IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER PHARMA AG, BAYER INTELLECTUAL PROPERTY GmbH, and BAYER HEALTHCARE PHARMACEUTICALS INC.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 12-1726-LPS-CJB
WATSON LABORATORIES, INC.,	)	
Defendant.	)	

REPORT AND RECOMMENDATION

In this Hatch-Waxman action filed by Plaintiffs Bayer Pharma AG, Bayer Intellectual Property GmbH and Bayer Healthcare Pharmaceuticals Inc. (collectively, "Bayer" or "Plaintiffs") against Defendant Watson Laboratories, Inc. ("Watson" or "Defendant"), Bayer alleges infringement of U.S. Patent No. 8,071,577 (the "'577 Patent").[1] Presently before the Court is the matter of claim construction. The Court recommends that the District Court adopt the constructions as set forth below.

I. BACKGROUND

A. The Parties

Bayer manufactures and sells the drug product known as Natazia®, an FDA-approved

[1] Shortly before instituting this action against Watson, Bayer filed suit against Lupin Ltd. and Lupin Pharmaceuticals Inc. (collectively, "Lupin") in a related case, alleging infringement of the same patent as that asserted here. *Bayer Pharma AG v. Lupin Ltd.*, Civil Action No. 12-1592-LPS-CJB, D.I. 1 (D. Del. Nov. 28, 2012). Lupin filed joint claim construction briefs with Watson. (*See id.* at D.I. 46, 51) Bayer and Lupin have since reached settlement, and Bayer's case against it has accordingly been closed. (*See id.* at D.I. 58)

oral contraceptive. (D.I. 1 at ¶¶ 15-17) Bayer is also the owner of the '577 Patent. (*Id.* at ¶ 22)

Watson is engaged in the business of developing, manufacturing, and distributing generic versions of branded drug products throughout the United States.[2] (D.I. 8 at ¶ 6)

B. The '577 Patent

The '577 Patent is entitled "Multi-Phase Contraceptive Preparation Based on a Natural Estrogen[.]" (D.I. 1, ex. A)[3] The patent is based on U.S. Appl. No. 11/578,771 and was issued on December 6, 2011. (*Id.*)

The invention of the '577 Patent relates to a multiphase product for contraception based on a combination of natural estrogen[4] and a synthetic progestogen (e.g., dienogest). (*Id.* at Abstract; cols. 1:8-10; 2:26-27) The patent's specification explains that the claimed composition, in comparison to other contraceptive products, "achieves a greater contraceptive reliability over the entire duration of the cycle, improves the cyclic bleeding behaviour, and controls side effects such as breast tenderness, headaches, depressive moods and libido changes and the like." (*Id.*, col. 2:3-10) While the product is "particularly suitable for oral administration," other forms of administration are also possible. (*Id.*, col. 2:36-40)

The '577 Patent contains just three claims, all of which are independent claims. (*Id.*, col. 4:15-53) Claims 1 and 2 are purportedly composition claims directed to the Natazia product

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[2] Bayer also originally brought suit against Watson Pharmaceuticals, Inc., but that party was later dismissed. (D.I. 17)

[3] The '577 Patent appears on the docket more than once, including also as an exhibit to the Joint Claim Construction Statement. (D.I. 51, ex. PX1) Further citations will simply be to the "'577 Patent."

[4] The Natazia® product contains estradiol valerate, which is converted to 17-beta estradiol, the natural human estrogen. (D.I. 55 at 1 n.1)

itself. (*Id.*, col. 4:16-41) Claim 3 is directed to the method of use of Natazia®. (*Id.*, col. 4:42-53)

C. Procedural History

This case arises out of Watson's submission of Abbreviated New Drug Application ("ANDA") No. 202349 to the United States Food and Drug Administration ("FDA"), which seeks approval to market a generic version of Bayer's Natazia® product. (D.I. 1 at ¶ 1) Bayer is the holder of approved New Drug Application No. 022252, which covers Natazia®. (*Id.* at ¶ 15) Natazia® tablets contain, as active ingredients, estradiol valerate and dienogest. (*Id.*)

Bayer filed suit against Watson on December 18, 2012, (D.I. 1), alleging that Watson's submission of ANDA No. 202349 infringes at least one claim of the '577 Patent under 35 U.S.C. § 271(e)(2), (*id.* at ¶¶ 28, 32). Further, Bayer alleges that upon FDA approval of Watson's ANDA, Watson will infringe the patent by making, using, offering to sell, and selling its generic oral contraception product. (*Id.* at ¶ 32)

On February 15, 2013, the Court was referred this case by Chief Judge Leonard P. Stark to hear and resolve all pretrial matters, up to and including the resolution of case-dispositive motions. (D.I. 15) The parties completed briefing on claim construction on December 13, 2013. (D.I. 65, 66) The parties thereafter jointly suggested that a *Markman* hearing was not necessary, (D.I. 69), and the Court accordingly cancelled the *Markman* hearing that had previously been scheduled for January 14, 2014.

II. STANDARD OF REVIEW[5]

[5] Because Watson contends that its proposed constructions for the disputed terms render claims 1 and 2 invalid for indefiniteness, and accordingly requests that this Court adopt its constructions and issue an order holding those claims invalid, (D.I. 54 at 20), the Court includes

A. Claim Construction

It is well-understood that "[a] claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using or selling the protected invention." *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989). The proper construction of claim terms is a question of law for the Court. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). The Court should generally give claim terms their "'ordinary and customary meaning[,]'" which is "the meaning that the term[s] would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (citations omitted). However, when determining the ordinary meaning of claim terms, the Court should not extract and isolate those terms from the context of the patent, but rather should endeavor to reflect their "meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321.

To that end, the Court should look first and foremost to the language of the claims, because "[i]t 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." *Id.* at 1312 (internal quotation marks and citations omitted). For example, the context in which a term is used in a claim may be "highly instructive." *Id.* at 1314. In addition, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable" in discerning the meaning of particular claim term. *Id.* This is "[b]ecause claim terms are normally used consistently throughout the patent, [and so] the usage of a term in one claim can often illuminate the meaning of the same term in other claims." *Id.*

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herein the applicable standards for both claim construction and indefiniteness.

