acetate

'394 patent, claim 1. As such, it is clear that the reference to reduced breakthrough bleeding in the preamble describes the result or benefit from practicing the invention, and is not a fundamental element of the invention itself.

Mylan contends that the reduced incidence of breakthrough bleeding described in the disputed preamble language is the "only thing" that distinguishes the invention from the prior art. Mylan Op. Br. at 12. However, the relevant question here is not whether the described reduction in breakthrough bleeding does or does not so distinguish the invention, but rather, the question is whether during prosecution the applicant "clearly and unmistakably relied" on this benefit to distinguish the invention from the prior art. *See Catalina*, 289 F.3d at 809 ("[P]reamble language merely extolling benefits or features of the claimed invention does not

limit the claim scope without clear reliance on those benefits or features as patentably significant.). The file history does not support such a finding.

During prosecution of the '394 patent, the PTO examiner rejected all pending claims as obvious. Pl. Ex. H at WC_LP0029558-59. The examiner reviewed the prior art disclosures and concluded that the claims were obvious because they "failed to patentably distinguish over the state of the art as represented by the cited references." *Id.* In its initial and subsequent responses to the examiner's rejection, contrary to Mylan's argument, the applicant distinguished the relevant reference based upon the dose and role of estrogen in the invention as well as the number of days of administration. While the applicant did describe the role of the estrogen in the invention as "control[ling] unscheduled bleeding" rather than contraception, Pl. Ex. H at WC_LP0029559, the Court does not find this to be evidence of "clear and unmistakable" reliance on the lower incidence of breakthrough bleeding described in the preamble. In short, Mylan has not identified anything in the prosecution history that the Court considers to be evidence of clear reliance on reduced breakthrough bleeding as patentably significant. Consequently, the Court finds that the disputed preamble term is not a claim limitation, and, therefore, no further construction of the term is required.

IV. CONCLUSION

For the reasons set forth above, the disputed claim terms will be construed as indicated. An appropriate Order shall accompany this Opinion.

/s/ Joel A. Pisano
JOEL A. PISANO, U.S.D.J.

Dated: April 8, 2013