Moreover, "[d]ifferences among claims can also be a useful guide," as when "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15.

In addition to the words of the claims, the Court should look to other intrinsic evidence. For example, the Court should analyze the patent specification, which "may reveal a special definition given to a claim term . . . that differs from the meaning [that term] would otherwise possess." *Id.* at 1316. In that case, "the inventor's lexicography governs." *Id.* Even if the specification does not contain a special definition of the term-at-issue, it "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Id.* at 1315 (internal quotation marks and citation omitted). That said, however, the specification "is not a substitute for, nor can it be used to rewrite, the chosen claim language." *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). In addition to the specification, a court should also consider the patent's prosecution history, if it is in evidence, because it "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention[.]" *Phillips*, 415 F.3d at 1317 (citations omitted).

Extrinsic evidence, "including expert and inventor testimony, dictionaries, and learned treatises[,]" can also "shed useful light on the relevant art." *Id.* (internal quotation marks and citations omitted). Dictionaries (especially technical dictionaries) may be useful in this process because they typically provide "the accepted meanings of terms used in various fields of science and technology[.]" *Id.* at 1318. However, the United States Court of Appeals for the Federal Circuit has cautioned that "heavy reliance on [a] dictionary divorced from the intrinsic evidence

risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is the specification." *Id.* at 1321. Overall, while extrinsic evidence may be useful, it is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *Id.* at 1317 (internal quotation marks and citations omitted); *accord Markman*, 52 F.3d at 981.

In utilizing these resources during claim construction, courts should keep in mind that "'[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.'" *Shire Dev., LLC v. Watson Pharms., Inc.*, 746 F.3d 1326, 1330 (Fed. Cir. 2014) (quoting *Phillips*, 415 F.3d at 1316).

B. Indefiniteness

A patent claim must "particularly point[] out and distinctly claim[] the subject matter which the inventor . . . regards as the invention." 35 U.S.C. § 112. If it does not, the claim is indefinite and therefore invalid. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2125 (2014). Recently, in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120 (2014), the Supreme Court of the United States set out the test to be applied in the indefiniteness inquiry: "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." *Nautilus*, 134 S. Ct. at 2124.[6]

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[6] The parties here filed their claim construction briefs prior to the Supreme Court's issuance of the *Nautilus* decision. The *Nautilus* Court rejected the test for indefiniteness that had previously been espoused by the Federal Circuit, one that considered whether patent claims were "amenable to construction" or "insolubly ambiguous." *Nautilus*, 134 S. Ct. at 2130 (internal quotation marks omitted); *see also Cal. Inst. of Tech. v. Hughes Commc'ns Inc.*, Case No. 2:13-

The primary purpose of the definiteness requirement is to ensure that patent claims are written in such a way that they give notice to the public of what is claimed, thus enabling interested members of the public (e.g., competitors of the patent owner) to determine whether they infringe. *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779-80 (Fed. Cir. 2002). Put another way, "[a] patent holder should know what he owns, and the public should know what he does not." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 731 (2002). Indefiniteness is to be evaluated from the perspective of someone skilled in the relevant art at the time the patent was filed. *Nautilus*, 134 S. Ct. at 2128 (citing cases).

Like claim construction, indefiniteness is a question of law for the court. *H-W Tech., L.C. v. Overstock.com, Inc.*, 758 F.3d 1329, 1332 (Fed. Cir. 2014); *Pi-Net Int'l Inc. v. JPMorgan Chase & Co.*, — F. Supp. 2d — , Civ. No. 12-282-SLR, 2014 WL 1997150, at *3 (D. Del. May 14, 2014). The Federal Circuit has stated that "[a]ny fact critical to a holding on indefiniteness . . . must be proven by the challenger by clear and convincing evidence." *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1366 (Fed. Cir. 2003); *see also Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1338 (Fed. Cir. 2008).[7]

III. DISCUSSION

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cv-07245-MRP-JEM, 2014 WL 3866129, at *3 (C.D. Cal. Aug. 6, 2014).

[7] In *Nautilus*, the Supreme Court left open the question of whether factual findings subsidiary to the ultimate issue of indefiniteness should, in fact, trigger the application of a "clear and convincing evidence" standard, noting that it would "leave th[is] question[] for another day." *Nautilus*, 134 S. Ct. at 2130 n.10. Other courts have noted the uncertainty regarding the applicability of this standard post-*Nautilus*. *See, e.g., In re MyKey Tech. Inc. Patent Litig.*, No. MDL 13-02461 GAF (PLAx), 2014 WL 2740733, at *6 & n.1 (C.D. Cal. June 17, 2014); *Cal. Inst. of Tech.*, 2014 WL 3866129, at *17 n.4.

The parties dispute the meaning of two sets of terms found in claims 1 and 2 of the '577 Patent, which the Court will refer to in shorthand as the "phase" terms or limitations and the "daily" terms or limitations. (D.I. 54 at 11, 16; D.I. 55 at 1) Although claims 1 and 2 are purportedly composition claims that cover the Natazia® product, Watson contends that "[t]he whole 'invention' disclosed in the patent is a *method* of using a particular combination of old, well-known and well-understood drugs in a particular order on a daily basis." (D.I. 65 at 2-3 (emphasis in original)) Resolution of the parties' disputes all boils down to whether, as Watson argues, claims 1 and 2 are hybrid claims that recite both a product and a method of using that product at the same time. (D.I. 54 at 1; D.I. 65 at 1-2) If so, Watson argues, the claims are indefinite and invalid as a matter of law. (D.I. 54 at 1; D.I. 65 at 2)

While the disputed terms are found in claims 1 and 2 only, claim 3 is also relevant to the parties' arguments. Accordingly, all three of the '577 Patent's claims are reproduced below, with the disputed terms highlighted:

> 1. A *multiphase product* for contraception comprising:
> a first *phase* of 2 *daily dosage units*, each comprising 3 mg of estradiol valerate,
> a second *phase* of 2 groups of *daily dosage units*, a first group comprising 5 *daily dosage units*, each of which comprises 2 mg of estradiol valerate and 2 mg of dienogest, and a second group comprising 17 *daily dosage units*, each of which comprises 2 mg of estradiol valerate and 3 mg of dienogest;
> a third *phase* of 2 two *daily dosage units*, each comprising 1 mg of estradiol valerate, and
> a fourth *phase* of 2 two *daily dosage units*, each comprising a pharmaceutically acceptable placebo.

('577 Patent, col. 4:16-28)

> 2. A *multiphase oral contraception product* comprising:
> a first *phase* of 2 *daily oral dosage units*, each comprising 3 mg

> of estradiol valerate,
> a second *phase* of 2 groups of *daily oral dosage units*, a first group comprising 5 *daily oral dosage units*, each of which comprises 2 mg of estradiol valerate and 2 mg of dienogest, and a second group comprising 17 *daily oral dosage units*, each of which comprises 2 mg of estradiol valerate and 3 mg of dienogest;
> a third *phase* of 2 *daily dosage units*, each comprising 1 mg of estradiol valerate, and
> a fourth *phase* of 2 *daily oral dosage units*, each comprising a pharmaceutically acceptable placebo.

(*Id.*, col. 4:29-41)

> 3. A method of oral contraception comprising orally administering to a woman:
> one oral dosage unit comprising 3 mg of estradiol valerate daily for 2 days,
> then one oral dosage unit comprising 2 mg of estradiol valerate and 2 mg of dienogest daily for 5 days,
> then one oral dosage unit comprising 2 mg of estradiol valerate and 3 mg of dienogest daily for 17 days,
> then one oral dosage unit comprising 1 mg of estradiol valerate daily for 2 days, and
> then one oral dosage unit comprising a pharmaceutically acceptable placebo daily for 2 days.

(*Id.*, col. 4:42-53)

The Court will first set out the general state of the law regarding the impermissible mixing of product and method claims, which is one way in which a claim may be found indefinite. It will then turn to construction of the disputed terms at issue.

A. Impermissible Mixing of Product and Method Claims

"A single patent may include claims directed to one or more of the classes of patentable subject matter, but no single claim may cover more than one subject matter class." *Microprocessor Enhancement Corp. v. Texas Instruments Inc.*, 520 F.3d 1367, 1374 (Fed. Cir. 2008). A single claim that recites two separate statutory classes of invention, such as a product

and a method of use of that product, does not apprise a person of ordinary skill in the art of its scope and is thus invalid under 35 U.S.C. § 112 ¶ 2. *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1384 (Fed. Cir. 2005). This is because such a claim makes it unclear whether infringement occurs when one creates a product that would allow the user to perform the method step recited in the claim, or instead when the user actually performs that step. *HTC Corp., v. IPCom GmbH & Co., KG*, 667 F.3d 1270, 1277 (Fed. Cir. 2012); *see also IPXL Holdings*, 430 F.3d at 1384. Accordingly, such a hybrid claim "is not sufficiently precise to provide competitors with an accurate determination of the metes and bounds of protection involved and is ambiguous and properly rejected under section 112, paragraph 2." *IPXL Holdings*, 430 F.3d at 1384 (internal quotation marks and citation omitted).

In *IPXL Holdings*, the Federal Circuit invalidated a claim directed to a "*system of claim 2* [including an input means] wherein . . . *the user uses the input means* to either change the predicted transaction information or accept the displayed transaction type and transaction parameters." *Id.* (internal citation omitted) (emphasis in original). The Court concluded that the claim "recite[d] both a system and the method for using that system[.]" *Id.* Due to the hybrid nature of the claim, the Court explained that "it is unclear whether infringement . . . occurs when one creates a system that allows the user to change the predicted transaction information or accept the displayed transaction, or whether infringement occurs when the user actually uses the input means to change transaction information or uses the input means to accept a displayed transaction." *Id.*

This Court applied the rationale of *IPXL Holdings* to invalidate composition claims that impermissibly included process limitations in *Aventis Pharma S.A. v. Hospira, Inc.*, 743 F. Supp.

2d 305 (D. Del. 2010). The two claims at issue in *Aventis* specified that they covered compositions, but went on to recite "whereby said composition *is used to form* an injectable solution" and "whereby said therapeutic composition *forms or is used to form* an injectable solution[.]" *Aventis Pharma*, 743 F. Supp. 2d at 320, 328 (internal citation omitted) (emphasis in original). The *Aventis* Court rejected the plaintiffs' argument that the disputed claim language simply provided the context in which the claimed composition is intended to be used. *Id.* at 329. Rather, the Court found that, based on the evidence presented at trial—and "by its own terms"—the claimed composition "actually *forms* an injectable solution or actually *is used* to form an injectable solution." *Id.* (emphasis in original). Like the claim at issue in *IPXL*, the *Aventis* Court explained that the hybrid claims before it fostered ambiguity as to when infringement of the claims would actually occur. *Id.* at 330. For instance, while the "*natural reading of the claim language* is that the infringement is only complete when the product actually 'forms or is used to form'" the injectable solution, one could instead take the view that the infringement is complete upon preparation of a stock solution capable of being used to form an "injectable solution" as recited in the claims. *Id.* at 330-31 (emphasis added).

Although it has been relied upon to find claims indefinite, the rule established in *IPXL Holdings* has been repeatedly recognized to be a narrow one. *See, e.g.*, *GPNE Corp. v. Apple, Inc.*, Case No.: 12-CV-02885-LHK, 2013 WL 4446819, at *20 (N.D. Cal. Aug. 13, 2013) ("[T]he scope of *IPXL* is very narrow."); *Synqor, Inc. v. Artesyn Techs., Inc.*, No. 2:07-CV-497-TJW-CE, 2010 WL 2991037, at *31 (E.D. Tex. July 26, 2010) ("The [c]ourt agrees with numerous other courts in that the holding in the *IPXL* case is very limited."); *Ricoh Co., Ltd. v. Katun Corp.*, 486 F. Supp. 2d 395, 402 (D.N.J. 2007) (explaining that in almost all cases in

which a party has argued that *IPXL Holdings* applies to invalidate a claim, the courts have found the rule inapplicable); *Collaboration Props., Inc. v. Tandberg ASA*, No. C 05-01940 MHP, 2006 WL 1752140, at *7 (N.D. Cal. June 23, 2006) (noting that *IPXL Holdings* stands "for [a] narrow rule"). To that end, courts have explained that the rule does not apply to claims containing language simply describing a system as well as the capabilities of the claimed system; rather, the rule applies to claims describing a system that also require the user of the recited system to take specific action. *Compare In re Katz Interactive Call Processing Patent Litig.*, 639 F.3d 1303, 1318 (Fed. Cir. 2011) (applying *IPXL* to invalidate system claims as indefinite where "the language used in [the claims at issue] . . . is directed to user actions, not system capabilities"), *with Microprocessor Enhancement Corp.*, 520 F.3d at 1375 (finding that claim was not indefinite under *IPXL* where it was "clearly limited to a pipelined processor possessing the recited structure and *capable* of performing the recited functions") (emphasis in original); *see also Invensys Sys., Inc. v. Emerson Elec. Co.*, — F. Supp. 2d — , Case No. 6:12-cv-799, 2014 WL 3884165, at *11 (E.D. Tex. Aug. 6, 2014); *Collaboration Props., Inc.*, 2006 WL 1752140, at *7. Accordingly, courts analyzing whether *IPXL Holdings* should apply to invalidate a patent claim must "focus on whether the claim language is directed to user actions rather than system capabilities." *H-W Tech., LC v. Overstock.com. Inc.*, 973 F. Supp. 2d 689, 696 (N.D. Tex. 2013); *see also Beneficial Innovations, Inc. v. Advance Publ'ns, Inc.*, Case No. 2:11-CV-299-JRG-RSP, 2014 WL 186301, at *2 (E.D. Tex. Jan. 14, 2014) (same).

B. Disputed Terms

1. The "phase" terms: "multiphase product," "multiphase oral contraception product" and "phase"

Watson argues that the "phase" limitations in claims 1 and 2 "require the administration of the product in the order recited in the claims." (D.I. 54 at 11 (emphasis omitted)) Therefore, Watson proposes the following constructions: "multiphase product" should be construed as "product administered to a patient in multiple sequential steps"; "multiphase oral contraception product" should be construed to mean "a contraception product orally administered to a patient in multiple sequential steps" and "phase" should be construed to mean "step." (*Id.*; *see also* D.I. 65 at 2) Bayer contends that "multiphase product" should be construed to mean a "product composed of multiple sets of dosage units"; "multiphase oral contraception product" should be construed to mean "a contraception product composed of multiple sets of oral dosage units" and that "phase" should be construed to mean "a set of dosage units[.]" (D.I. 51; D.I. 54 at 11; D.I. 55 at 6) The crux of the dispute is whether this claim language includes a requirement that the drug be actually administered in the recited order, or instead whether it simply describes the sets of physical components of the claimed drug.

a. The Claim Language

The Court looks first to the claim language itself. On their face, these claims are directed to a drug product made up of four "phases" of a particular number of "daily dosage units" or "daily oral dosage units"—dosage units that are described as being "compris[ed]" of specific pharmaceutical ingredients. ('577 Patent, col. 4:16-41) None of the claim language in claims 1 or 2 explicitly requires that the drug be actually administered—by, for example, facially requiring that these ingredients be "administered to a user" or by the use of some other similar wording.[8]

[8] Watson does not devote much space in its briefing in an attempt to assert otherwise. Its only real argument that the claim language, on its face, supports a construction of the "phase" limitations to require method of use steps is that in the preamble of the claims, "[t]he

In addition to being highly illuminating in the claim construction inquiry, the claim language is the key to the mixed-claim inquiry. As explained above, the courts engaging in this type of inquiry have tended to find a claim indefinite under the meaning of *IPXL* when the explicit language of a claim purportedly covering an apparatus was, on its face, directed to the actual use of such product. *See, e.g.*, *In re Katz*, 639 F.3d at 1318 (finding the claims at issue invalid where "*the language used in [the] claims* ('wherein . . . callers digitally enter data' and 'wherein . . . callers provide . . . data') is directed to user actions, not system capabilities") (emphasis added); *H-W Tech., LC*, 973 F. Supp. 2d at 697 (invalidating a purported apparatus claim under *IPXL*, where the claim stated "'wherein said user completes a transaction'" and "'wherein said user selects'" an offer, as "*[t]he language used* does not merely describe functional limitations of the apparatus . . . but is instead directed toward user action") (emphasis added), *aff'd*, 758 F.3d 1329, 1336 (Fed. Cir. 2014); *Ariba, Inc. v. Emptoris, Inc.*, Civil Action No. 9:07-CV-90, 2008 WL 3482521, at *7-8 (E.D. Tex. Aug. 7, 2008) (invalidating claim directed to an apparatus where one of the claim's elements was set out in language clearly indicating that it was "a method step that is conducted by some person or system other than the claimed device"). Here, in contrast, the absence in claims 1 and 2 of clear language requiring

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very claim language requires that the 'multiphase' products be '*for contraception*' (claim 1) or achieve '*contraception*' (claim 2)—a result that cannot occur unless the product is actually administered." (D.I. 54 at 15) It is well-settled that "a preamble is not limiting where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (internal quotation marks and citation omitted). Here, the Court finds that the use of the instant phraseology in the preamble of claims 1 and 2 is meant to state only the intended use of the invention (that the composition be used for contraception), and is not a claim limitation. This conclusion is bolstered by the analysis below, which concludes that the claims themselves describe only the physical composition of the claimed drug products, a structurally complete invention. *See id.* at 809.

user action puts these claims in a different category from those found to be invalid in *IPXL* and the cases interpreting it. *See also Leader Techs., Inc. v. Facebook, Inc.*, 770 F. Supp. 2d 686, 710 (D. Del. 2011) (rejecting defendant's argument that the claims impermissibly mixed an apparatus and a method, after "[*r*]*eviewing the disputed claim language in the context of the claim*" and concluding that "there is nothing in the claims that requires the user to perform certain steps or take certain actions for the claim elements to be satisfied") (emphasis added); *see also Radware, Ltd. v. A10 Networks, Inc.*, Case Nos. C-13-02021, C-13-02024 RMW, 2014 WL 2738538, at *3-4 (N.D. Cal. June 11, 2014) (rejecting defendant's argument that claims at issue were improperly directed to both apparatus and method steps where the claim language did "not call out affirmative steps that must be taken to infringe, as in *IPXL*").[9]

The conclusion that the language of claims 1 and 2 does not contain method elements is bolstered by looking to claim 3 of the '577 Patent, which undisputedly *is* a method claim and *does* require clear user action: the "administ[ration]" of the contraceptive product to a woman in the order set out in the claim itself. ('577 Patent, col. 4:42-53); *see also Radware, Ltd.*, 2014 WL 2738538, at *4 (comparing the language contained in claim at issue to that in patent's clear method claims in rejecting a mixed-claim indefiniteness argument). More specifically, here

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[9] Watson contends that it is "immaterial that claims 1 and 2 do not specify a 'user'" because "[i]t is the inclusion of method elements that rendered the putative product claims in *IPXL* and its progeny indefinite, not the precise language of the claims themselves, or whether they specified a 'user.'" (D.I. 65 at 14) To the contrary, as the cases referenced above indicate, it cannot be seriously disputed that courts do indeed look to the "precise language of the claims" in determining whether putative product claims improperly include method steps. While a claim's explicit reference to user action may not be absolutely required in order to find the claim violative of the rule set out in *IPXL* and its progeny, the absence of such explicit language clearly places a defendant in a much more difficult position when arguing that a court should find the claim at issue indefinite.

claim 3 recites a method of oral contraception in which the user of the contraceptive is administered dosage units made up of specific pharmaceutical ingredients daily, in a specific sequential fashion, over the course of a 28-day period. ('577 Patent, col. 4:42-53) These requirements are made most explicit when the claim explains that, pursuant to the method, a woman would take one oral dosage unit daily "for 2 days," "then" one oral dosage unit daily "for 5 days," "then" one oral dosage unit daily "for 17 days," "then" one oral dosage unit daily "for 2 days," and "then" one oral dosage unit daily "for 2 days." (*Id.*) In reading this language of claim 3, it cannot be disputed that these are the words that the patentee chose to use when it wanted to clearly describe the administration of the composition at issue "in multiple sequential steps." If the patentee was actually describing (even in part) a method of administration in claims 1 and 2, it stands to reason that it could have (and would have) used at least some of this same claim 3 phraseology: i.e., it would have written that a particular unit should be taken "for [a particular number of] days" and "then" another unit "for [another particular number of] days" and so on. And so, when one compares claim 3's clear step-related language to the language actually used in claims 1 and 2 (claims that instead refer to a "phase" as being made of a particular number of daily dosage units "compris[ed]" of certain ingredients) the difference is stark. To the Court, this difference in language makes a difference—it suggests that claims 1 and 2 would not be viewed by a person of skill in the art as including method of use steps.

Additionally, as Bayer points out, (D.I. 55 at 10), it is telling that the "phase" limitations that are found in claims 1 and 2 are absent from claim 3. This is so despite the fact that the three claims share many other of the same terms. ('577 Patent, col. 4:16-53) "[S]ubstantive differences between [] claims. . . . can be a 'useful guide in understanding the meaning of

particular claim terms.'" *Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 632 F.3d 1246, 1254 (Fed. Cir. 2011) (quoting *Phillips*, 415 F.3d at 1314). If the patentee here was using the term "phase" in the claims to refer to a step in the regimen in which a drug is actually administered, one would expect, at a minimum, that same "phase" language would be used in the patent's clear, undisputed method claim. But it is not.

For all of these reasons, the claim language strongly supports Bayer's position.

b. The Specification (and Intrinsic Evidence Cited Therein)

Turning next to the '577 Patent's very short specification, Watson focuses on two lines of argument.[10]

First, Watson points to a few particular passages in the specification—none of which contain the "phase"-related language in claims 1 and 2—to support the proposition that when the '577 Patent "describes the 'invention' itself, [the patentee] repeatedly refers to an 'administration regimen'—clearly denoting a method and not a structural element of a product." (D.I. 54 at 12 (quoting '577 Patent at col. 2:51-54; *id.*, col. 3:26-30 & 3:49-54); *see also* D.I. 65 at 3) Watson is correct that the cited portions of the specification refer to an "administration regimen." Each of these cited passages, however, are found in the "Exemplary Embodiments" section of the specification, which begins by explaining that "[t]he invention is to be demonstrated *by some examples of use.*" ('577 Patent, col. 2:51-52 (emphasis added)) This section of the specification goes on to describe two "[u]se [e]xample[s]" that are all about the *use* of the claimed product. (*Id.*, col. 2:51-4:14) The difficulty here for Watson is that it is not clear that these references to

[10] In its Rebuttal Claim Construction Brief, (D.I. 66), Bayer did not make any reference to any of the arguments Watson made in its Opening Claim Construction Brief, (D.I. 54 at 12-13), regarding these particular portions of the specification.

the "invention" being an "administration regimen" can only mean that the "phase" language in claims 1 and 2 must be construed to reference method steps. The "use of the administration regimen" described in these portions of the specification could well be meant to reference the regimen set out in the third of the patent's three claims—the clear method of use claim.

Watson also points to portions of the specification that do use the term "phase," (D.I. 54 at 12; D.I. 65 at 3), and here it has more to work with. For example, Watson cites to a portion of the specification discussing "Related Art" and referencing the patent EP 0 770 388 B1. (D.I. 54 at 12; D.I. 65 at 3) That patent is described as indicating a combination of oestradiol valerate with dienogest:

> In this case, in the *first phase* 3 daily dose units of 3 mg of oestradiol valerate, in the *second phase*, in the first group, 4 daily dose units of 2 mg of oestradiol valerate plus 1 mg of dienogest, in the second group of this *second phase* 16 daily dose units of 2 mg of oestradiol valerate plus 2 mg of dienogest and in the *third phase* 2 daily dose units of 1 mg of oestradiol valerate *are administered.*

('577 Patent, col. 1:41-47 (emphasis added)) Watson rightly notes that this language can be read to indicate that "phases" as referenced in the patent are not physical sets of drug dosage units, but instead steps or stages in which drugs "are actually 'administered.'" (D.I. 65 at 3)

On the other hand, there are portions of the specification cited by the parties in which the use of the term "phase" does appear to reference sets of dosage units. For example, an earlier reference to the EP 0 770 388 B1 patent notes that it describes a "multiphase product *whose first phase consists of* 2 to 4 daily dose units"; it goes on to refer to what the remaining "phase[s]" of that product "consist[] of[.]" ('577 Patent, col. 1:22-39 (emphasis added); *see* D.I. 55 at 6) And the "Summary of the Invention" section of the '577 Patent makes similar references. In that

section, the patentee explains that a goal of the invention is to "provide a *composition* for hormonal contraception based on a natural oestrogen" that is more effective than existing contraceptive products. (*Id.*, col. 2:3-10 (emphasis added); *see* D.I. 55 at 6) It then describes how this goal is "achieved according to the invention by a multiphase product for contraception" whose "first phase consists of" certain daily dosage units (and then goes on to reference what the other "phase[s]" of the product "consist[] of" or "contain[]"). (*Id.*, col. 2:11-25; *see* D.I. 55 at 6)

Additionally, as Bayer points out, the specification also cites to a number of prior art references that similarly describe multiphase oral contraceptive products—references that also appear to utilize the term "phase" to "denote a set of dosage units in a contraceptive composition[.]" (D.I. 55 at 7-9)[11] The Federal Circuit has explained that "prior art cited in a

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[11] By way of just one example, U.S. Patent No. 4,621,079 (the "'079 Patent"), cited in the '577 Patent, claims:

> 1. A *multiphase* combination *composition* suitable for oral contraception comprising 21 separate dosage units suitable for daily administration of one dosage unit per day consisting essentially of
> as a first *phase* 4-6 units *comprising*, in admixture with a pharmaceutically acceptable carrier, ethinylestradiol as estrogen in a low contraceptively effective dose of up to 0.05 mg and gestodene as gestagen in a low contraceptively effective dose of up to 0.07 mg;
> as a second *phase*, 4-6 units *comprising*, in admixture with a pharmaceutically acceptable carrier, ethinylestradiol in the same dose or a higher dose than that of the first phase, up to twice the first-phase dose, and gestodene in the same or a higher dose than that of the first phase up to one and one-half that of the first-phase and,
> as a third *phase*, 9-11 units *comprising*, in admixture with a pharmaceutically acceptable carrier, ethinylestradiol in the same dose or a lower dose than the second phase, as low as that of the first phase, and gestodene in a dose higher than that of the second phase, up to three times that of the first

patent or cited in the prosecution history of the patent constitutes intrinsic evidence" that may be considered during claim construction. *V-Formation, Inc. v. Benetton Grp. SpA*, 401 F.3d 1307, 1311 (Fed. Cir. 2005) (internal quotation marks and citations omitted); *cf. Arthur A. Collins, Inc. v. N. Telecom Ltd.*, 216 F.3d 1042, 1045 (Fed. Cir. 2000) ("When prior art that sheds light on the meaning of a term is cited by the patentee, it can have particular value as a guide to the proper construction of the term, because it may indicate not only the meaning of the term to persons skilled in the art, but also that the patentee intended to adopt that meaning."). The Court acknowledges the force of Watson's counter: that the '577 Patent cites to many prior art references "comprising thousands of pages of documents" and that it "is [thus] not remarkable that Bayer might be able to locate *something* it could attempt to rely on by scouring that mass of paper." (D.I. 65 at 5-6 (emphasis in original)) But the citations at least make the point that a "phase" is sometimes referred to in the art in a way that references a physical set of dosage units, a fact that bolsters Bayer's overall position, at least to some degree.[12] *See Synqor, Inc.*, 2010 WL 2991037, at *31 (considering, *inter alia*, prior art references about capabilities of parts of a claimed structure in finding that the skilled artisan "would understand that the claimed language describes the structure and capabilities of the claimed apparatus and is not merely a method step").

In the end, the Court concludes that the best reading of the specification is that it can, at a

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phase.

(D.I. 55 at 8-9 (citing D.I. 51, ex. PX3, '079 Patent, col. 6:22-45) (emphasis added))

[12] Additionally, it is notable that in making its counter-argument here, Watson did not point the Court to any portions of the thousands of pages of referenced prior art that use the term "phase" in a way that supports its proffered constructions.

minimum, support a reading of "phase" that encompasses *either* the concept of a set of daily dosage units *or* that of a step in a process, depending on how the term is later used in the '577 Patent's claims.

c. The Prosecution History

Watson relies heavily on the prosecution history of the '577 Patent in asserting that the "phase" language must be construed to denote method steps of a precise administration regimen. During prosecution of the '577 Patent, the United States Patent and Trademark Office ("PTO") initially rejected Bayer's claims as obvious over the prior art in a series of three office actions. (*See* D.I. 54 at 5-10) To overcome the rejections, Watson argues, "Bayer described its claimed 'multiphase product' as a 'regimen,' and in order to distinguish the prior art, argued repeatedly that the steps of the regimen were critical" as "it was able to achieve success '*only*' by performing that regimen precisely as stated in the patent." (*Id.* at 5 (emphasis in original))

Bayer, unsurprisingly, takes a different view. It notes that "[i]t is axiomatic that a product invented for a particular use can be patented separately and independently from the use of that product." (D.I. 66 at 2 (citing *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002))) Indeed, to that end, the Federal Circuit has explained that "the patentability of apparatus or composition claims depends on the claimed structure, not on the use or purpose of that structure." *Catalina Mktg. Int'l*, 289 F.3d at 809; *see also Marrin v. Griffin*, 599 F.3d 1290, 1294 (Fed. Cir. 2010); *In re Gardiner*, 171 F.2d 313, 315-16 (C.C.P.A. 1948) ("It is trite to state that the patentability of apparatus claims must be shown in the structure claimed and not merely upon a use, function, or result thereof."). This means that a patent grants the right to exclude others from making, using, selling, offering to sell, or importing the claimed

composition for any use, whether or not the patentee envisioned such use. *Catalina Mktg. Int'l*, 289 F.3d at 809.[13] Even if the patentee describes the intended use of the composition in the preamble of the claims, such statements would rarely limit the use of the composition to that method, unless the applicant clearly and unmistakably relied on those uses or benefits to distinguish prior art.[14] *Id.*

Bayer further notes that a patentee explaining the nonobviousness of his composition during patent prosecution may of course do so by setting out its beneficial uses and surprising properties. (*See* D.I. 66 at 3 ("A patentee is free to rely on the surprising discovery of a product's properties to support the patentability of a claim to the product itself—a claim that covers all uses.")) It asserts that in the cited portions of the prosecution history here, that is what it was doing—"rely[ing] on the surprising discovery of a product's properties to support the patentability of a claim to the product itself—a claim that covers all uses." (*Id.*) Indeed, especially when such a composition is composed of known ingredients, as was the case here, such a focus would not be surprising. *See In re Kollman*, 595 F.2d 48, 51 (C.C.P.A. 1979) (where "applicants concede that each of the components of the claimed compositions is a known

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[13] *See also Union Oil Co. of Cal. v. Atl. Richfield Co.*, 208 F.3d 989, 995 (Fed. Cir. 2000) (explaining that a claim reciting "an unleaded gasoline suitable for combustion in an automotive engine" was directed to a composition of matter and "[t]he scope of these composition claims cannot . . . embrace only certain uses of that composition[,]" for "[o]therwise these composition claims would mutate into method claims"); *Laboratoires Perouse, S.A.S. v. W.L. Gore & Assoc., Inc.*, 528 F. Supp. 2d 362, 378 n.10 (S.D.N.Y. 2007) (noting that "the scope of an apparatus claim does not depend on whether it is actually used for its intended purpose or not").

[14] With that said, to the extent a subsequent inventor invents a new method of using the composition that is useful and nonobvious, the new inventor could obtain a patent on that new method (and thus block the first inventor's ability to use its patented composition via the new method). *Catalina Mktg. Int'l*, 289 F.3d at 809-10.

herbicide[,]" stating that "in order to establish the patentability of their compositions, applicants must show that the combination of these known herbicides produces a composition having unexpected properties"); *see also In re Sullivan*, 498 F.3d 1345, 1347, 1352 (Fed. Cir. 2007) (submitting evidence describing "an unexpected property or result from the use" of the claimed invention, a composition claim for an antivenom, in arguing to PTO that invention was nonobvious).

Watson does point to a number of instances in the prosecution history where the patentee or its counsel describe the invention, and in doing so, uses the term "phase" in a way that appears to reference a period of administration.[15] The Court addresses the most compelling of these instances below. But in each case, the Court cannot conclude that the statements are "clear and unmistakable" indications that references to a "phase" (as the term is used in claims 1 and 2) are references to "steps" and not to a set of dosage units. *TecSec, Inc. v. Int'l Bus. Machs. Corp.*, 731 F.3d 1336, 1346 (Fed. Cir. 2013); *see also* (D.I. 65 at 8).

For example, in a declaration submitted to the Examiner, one of the named inventors described the administration regimen discussed in the '577 Patent, noting that a "'person of ordinary skill in the art could not [have] achieve[d] [the results achieved by this regimen] solely based on routine optimization of, e.g., *the administration period* of *phase 2* or other phases[.]'" (D.I. 54 at 7, 14 (quoting D.I. 51, ex. DX2 at 6 at ¶ 11 (emphasis added by Watson)); *see also id.* (citing D.I. 51, ex. DX2 at 6 at ¶ 11 (noting that a skilled person in the art had a choice in devising effective contraceptive regimens from many variables, including different types and

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[15] In its Rebuttal Claim Construction Brief, (D.I. 66), Bayer does not specifically address many of these particular portions of the prosecution history called out by Watson in Watson's Opening Claim Construction Brief, (D.I. 54 at 13-16).

doses of ingredients, but also from "several possible ranges of duration of the five phases of the administration periods")) But in that same sentence, the inventor notes that the results could also not have been achieved without "a high amount of progestin in phase 2 or other phases"—a reference to the *content* of the dosage unit that makes up a "phase[.]" (D.I. 51, ex. DX2 at 6 at ¶ 11)[16]

Similarly, Watson references a statement by the patentee's counsel to the Examiner, made in an attempt to overcome rejection of the claims, that "'any skilled artisan could have followed an infinite number of different avenues, [including] . . . *different lengths of phases*[.]'" (D.I. 54 at 8, 14 (quoting D.I. 51, ex. DX5 at 6 (emphasis added by Watson))) But the same sentence also references another of those "different avenues" that could have been followed—"different doses and hormone ratios in all/some phases[.]" (D.I. 51, ex. DX5 at 6) That latter reference could reasonably be read to mean that a "phase" of the kind called out in claims 1 and 2 can be understood to refer to a set of doses and ingredients, not necessarily a stage or step in a process.[17]

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[16] In a table referenced by the inventor in the same submission, Watson points out that there are rows referencing the various phases of the regimen (i.e., "Phase 1[,]" "Phase 2" and so on) and then a column titled "This Invention" that includes a sub-column referencing the number of "day[s]" associated with each "[p]hase." (D.I. 54 at 7-8, 13-14 (citing D.I. 51, ex. DX2 at Table 3)) However, the "This Invention" column also contains another sub-column—one that makes reference to an "amount" of a particular ingredient making up the *content* of that same "[p]hase." (D.I. 51, ex. DX2 at Table 3)

[17] Watson also points to a later reference to the label for Natazia® made by the patentee's counsel to the FDA, which states that the pills making up Natazia® "'must be taken [in an order] exactly as directed.'" (D.I. 54 at 9, 15 (quoting D.I. 51, ex. DX8 at 6)) But it is hard to claim that in this document, the patentee was arguing only for the patentability of a method of use, or that it was clearly defining "phase" to mean "step," when the patentee repeatedly made statements such as that the "subject matter of the claims of this application, on the other hand, is clearly demonstrated as providing a contraceptive *multiphase product and method* which are effective for contraception[.]" (D.I. 51, ex. DX8 at 4 (emphasis added); *see also id.* at 6 ("As is evident, this FDA approved *multiphase product is the same as that of claim 6*

Thus, the Court is not persuaded that the prosecution history clearly and unmistakably defines "phase" in a manner different from how the term is used in claims 1 and 2.

d. Conclusion

For the foregoing reasons, the Court declines to adopt Watson's proposed construction, which would inject method of use steps into the claims. Rather, the Court finds that claims 1 and 2 use the term "phase" to refer to physical components of a claimed composition. The other intrinsic evidence[18] set out above does not give the Court enough cause to alter that view. If, as Watson suggests, (D.I. 65 at 13), the inventions claimed in claims 1 and 2 are invalid as obvious, a fact finder will say so. But claim construction is not the time to resolve that question.

Accordingly, the Court recommends that "multiphase product" be construed to mean a "product composed of multiple sets of dosage units"; that "multiphase oral contraception product" should be construed to mean "a contraception product composed of multiple sets of oral dosage units"; and that "phase" be construed to mean "a set of dosage units."

[i.e., what became claim 1 of the '577 Patent] and provides the same method as that of claim 10 [i.e., what became claim 3 of the patent] of this application." (emphasis added)))

[18] Watson does point to one piece of extrinsic evidence: a dictionary definition of "phase" that assertedly indicates that the term's plain meaning is "a part or step in a process." (D.I. 54 at 12 (emphasis and internal quotation marks and citation omitted)) A review of even that dictionary excerpt provided by Watson, however, notes alternative definitions for "phase" that appear to refer not to a "step in a process," but instead to a physical component different from other physical components: "a homogeneous, physically distinct, and mechanically separable portion of matter present in a nonhomogeneous physicochemical system" and "an individual or subgroup distinguishably different in appearance or behavior from the norm of the group to which it belongs[.]" (*Id.*, ex. 1 at 1) Indeed, other dictionaries tell a similar story. *See, e.g.*, *Stedman's Med. Dictionary* (27th ed. 2000) (defining "phase" as, *inter alia*, both "[a] stage in the course of change or development" and "[a] homogeneous, physically distinct, and separable portion of a heterogeneous system; e.g., oil, gum, and water are three *phases* of an emulsion") (emphasis in original).

2. The "daily" terms: "daily dosage units" and "daily oral dosage units"

Watson argues that the "daily" limitations in claims 1 and 2 require the administration of the drugs on a daily basis. (D.I. 54 at 16) Therefore, Watson proposes that "daily dosage units" be construed to mean "dosage units administered to a patient daily" and "daily oral dosage units" be construed to mean "oral dosage units administered to a patient daily." (*Id.*; *see also* D.I. 65 at 10) Bayer contends that no construction of these terms is necessary as "[t]hese terms explain that the dosage units are capable of or intended to be taken daily." (D.I. 55 at 11)

For the same reasons as described above in reference to the "phase" terms, the Court declines to construe these "daily" terms so that they inject method steps into claims 1 and 2. Watson's proposals essentially ask the Court to define these terms by re-shuffling their words, with the exception that "daily" be construed to mean "administered to a patient daily." However, as explained above, none of the claim language in composition claims 1 or 2 explicitly requires that the drug be actually administered to a patient in a certain manner.

In support of its proposal, Watson contends that "[t]he 'daily' requirement has nothing to do with the structure or composition of the dosage unit itself, but can only refer to how the dosage unit *is meant to be used.*" (D.I. 54 at 17 (emphasis added)) Watson is correct in this regard, but this does not mean that the claims therefore require *actual use* in that fashion. In the absence of explicit language requiring administration, the Court finds that the "disputed claim language . . . merely provide[s] the context in which the claimed composition is intended to be used." *Aventis Pharma S.A.*, 743 F. Supp. 2d at 329. Because the "daily" language is included in claims directed to compositions, and the claims at issue do not require someone to take a specific action, the "daily" limitations are merely reciting capabilities of the claimed composition rather

than actions required of the user. *See Invensys Sys. Inc.*, 2014 WL 3884165, at *11 (rejecting defendants' argument that claims at issue impermissibly combined system and method claims where "the challenged claims are merely reciting capabilities of the system claimed, not actions required of the system user").

For these reasons, the Court recommends that Watson's proposed constructions for the "daily" terms be rejected. The Court finds that no further construction of the terms is necessary, as it has resolved the dispute between the parties here. *See Finjan, Inc. v. Secure Computing Corp.*, 626 F.3d 1197, 1207 (Fed. Cir. 2010) ("Unlike *02 Micro* [*Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351 (Fed. Cir. 2008)], where the court failed to resolve the parties' quarrel, the district court rejected [d]efendants' construction."). The Court finds that the terms have an understandable plain and ordinary meaning that is clear in the context of the patent. Rearranging the wording of the claims to further emphasize that the dosage units are capable of being taken daily is unnecessary.

C. Watson's Requested Order

Watson additionally requests that this Court issue an order holding claims 1 and 2 invalid for impermissibly mixing product and method steps. (D.I. 65 at 2, 15) As the Court does not recommend that Watson's proposed constructions be adopted, however, it recommends that Watson's request in this regard be denied.

IV. CONCLUSION

For the foregoing reasons, the Court recommends that the District Court adopt the following constructions:

1. "multiphase product" should be construed to mean "product composed of multiple

sets of dosage units";

2. "multiphase oral contraception product" should be construed to mean "a contraception product composed of multiple sets of oral dosage units";

3. "phase" should be construed to mean "a set of dosage units";

4. "daily dosage units" should be afforded its plain and ordinary meaning; and

5. "daily oral dosage units" should be afforded its plain and ordinary meaning.

The Court also recommends that Watson's request for an order finding claims 1 and 2 invalid as indefinite be DENIED.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Henderson v. Carlson*, 812 F.2d 874, 878–79 (3d Cir. 1987); *Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006).

The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the District Court's website, located at http://www.ded.uscourts.gov.

Dated: September 30, 2014

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE