IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

GILEAD SCIENCES, INC. and EMORY UNIVERSITY,

Plaintiffs,

v. // **CIVIL ACTION NO. 1:14CV99**
(Judge Keeley)

MYLAN INC. and MYLAN PHARMACEUTICALS INC.,

Defendants.

MEMORANDUM OPINION AND ORDER CONSTRUING PATENT CLAIMS

This patent infringement case involves four United States patents issued to the plaintiffs, Gilead Sciences, Inc. and Emory University ("Gilead"), including 8,716,264 ("the '264 patent"), 6,642,245 ("the '245 patent"), 6,703,396 ("the '396 patent"), and 8,592,397 ("the '397 patent") (collectively, the "patents-in-suit"). The '397 and '264 patents, entitled "Compositions and Methods for Combination Antiviral Therapy," derive from provisional U.S. patent applications 60/440,246 and 60/440,308, and share almost identical specifications. The parties do not dispute the meaning of the claims asserted in the '245 and '396 patents.

The patents-in-suit cover chemically stable fixed dose combination formulations of tenofovir disoproxil fumarate ("TDF") and emtricitabine ("FTC"), a combination therapy used to treat HIV, as well as methods of treating HIV using said pharmaceutical dosage forms. Gilead uses the formulations and methods described in these patents in a commercial product known as Truvada®.

MEMORANDUM OPINION AND ORDER CONSTRUING PATENT CLAIMS

I. BACKGROUND

In a letter dated April 24, 2014, the defendants, Mylan Inc. and Mylan Pharmaceuticals, Inc., (collectively, "Mylan"), notified Gilead that they had filed an Abbreviated New Drug Application ("ANDA") seeking United States Food and Drug Administration ("FDA") approval to market a tablet containing 200 mg of FTC and 300 mg of TDF ("generic combination tablet"). Mylan also filed a certification with the FDA alleging that certain claims of the four patents-in-suit are invalid, unenforceable and not infringed by Mylan's manufacture or sale of its generic combination tablet. Gilead in response filed this patent infringement action against Mylan pursuant to the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act"). See 21 U.S.C. §§ 355, 360cc; 35 U.S.C. §§ 156, 271.

Gilead contends that the product described in Mylan's ANDA infringes claims in the patents-in-suit, specifically claim 6 of the '245 patent; claims 1, 3-5, 13, 15, and 16 of the '396 patent; claims 1-6, 14-16, and 19 of the '397 patent; and claims 1-3, 9, 16, 17, 33, and 34 of the '264 patent (collectively, the "asserted claims").[1]

[1] The parties do not dispute the meaning of any claim terms in the '245 and '396 patents.

The parties have identified three terms and phrases from the asserted claims in need of construction for which they have proposed competing claim constructions. They also have submitted eight agreed claim constructions. Following a claims construction hearing on April 14, 2014, and after considering the parties' briefs and arguments, for the reasons discussed, the Court adopts the following constructions.

II. LEGAL STANDARDS

The construction of patent claims presents a matter of law governed by federal statutes and the decisions of the Supreme Court of the United States and the United States Court of Appeals for the Federal Circuit. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995). When interpreting the meaning of a claim, a court may consider the claims, the specifications, and the prosecution histories as intrinsic evidence. Id. (quoting Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1561 (Fed. Cir. 1991)). According to a fundamental principle of claim construction, the invention itself, and the scope of a patentee's right of exclusion, will be defined by the patent's claims. See Phillips v. AWH Corporation, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004)); see

also Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("[W]e look to the words of the claims themselves . . . to define the scope of the patented invention."). The description of an invention in the claims, therefore, limits the scope of the invention. Id.

Claim terms should be construed according to their "ordinary and customary" meaning, which is "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 1313. Claim construction therefore requires a court to determine how a person of ordinary skill in the art would have understood the disputed term or phrase in question. "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Id.

When construing patent claims, then, a court must consider the context of the entire patent, including both asserted and unasserted claims. Id. at 1314. Because a patent will ordinarily use patent terms consistently, "the usage of a term in one claim can often illuminate the meaning of the same term in other claims." Id. at 1314. Accordingly, "[d]ifferences among claims" can provide

insight into "understanding the meaning of particular claim terms," and "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 (citing Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 910 (Fed. Cir. 2004)).

Aside from the claims themselves, the specification in the patent often provides the "'best source for understanding a technical term.'" Id. at 1315 (quoting Multiform Desiccants,Inc. v. Medzam, Ltd., 133 F.3d 1473, 1478 (Fed. Cir. 1998)). Pursuant to 35 U.S.C. § 112, ¶ 1, an inventor must use the specification to describe his claimed invention in "full, clear, concise, and exact terms." Accordingly, "[t]he claims of a patent are always to be read or interpreted in the light of its specifications." Schriber-Schroth Co. v. Cleveland Trust Co., 311 U.S. 211, 217 (1940).

An inventor may alter the "ordinary and customary" meaning of a term, however, by acting as his own lexicographer. This occurs, for example, when the patent specification defines a term in a manner different from its ordinary and customary meaning. Phillips, 415 F.3d at 1316. Thus, it is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims."

Id. at 1317.

Nevertheless, a court may not import a limitation into the claims from the specification. Id. at 1323. Moreover, the Federal Circuit has "repeatedly warned" against limiting the claims to the embodiments specifically described in the specification. Id. In other words, a court should not construe the patent claims as being limited to a single embodiment simply because the patent describes only one embodiment. Id. (citing Gemstar-TV Guide Int'l Inc. v. Int'l Trade Comm'n, 383 F.3d 1352, 1366 (Fed. Cir. 2004)).

The prosecution history of a patent may also provide insight into the meaning of a term or phrase. "Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent." Id. at 1317. The inventor's limitation of the invention during the patent's prosecution may suggest that a claim has a narrower scope than it otherwise might have. Id.

Finally, when determining the ordinary and customary meaning of a term, a court must be cautious when considering extrinsic evidence, such as expert testimony, dictionaries, and learned treatises. Id. Nevertheless, such sources may be reliable if they were publicly available and show "'what a person of skill in the art would have understood disputed claim language to mean.'"

Id. at 1314 (quoting Innova, 381 F.3d at 1116).

It is with these legal principles in mind that the Court turns to the construction of the three disputed terms or phrases among the asserted claims of the patents-in-suit.

III. ANALYSIS

A. "Fixed dose combination"

Gilead argues that the preamble phrase "fixed dose combination," as used in claims 1 and 19 of the '397 patent and claims 1-3 of the '264 patent, is limiting and must be construed by the Court. The parties have stipulated that the term means "a unit dosage formulation comprising a fixed amount of each active pharmaceutical ingredient." Mylan argues that the phrase "fixed dose combination" is non-limiting, and, as such, need not be construed by the Court.[2] See Durr Sys., Inc. v. FANUC Ltd., 463 F.Supp.2d 663, 679 (E.D. Mich. 2006) ("The preamble is not a limitation, and therefore need not be construed.").

According to Gilead, its proposed construction is supported by the claims, the specifications, and the prosecution histories of the patents-in-suit. It argues that Mylan's position is internally

[2] The parties originally disputed the meaning of the term "chemically stable," part of the same preamble. The parties now agree that "chemically stable" is non-limiting and need not be construed by the Court.

inconsistent because it agreed to a stipulated construction of the term, which implies that the term is limiting. Mylan contends that the intrinsic evidence supports its proposed construction, and urges the Court to follow the default rule and find that the entire preamble is non-limiting.

The Court must resolve whether to treat a preamble as a limitation by reviewing the entire patent "to gain an understanding of what the inventors actually invented and intended to encompass by the claim." Catalina Marketing Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002) (quoting Corning Glass Works v. Sumitomo Electric U.S.A., Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989)). A preamble limits an invention if "it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." Id. (quoting Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1309 (Fed. Cir. 1999)). A preamble is not limiting if the patent defines a structurally complete invention in the body of the claim, and uses the preamble to state a purpose or intended use for the invention. Id. (quoting Rowe v. Dror, 112 F.3d 473, 478 (Fed. Cir. 1997)).

A patentee's reliance on a preamble during prosecution to distinguish the invention from the prior art can transform the preamble into a claim limitation because the preamble is being used

to define the invention. Id. at 808-09. Part of a preamble can be limiting, while another part of a preamble can be non-limiting. Intervet Am., Inc., v. Kee-Vet Laboratories, Inc., 887 F.2d 1050, 1055 (Fed. Cir. 1989).

1. The Claims

According to Gilead, the preamble term "fixed dose combination" adds "life, meaning, and vitality" to the claim because the claim language does not embody the concept of a "fixed dose combination." See Catalina Marketing, 289 F.3d at 808 (quoting Pitney Bowes, 182 F.3d at 1309). Gilead argues that the term "fixed dose combination" refers to a co-formulation of TDF and FTC, and not merely co-administration of the two products, which is a concept not embodied by any other language in the claim.

Mylan contends that the term "fixed dose combination" is unnecessary to understand the remainder of the claim, which goes on to define the invention as "comprising 300 mg [TDF] and 200 mg [FTC]; a binder . . . ; a disintegrant . . . ; and a lubricant . . . ." ('397 patent, col. 32:4-13). According to Mylan, it is apparent from the claim language that the invention is meant for co-formulation, and not merely co-administration. Similarly, Mylan argues that the presence of the term "fixed dose combination" in the preamble of the '264 patent is unnecessary to add "life,

meaning, and vitality" to the claim, which goes on to state "comprising 300 mg [TDF] and 200 mg [FTC] wherein the combination exhibits less than 10% degradation . . . after six months . . . when packaged and stored with silica gel dessicant [sic] . . . ." ('264 patent, col. 30:46-52).

As an initial matter, the Court agrees that the language of the claim plainly describes the combination of TDF and FTC as a co-formulation, rather than a product for co-administration. It would be nonsensical to interpret the claim otherwise, for why would the claim describe the combination of TDF and FTC with a binder, lubricant, and disintegrant were it only discussing two separate products for co-administration? ('397 patent, col. 32:4-13). Similarly, why would the inventors care so much about degradation between the active pharmaceutical ingredients in TDF and FTC were they simply together in the same package, rather than in the same fixed dose formulation? ('264 patent, col. 30:46-52). See Phillips, 415 F.3d at 1314 (citing Brown v. 3M, 265 F.3d 1349, 1352 (Fed. Cir. 2001) (recognizing that claim meaning will sometimes be "readily apparent even to lay judges," and that "claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.")).

That being said, the claims themselves fail to shed sufficient

light on the meaning of this term. The Court therefore must look beyond the claims to the specifications and prosecution histories of the patents-in-suit to construe this phrase.

2. The Specifications

According to Gilead, the specifications provide intrinsic support for its proposed construction. A specification may define a claim term explicitly or by implication. Astrazeneca AB, Aktiebolaget Hassle, KBI-E, Inc. v. Mutual Pharm. Co., Inc., 384 F.3d 1333, 1339-40 (Fed. Cir. 2004). In any event, "the claims cannot be of broader scope than the invention that is set forth in the specification." On Demand Machine Corp. v. Ingram Industries, Inc., 442 F.3d 1331, 1340 (Fed. Cir. 2006).

Here, the specifications describe the stability concerns that could arise when TDF and FTC are combined. The specification of the '397 patent notes that TDF and FTC "have relatively low pKa values, indicative of the potential to cause acidic hydrolysis of the active ingredients." ('397 patent, col. 12:10-14). As such, "[i]t is desirable to formulate a therapeutic combination of [TDF and FTC] . . . with a minimum of impurities and adequate stability." ('397 patent, col. 12:25-28).

According to Gilead, these stability concerns do not make sense unless TDF and FTC are combined for co-formulation, rather

than mere co-administration. Again, the Court agrees that the specification implies that the invention covers a co-formulation, rather than just co-administration, of TDF and FTC. To interpret the specification otherwise would improperly broaden the scope of the invention. See On Demand Machine, 442 F.3d at 1340. It does not necessarily follow, however, that the preamble term "fixed dose combination" is necessary to breathe life and vitality into the claim.

3. The Prosecution Histories

Beyond the specifications and claim language, Gilead claims that further support for its proposed construction can be found in the prosecution histories of the patents-in-suit. See Ormco Corporation v. Align Technology, Inc., 498 F.3d 1307, 1314 (Fed. Cir. 2007). "Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent." Phillips, 415 F.3d at 1317; see also Sentry Prods., Inc. v. Eagle Mfg. Co., 400 F.3d 910, 915 (Fed. Cir. 2005) (holding that the prosecution history may modify a claim term's scope if the patentee "expressly disclaimed" the prior art's subject matter).

In its application for the '397 patent, Gilead initially submitted the following as claim 1:

> 1. A method for the treatment or prevention of the symptoms or effects of an HIV

> infection in an infected animal which comprises administering to said animal a therapeutically effective amount of a combination comprising [TDF] or a physiologically functional derivative thereof, and [FTC] or a physiologically functional derivative thereof.

('397 Application, 8-20-2008, p. 50). Some of the initial claims in the '397 patent expressly permitted dosage of FTC and TDF by co-administration. ('397 Application, 8-20-2008, p. 53). The United States Patent and Trademark Office ("PTO") rejected these claims as obvious based on the prior art, which "encourages the addition of other antiviral compounds to [FTC]." ('397 Office Action, 5-7-2010, p. 4).

In response, the inventors argued that the prior art had not provided "any motivation to combine FTC and TDF in a co-formulation, as they are directed . . . to formulations of FTC and TDF alone." ('397 Amendment/Response to Office Action, 9-27-2012, Dkt. No. 100-1 at 116). Gilead therefore added the phrase "a chemically stable combination of [TDF] and [FTC]," including parameters for stability and specific excipients:

> 47. (Original) A chemically stable combination of [TDF and FTC].
> 64. (New) The pharmaceutical dosage form of Claim 48 wherein less than 5% degradation of the [TDF and FTC] occurs after six months at 40○C/75% relative humidity when packaged and stored with desiccant.
> 65. (New) The pharmaceutical dosage form of

> Claim 48 comprising 300 mg [TDF], 200 mg [FTC], pregelatinized starch, croscarmellose sodium, lactose monohydrate, microcrystalline cellulose, and magnestium stearate.

('397 Amendment/Response to Office Action, 6-20-2013, Dkt. No. 100-1 at 63-64). The PTO did not accept the amendment, however, proposing its own version of the claim:

> 47. (Currently Amended) A chemically stable fixed dose combination pharmaceutical dosage form comprising 300 mg [TDF] and 200 mg [FTC]; a binder . . . ; a disintegrant . . . ; and a lubricant . . . wherein said pharmaceutical dosage form exhibits less than 10% degradation of the [TDF] or [FTC] after 6 months when packaged and stored with silica gel dessicant [sic] at 40○C/75% relative humidity.

('397 Notice of Allowance, 10-7-2013, Dkt. No. 100-1 at 70). The PTO allowed the claim after this amendment, explaining that tables 1 and 2 in the specification "provide stability data for a fixed dose combination comprising [TDF and FTC]." Id. at 75. Tables 1 and 2 describe the proportions of each active pharmaceutical ingredient and excipient in the combination tablet ('397 patent, col. 26:1-19; col. 27:44-63).

Mylan argues that the prosecution history of the '264 patent highlights that Gilead's amendments were to clarify the stability profile of the product, rather than to repeat that the invention

was a co-formulation. As of November 14, 2013, Gilead was proposing the following claim:

> 47. (Currently Amended) A chemically stable combination comprising [of] [TDF] and [FTC].

('264 Amendment/Response to Office Action, 11-14-2013, Dkt. No. 107-1 at 175). On December 19, 2013, the PTO filed a Notice of Allowability, amending Claim 47 as follows:

> 47. (Currently Amended) A chemically stable fixed-dose combination comprising 300 mg of [TDF] and 200 mg of [FTC] wherein the combination exhibits less than 10% degradation of the [TDF and FTC] after six months at 40○C/75% relative humidity when packaged and stored with silica gel desiccant at 40○C/75% relative humidity.

('264 Notice of Allowability, 12-19-2013, Dkt. No. 107-1 at 71 (emphasis in original)). The examiner's statement of reasons for allowance explained that "[t]he prior art does not teach or suggest instant chemically stable fixed-dose combination of 300 mg [TDF] and 200 mg of [FTC] having the instantly claimed degradation profile." Id. at 76.

4. Analysis

After considering the patent claims, specifications, and prosecution history, the Court concludes that Mylan's proposal is the best fit. The Court begins with the presumption that terms in the preamble are non-limiting. Allen Eng'g Corp. v. Bartell

Indus., Inc., 299 F.3d 1336, 1346 (Fed. Cir. 2002).

It is apparent from the claim language that the preamble term "fixed dose combination" refers to the product precisely defined later in the claim as "comprising 300 mg [TDF] and 200 mg [FTC]; a binder . . . ; a disintegrant . . . ; and a lubricant . . . ." ('397 patent, col. 32:4-13). As previously stated, the invention would not require a binder, a lubricant, and excipients were it merely two types of different pills combined in one package for co-administration.

Next, the patent specifications reinforce that the changes in the claim language were aimed at the stability of the combination tablet. The specification of the '397 patent notes that TDF and FTC "have relatively low pKa values, indicative of the potential to cause acidic hydrolysis of the active ingredients." ('397 patent, col. 12:10-14). As such, "[i]t is desirable to formulate a therapeutic combination of [TDF and FTC] . . . with a minimum of impurities and adequate stability." ('397 patent, col. 12:25-28). Clearly, the PTO's concerns about stability and co-formulation go hand-in-hand, for the active pharmaceutical ingredients would not come into close contact in a co-administration regimen.[3] It is

[3] See United States Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER), Guidance for Industry, Fixed Dose Combinations,

stability, however, and not co-formulation, that the specification largely addresses. See Catalina Marketing, 289 F.3d at 809 ("[P]reambles describing the use of an invention generally do not limit the claims because the patentability of apparatus or composition claims depends on the claimed structure, not on the use or purpose of that structure."). The claimed structure is described specifically after the word "comprising," whereas the preamble generally describes the use or purpose of the invention. See id.

Finally, the prosecution histories of the '397 and '264 patents establish that the PTO was concerned with both ensuring that the invention was for co-formulation (which made it non-obvious over the prior art), and also establishing that it was stable. The claim in the '397 patent went through several iterations before final approval, with more specificity added after each round of editing. Once the inventors had thoroughly explained

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Co-Packaged Drug Products, and Single-Entity Versions of Previously Approved Antiretrovirals for the Treatment of HIV, fn. 2 (Oct. 2006) *available at* http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm079742.pdf ("[A] *co-packaged product* consists of two or more separate drug products in their final dosage form, packaged together with appropriate labeling to support the combination use. A *fixed dose combination* product is one in which two or more separate drug ingredients are combined in a single dosage form." (emphasis in original)).

that the generic combination tablet was meant to be a co-formulation, however, final approval seemed to hinge on the stability data in tables 1 and 2 of the specification. ('397 Notice of Allowance, 10-7-2013, Dkt. No. 100-1 at 70, 75). This is consistent with the prosecution history of the '264 patent, where the PTO issued a notice of allowance after amending the claim to include more detail about the stability profile of the invention. ('264 Notice of Allowability, 12-19-2013, Dkt. No. 107-1 at 71, 76).

Gilead's argument that Mylan is attempting to sweep in prior art references to products that were merely co-administered, and not co-formulated, is unavailing. It is obvious from the claim language and the prosecution history that patentability hinged on the product being a chemically stable co-formulation. In light of the detail about the generic combination tablet in the rest of the claim, the Court finds unpersuasive Gilead's argument that the preamble term "fixed dose combination" is limiting,.

For these reasons, the Court **ADOPTS** Mylan's proposed construction that "fixed dose combination" is non-limiting, and will not construe that term. See Durr Sys., Inc., 463 F.Supp.2d at 679 ("The preamble is not a limitation, and therefore need not be construed.").

B. "Less than [X%] degradation of [the TDF] over a 24-hour period"

Gilead construes the term "less than [X%] degradation of [the TDF] over a 24-hour period," as used in claims 3-5 of the '397 patent and claims 16-17 of the '264 patent, to mean "less than [X%] degradation of [the TDF] over one or more 24-hour periods." Mylan construes it to mean "less than [X%] degradation of [the TDF] over any (every) 24-hour period."

Gilead argues that, consistent with the patent specifications and Federal Circuit precedent, "a" means "one or more." See Baldwin Graphic Sys., Inc. v. Siebert, Inc., 512 F.3d 1338, 1342 (Fed. Cir. 2008) (describing the general rule that "a" or "an" means "one or more" unless the language of the claims, the specification, or the prosecution history necessitate a departure from the rule). Gilead contends that nothing in the intrinsic record indicates that "a" should be construed as anything other than "one or more."

Mylan urges the Court to reject Gilead's proposed construction because the claim would include unstable products, which was unintended by the inventors. According to Mylan, under Gilead's proposed construction, "a product that undergoes degradation of 10% over every 24-hour period, except that over one 24-hour period it degrades only 9.9%, would be found to infringe" the claim (Dkt. No.

107 at 18). A person of ordinary skill in the art ("POSA"), however, would never consider a product with 10% daily degradation to be stable during storage, and interpreting the patent in that manner would expand the claim to include unstable products. Mylan points to the prosecution history, which describes the novelty of the invention as the discovery of stable formulations, and argues that its proposed construction of "less than [10%/1%/.1%/.01%] degradation of [TDF] over any 24-hour period" would avoid a situation "where an unstable product . . . is encompassed by the claims."

There is a "'heavy presumption' that a claim term carries its ordinary and customary meaning." CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002). This presumption does not apply, however, where "the patentee acted as his own lexicographer and clearly set forth a definition of the disputed claim term in either the specification or prosecution history." Id. (citing Johnson Worldwide Associates, Inc. v. Zebco Corp., 175 F.3d at 990 (Fed. Cir. 1999)). To determine whether a disputed term has a definition different from its ordinary and customary meaning, courts may consider the claims, the specification, and the prosecution history. See Bell Atlantic Network Services, Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1268-69 (Fed. Cir.

2001).

1. The Claims

Claims 16 and 17 of the '264 patent depend from claims 10 and 11. ('364 patent, col. 31:7-13, 25-36).

> 10. A chemically stable fixed-dose combination comprising 300 mg [TDF] and 200 mg [FTC] wherein the combination exhibits less than 10% degradation of [TDF] over a 24-hour period.
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> 11. The chemically stable form of claim **10**, in the form of a pharmaceutical dosage form.
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> 16. The pharmaceutical dosage form of claim **11**, wherein the combination exhibits less than 10% degradation of the [TDF and FTC] after six months at 40○C/75% relative humidity when packaged and stored with silica gel desiccant at 40○C/70% relative humidity.
>
> 17. The pharmaceutical dosage form of claim **11** wherein the combination exhibits less than 5% degradation of the [TDF and FTC] after 6 months at 40○C/75% relative humidity when packaged and stored with silica gel desiccant at 40○C/70% relative humidity.

('364 patent, col. 31:7-13, 25-36 (emphasis added)). Similarly, claims 3-5 in the '397 patent depend from claim 1.

> 1. A chemically stable fixed dose combination pharmaceutical dosage form comprising 300 mg [TDF] and 200 mg [FTC]; a binder . . . ; a disintegrant . . . ; and a lubricant . . . ; wherein said pharmaceutical dosage form exhibits less than 10% degradation of the [TDF or FTC] after six months when packaged and stored with silica gel dessicant [sic] at

> 40○C/75% relative humidity.
>
> 3. The pharmaceutical dosage form of claim **1** where there is less than 1% degradation of [TDF] over a 24-hour period.
>
> 4. The pharmaceutical dosage form of claim **1** where there is less than 0.1% degradation of [TDF] over a 24-hour period.
>
> 5. The pharmaceutical dosage form of claim **1** where there is less than 0.01% degradation of [TDF] over a 24-hour period.

('397 patent, col. 30:51-65, col. 31:1-9 (emphasis added)). According to Gilead, the Court should only consider the claims it is asserting in this litigation–claims 16-17 of the '264 patent, and claims 3-5 in the '397 patent–and ignore Mylan's "hypothetical argument" based on claim 10 of the '264 patent. As is clear from the claim language, however, the claims asserted in this litigation depend from claims 10 and 11 in the '264 patent and claim 1 in the '397 patent. See Wahpeton Canvas Co., Inc. v. Frontier, Inc., 870 F.2d 1546, 1553 (Fed. Cir. 1989) ("a dependent claim includes all the limitations of the claim from which it depends.").

It is well-established that a court can look to unasserted claims when construing disputed patent claims. See Phillips, 415 F.3d at 1314. Therefore, Mylan's argument that, based specifically on claim 10 of the '264 patent, Gilead's proposed construction would include unstable products, is well-taken and must be

carefully considered.

Mylan contends that, under Gilead's proposed construction, a formulation that degrades 10% daily, but only 9.9% during one 24-hour period, would infringe claim 10 because it has degraded less than 10% during "one or more" 24-hour periods. Such a formulation, however, would be unstable after several days, and is improperly encompassed within the scope of the patent. By way of contrast, under Mylan's proposed construction, a formulation that degrades 10% daily, but only 9.9% during a single 24-hour period, would not infringe claim 10 because it has not degraded under 10% during "every" 24-hour period.

While, at first blush, this construction may seem attractive, the Court is unconvinced that Mylan's proposed construction fares any better than that of Gilead when it comes to product stability. Under Mylan's proposed construction, a formulation that degrades 9.9% "every" day, but not more than 9.9% during a single 24-hour period, would fall within the scope of the claim. After several days, however, such a product would be just as unstable as the product Mylan claims would be covered by Gilead's proposed construction.[4]

[4] To Mylan's credit, it attempted to argue that claim 10 is invalid, regardless of the construction adopted by the Court (Dkt. No. 107 at 12). The Court, however, declined to consider

Moreover, Gilead's proposed construction makes sense when one considers the claims it actually asserts in this litigation. The '397 patent covers a product that exhibits "less than [1%/.1%/.01%] degradation of [TDF] over a 24-hour period" and "less than 10% degradation of the [TDF or FTC] after 6 months . . . ." ('397 patent, col. 30:61-65, col. 31:1-9). Under Gilead's construction, "less than [1%/.1%/.01%] degradation of [TDF] over one or more 24-hour periods," an infringing product must degrade less than [1%/.1%/.01%] over one or more 24-hour periods, and less than 10% in total after six months. This scenario does not implicate Mylan's hypothetical where an infringing product could degrade 10% per day, with one 24-hour period dipping below 10%.

Similarly, the '264 patent covers a product that exhibits "less than [10%/5%] degradation of the [TFD and FTC] after six months" under certain storage conditions, and "less than 10% . . . over a 24-hour period." ('264 patent, col. 31:7-13, 25-36). Under Gilead's construction, an infringing product would have to degrade less than [10%/5%] over a six-month period, and less than 10% over one or more 24-hour periods. Again, these claims, when read together, do not include obviously unstable products within their scope.

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indefiniteness at the claim construction stage (Dkt. No. 129).

In short, the Court does not discern any claim language that would induce it to deviate from the general rule that "a" means "one or more." See Baldwin Graphic Sys., 512 F.3d at 1342. It therefore turns next to the specifications and the prosecution history to determine whether they "necessitate a departure from the rule." Id. at 1342-43.

2. The Specifications

Gilead contends that the specifications support applying the general "a" rule. In pertinent part, the specifications state:

> The term "chemical stability" means that the two primary antiviral agents in combination are substantially stable to chemical degradation . . . "[s]ubstantially" in this context means at least about less than 10%, preferably less than 1%, more preferably less than 0.1%, more preferably yet, less than 0.01% acid degradation of [TDF] over a 24-hour period when the products are in a pharmaceutical dosage form.

('397 patent, col. 3:44-47, 58-63). Gilead concludes that nothing in the specification warrants a departure from the general rule.

Mylan argues that, in the specification, the inventors "repeatedly highlighted that the novelty of the claimed invention centered on the discovery of stable formulations." (Dkt. No. 107 at 17). Although the Court agrees with this uncontroversial proposition, it does not necessarily follow that the specification requires a departure from the general "a" rule. Rather, the

specification does not lend support to any one position over another, thus requiring the Court to apply the general rule unless the prosecution history demonstrates a different intent.

3. The Prosecution Histories

The prosecution histories of the patents-in-suit further undermine Mylan's proposed construction. Mylan argues that the prosecution history establishes the inventors' intent to claim stable formulations. In support, it offers the following:

> The specification teaches that one of ordinary skill in the art at the time would have reasonably expected TDF and FTC to be incompatible in co-formulation and storage . . . [o]n the contrary [the specification] discloses that the TDF + EFV co-formulation, when stored for 6 months under relatively harsh conditions . . . suffered only minor losses in drug potency.

('264 patent, Amendment in Response to Non-Final Office Action, 3-31-2010, at 13-14). On December 19, 2013, the PTO issued a notice of allowance, including the following claim:

> 47. (Currently Amended) A chemically stable <u>fixed dose</u> combination comprising <u>300 mg of</u> [TDF] and <u>200 mg of</u> [FTC] <u>wherein the combination exhibits less than 10% degradation of the [TDF and FTC] after six months at 40○C/75% relative humidity when packaged and stored with silica gel desiccant at 40○C/70% relative humidity</u>.

('264 patent, Notice of Allowance, 12-19-2013, at 2, Dkt. No. 107-1 at 71 (emphasis in original)). The examiner's reason for allowance

was that "[t]he prior art does not teach or suggest instant chemically stable fixed-dose combination of 300 mg of [TDF] and 200 of [FTC] having the instantly claimed degradation profile." Id. at 7, Dkt. No. 107-1 at 76. In short, the prosecution history is in accord with Mylan's argument that "[e]xpanding the claims to include unstable products is entirely inconsistent with the inventors' arguments to the PTO that stability in storage was a surprising and unexpected result." (Dkt. No. 107 at 18). For the reasons already discussed, however, the Court does not believe that the language of the asserted claims sweeps in unstable products.

The prosecution histories, thus, fail to support Mylan's argument. None of the intrinsic evidence supports a construction other than the general "a" rule. The Court therefore **CONSTRUES** "less than [X%] degradation of [the TDF] over a 24-hour period" to mean "less than [X%] degradation of [the TDF] over one or more 24-hour periods."

C. "Treatment of the symptoms or effects of an HIV infection"

Gilead construes the term "treatment of the symptoms or effects of an HIV infection," as used in claims 15-16 of the '397 patent and claims 33-34 of the '264 patent, to mean "treatment of the symptoms or effects of an HIV infection that is therapeutically effective." Mylan construes it to mean "treatment of the symptoms

or effects of an HIV infection to any extent."

Gilead argues that its proposed construction is consistent with the specifications and prosecution history, while Mylan's proposed construction attempts to sweep in prior art references. Mylan contends that its proposed construction mirrors the ordinary meaning of the term, does not attempt to read into the claim unsupported limitations, and is supported by the prosecution history. It argues that Gilead's proposed construction improperly reads limitations from the specification into the claims, and would render the claim invalid for lack of enablement.

1. The Claims

The Court must first look to the claim language to discern the meaning of "treatment." Claims 15 and 16 of the '397 patent depend from claims 1 and 6. In relevant part, these claims provide:

> 1. A chemically stable fixed dose combination pharmaceutical dosage form comprising 300 mg [TDF] and 200 mg [FTC]; a binder . . . ; a disintegrant . . . ; and a lubricant . . . ; wherein said pharmaceutical dosage form exhibits less than 10% degradation of the [TDF or FTC] after six months when packaged and stored with silica gel dessicant [sic] at 40○C/75% relative humidity.
>
> 6. The pharmaceutical dosage form of claim **1** wherein less than 5% degradation of the [TDF or FTC] occurs after six months at 40○C/75% relative humidity when packaged and stored with desiccant.

> 15. A method for the treatment of the symptoms or effects of an HIV infection in an infected animal which comprises administering to said animal the pharmaceutical dosage form of claim **1**.
>
> 16. A method for the treatment of the symptoms or effects of an HIV infection in an infected animal which comprises administering to said animal the pharmaceutical dosage form of claim **6**.

('397 patent, col. 30:51-65; col. 31:10-13, 50-57 (emphasis in original)). Claim 15 depends from claim 1, while claim 16 depends from claim 6, which depends from claim 1. See Wahpeton Canvas, 870 F.2d at 1553 ("a dependent claim includes all the limitations of the claim from which it depends.").

Claim 15 covers a method for treating the symptoms or effects of an HIV infection which comprises administering to the infected animal the combination pharmaceutical dosage form of 300 mg of TDF and 200 mg of FTC, made with certain binders and excipients, that degrades less than 10% after six months when packaged and stored under certain conditions.

Claim 16 also covers a method for treating the symptoms or effects of an HIV infection, which comprises administering the combination pharmaceutical dosage form of 300 mg of TDF and 200 mg of FTC, made with certain binders and excipients, that degrades less than 5% after six months when packaged and stored under

certain conditions.

Similarly, claims 33 and 34 of the '264 patent depend from claims 2, 11, 9, and 13, which in turn depend from claims 1 and 10.

> 1. A chemically stable fixed-dose combination comprising 300 mg of [TDF] and 200 mg of [FTC] wherein the combination exhibits less than 10% degradation of the [TDF] and [FTC] after six months at 40○C/75% relative humidity when packaged and stored with silica gel desiccant at 40○C/70% relative humidity.
>
> 2. The chemically stable combination of claim **1** in the form of a pharmaceutical dosage form.
>
> 9. The pharmaceutical dosage form of claim **2** wherein less than 5% degradation of the [TDF] and [FTC] occurs after six months.
>
> 10. A chemically stable fixed-dose combination comprising 300 mg of [TDF] and 200 mg of [FTC] wherein the combination exhibits less than 10% degradation of [TDF] over a 24-hour period.
>
> 11. The chemically stable combination of claim **10**, in the form of a pharmaceutical dosage form.
>
> 13. The pharmaceutical dosage form of claim **11**, wherein there is less than 1% degradation of [TDF].
>
> 33. A method for the treatment of the symptoms or effects of an HIV infection in an infected animal which comprises administering to said animal the pharmaceutical dosage form of claim **2** or **11**.
>
> 34. A method for the treatment of the symptoms or effects of an HIV infection in an infected animal which comprises administering to said

> animal the pharmaceutical dosage form of claim **9** or **13**.

('397 patent, col. 30:46-54; col. 31:4-13, 16-18; col. 32:35-42 (emphasis in original)).

Taken together, then, claim 33 covers a method for treating the effects or symptoms of an HIV infection by administering (1) a chemically stable pharmaceutical dosage form combination of 300 mg of TDF and 200 mg of FTC exhibiting less than 10% degradation of TDF over a 24-hour period; or (2) a chemically stable pharmaceutical dosage form combination of 300 mg of TDF and 200 mg of FTC exhibiting less than 10% degradation of TDF and FTC after six months under certain package and storage conditions.

Claim 34 covers a method for treating the effects or symptoms of an HIV infection by administering (1) a chemically stable pharmaceutical dosage form combination of 300 mg of TDF and 200 mg of FTC exhibiting less than 5% degradation of TDF and FTC after six months when packaged and stored under certain conditions; or (2) a chemically stable pharmaceutical dosage form combination of 300 mg of TDF and 200 mg of FTC exhibiting less than 1% degradation of TDF over a 24-hour period.

Both the '397 and the '264 patents lack any definition of "treatment" in the claim language. Therefore, the Court must look to the specifications to discern what type of "treatment" the

inventors intended their patents to cover.

2. The Specifications

Gilead points to repeated references to "therapy" and "therapeutic combinations" in the '397 and '265 patents' titles, abstracts, and specifications to establish that the inventors intended their treatment to be "therapeutically effective." Mylan contends that Gilead's proposed construction improperly imports a limitation from the specification into the claims.

Gilead points to the specification of the '264 patent, which explains that the invention relates to "therapeutic combinations," and encompasses "a method for the treatment or prevention of the symptoms or effects of an HIV infection in an infected animal which comprises administering to, i.e. treating, said animal with a therapeutically effective amount [of TDF and FTC] . . . ." ('264 patent, col. 2:41, 47-51 (emphasis added)). It contends that the specifications "make it plain that the claimed methods of treatment are those that are therapeutically effective." (Dkt. No. 100 at 23).

Mylan argues that "therapeutically effective" refers to the amount of TDF and FTC, and does not define "treatment." Rather, if "treatment" means, as Gilead argues, "therapeutically effective treatment," then it would be redundant for "therapeutically

effective" to also refer back to "treatment." Finally, Mylan contends that the phrase "administering to, i.e. treating," equates treatment with administering, with no efficacy component.

The Court agrees that "therapeutically effective" clearly refers to the amount of TDF and FTC, and not to "treatment." That being said, it is unclear whether the inventors, by including "administering to, i.e. treating," meant to define treatment as any treatment, rather than as a therapeutically effective treatment.

3. The Prosecution Histories

Gilead argues that the prosecution histories of both patents clarify that treatment must be "effective," "particularly since HIV is a chronic and life-threatening disease, requiring long-term treatment with anti-viral medications." (Dkt. No. 100 at 23). The inventors initially included claims directed to "[a] method for the treatment of the symptoms or effects of an HIV infection in an infected animal which comprises administering to said animal a therapeutically effective amount of a composition . . . ." ('397 patent, Amendment/Response to Office Action, 9-27-2012, at 2).[5]

The inventors argued that a POSA would not have anticipated that a TDF and FTC co-formulation would effectively treat HIV.

[5] See also '264 patent, Amendment/Response to Office Action, 9-27-2012, at 2.

> It is well-known that HIV infections are chronic, and require long-term treatment, for example with antiviral medications. As discussed below, long-term treatment of HIV with antiviral medications, particularly combinations of antiviral medications, is complicated and unpredictable, particularly due to the development of drug resistance by the HIV virus. Thus, effective treatment of HIV with combinations of antiviral medications requires careful consideration of factors relating to drug resistance and their impact on long-term treatment . . . .

('397 patent, Amendment/Response to Office Action, 9-27-2012, at 13). The inventors stressed that a POSA would not have expected the combination of TDF and FTC "to provide effective long-term treatment for HIV." Id. at 18.

Significantly, however, the inventors later cancelled that claim, presenting a new claim directed to "[a] method for the treatment of the symptoms or effects of an HIV infection which comprises administering to said animal the pharmaceutical dosage form . . . ." ('397 patent, Amendment/Response to Office Action, 6-20-2013, at 4).[6] Mylan argues that the inventors' omission of the "therapeutically effective" language proves that they affirmatively chose not to include such a limitation in their claims.

Gilead asserts that the inventors cancelled their original

[6] See also '265 patent, Amendment/Response to Office Action, 11-14-2013, at 5).

claims because the amended claims include specific dosage amounts of FTC and TDF, thus rendering the phrase "therapeutically effective" redundant. This statement, however, seems to be incorrect. Although claim 1 in the '397 patent originally included the "therapeutically effective" language, with no mention of the amount of FTC and TDF used, claims 3-7 specify the amounts of FTC and TDF to be used and refer back to claim 1 ('397 patent, Amendment/Response to Office Action, 9-27, 2012, at 2-3). Thus, as of September 27, 2012, some of the claims included both the "therapeutically effective" language and an amount of TDF and FTC. If the inventors chose to take "therapeutically effective" out at a later date, it was not because it suddenly became redundant.

The prosecution history demonstrates that the inventors knew the difference between effective and ineffective treatment, having relied upon the fact that their treatment was effective to distinguish it from the prior art. See '397 patent, Amendment/Response to Office Action, 9-27-2012. Nevertheless, the inventors inexplicably chose to remove the "therapeutically effective treatment" language in their claim, and replace it with the broader term "treatment." It could be, as Mylan argues, that the inventors gave up the narrower definition of "therapeutically effective treatment" in an effort to broaden their claim. It could

also be, however, that the inventors omitted "therapeutically effective" because they thought it obvious that "treatment" meant "therapeutically effective treatment," particularly in light of their arguments during prosecution. Because the intrinsic evidence does not fully explain what the inventors meant by "treatment," the Court must look to the extrinsic evidence. See Markman, 52 F.3d at 980; Phillips, 415 F.3d at 1317.

4. Extrinsic Sources

Gilead and Mylan rely on the testimony of their experts to explain what a POSA would have understood "treatment" to mean at the time of the invention. Gilead's expert, Dr. Carlo Federico-Perno, a medical doctor and virologist, explains that doctors would only consider a drug to "treat" an HIV-infected patient if it produced a meaningful drop in HIV viral load (Dkt. No. 102 at 9-10).[7] The overall goal of HIV treatment is to keep HIV viral load levels as low as possible, for as long as possible, to decrease the complications of HIV and slow the progression to AIDS. Id. at 10. Because viral load typically fluctuates due to random variations in a patient's blood, doctors only consider a particular drug to

[7] Viral load refers to the number of "copies" of HIV present in a given volume of blood (Dkt. No. 102 at 10). It is typically measured as the amount of HIV-RNA copies per milliliter of blood (copies/mL). Id. at fn. 8.

"treat" HIV when it causes a "profound drop[] in HIV-RNA viral load." Id. at 10-11. Dr. Perno opines that the ordinary meaning of "treatment" to a POSA "requires a therapeutically effective component to the claim term."

Mylan points to the testimony of its expert, Dr. Chloe Thio, M.D., and the dictionary definition of "treatment." Dr. Thio explains that she understands Gilead's position to be that a "therapeutically effective" treatment would result in "additive or synergistic effects." (Dkt. No. 107-2 at 6). She opines that a POSA would not understand "treatment" in that manner, but would interpret treatment to mean "treatment . . . to any extent," meaning treatment having any "positive or beneficial effect."[8] Id. at 6, 8. Mylan also contends that the dictionary definition of "treatment," meaning "seeking cure or relief," supports its position that treatment means treatment to any extent (Dkt. No. 107 at 25).

During oral argument, Gilead clarified that it does not interpret "therapeutically effective" as requiring "additive or synergistic effects." Given that, much of Dr. Thio's testimony about what a POSA would have understood or been capable of testing

[8] Interestingly, this contradicts Mylan's position at oral argument, when counsel represented that "treatment" included non-beneficial outcomes.

at the time of the invention is irrelevant. Dr. Thio averred that reading "treatment" to mean "treatment to any extent" would not include negative outcomes because a POSA "would have expected a treatment consisting of the combination of TDF and FTC to have a positive effect on the patient." (Dkt. No. 107-2 at 8). Apparently, then, Mylan's position is that "treatment" means "treatment to any extent," which actually means "treatment to any positive or beneficial extent." See id.

5. Analysis

The difference between Mylan and Gilead's positions, once miles wide, is now razor thin. Apparently, it comes down to how beneficial a "therapeutically effective" treatment must be, and whether a POSA could divine such treatment from the claims. At this juncture, it is incumbent on the Court to address Mylan's lack of enablement argument.

An invention fails for lack of enablement when one reasonably skilled in the art cannot make or use the invention from the disclosures in the patent, coupled with information known in the art, without undue experimentation. See United States v. Telectronics, Inc., 857 F.2d 778, 785 (Fed. Cir. 1988). The Federal Circuit instructs that "claims are generally construed so as to sustain their validity, if possible." Whittaker Corp. by

Technibilt Div. v. UNR Industries, Inc., 911 F.2d 709, 711-12 (Fed. Cir. 1990) (citing ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577 (Fed. Cir.1984)). This axiom only applies, however, when a claim's construction is consistent with the claim's language and the written description. Rhine v. Casio, Inc., 183 F.3d 1342, 1345 (Fed. Cir. 1999). In other words, a court may not rewrite a claim to preserve its validity. Id. (citing Becton Dickinson & Co. v. C.R. Bard, Inc., 922 F.2d 792, 799 & n.6 (Fed. Cir. 1990)).

Mylan argues that Gilead's proposed construction would render the claim invalid for lack of enablement. It contends that Gilead's proposed construction of "treatment" would fail because the patent does not disclose when the treatment is therapeutically effective. Gilead counters that a POSA would have been able to determine when HIV treatment was therapeutically effective by referencing the Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents ("HIV Treatment Guidelines") referenced both by Gilead's expert, Dr. Patrick Sinko, and Mylan's expert, Dr. Thio.[9]

[9] On February 4, 2002, the Panel on Clinical Practices for Treatment of HIV Infection, convened by the United States Department of Health and Human Resources, issued the HIV Treatment Guidelines (Dkt. No. 101 at 76).

The HIV Treatment Guidelines state that the primary goals of HIV treatment are (1) "maximal and durable suppression of viral load"; (2) "restoration and/or preservation of immunologic function"; (3) "improvement of quality of life" and, (4) "reduction of HIV-related morbidity and mortality." (Dkt. No. 101 at 80). Successful therapy would result in a one-$\log_{10}$ decrease at eight weeks, and "no detectable virus (>50 copies/mL) at 4-6 months after initiation of treatment." Id.

Although Dr. Perno did not mention the HIV Treatment Guidelines by name, his declaration mirrored its recommendations. He averred that some changes in a patient's HIV viral load, such as a 0.3-log drop, often occur due to random variations in the patient's body (Dkt. No. 102 at 9-10). A clinically significant result, however would be a minimum of a log or greater drop in viral load. Id. "[A] meaningful result of antiviral therapy is considered, by all guidelines, as a reduction of viral replication strong enough to decrease levels of viral load in plasma toward undetectability." Id. Dr. Perno's testimony aligns with the HIV Treatment Guidelines, which Dr. Sinko averred were known to a POSA at the time of the invention (Dkt. No. 101 at 7).

Mylan's expert, Dr. Thio, did not disagree. She stated that Dr. Perno's declaration "sets forth an accurate scientific standard

for evaluating whether a treatment has been effective to a clinically relevant extent." (Dkt. No. 107-2 at 7). Mylan insists, however, that a POSA would not have been able to make the invention without undue experimentation because the patent did not contain any in vitro data, thus making the claim invalid for lack of enablement.

The intrinsic and extrinsic evidence are consistent, and weigh in favor of Gilead's proposed construction. The patent claims and specifications are silent as to the definition of "treatment," but the prosecution history makes clear that the inventors intended to claim a treatment that was effective, meaning one that meaningfully treated HIV viral load. Indeed, the patentability of the invention over the prior art depended on it being an effective treatment, as opposed to the many ineffective treatments that were already disclosed.

The extrinsic evidence is consistent with the prosecution history, and convinces the Court that a POSA would not have had to engage in "undue" experimentation to determine the threshold for clinical effectiveness. Telectronics, Inc., 857 F.2d at 785. Dr. Sinko and Dr. Perno both averred that the relevant standard at the time of the invention, the HIV Treatment Guidelines, clearly set forth the parameters for effectiveness of HIV treatment.

Dr. Thio, Mylan's expert, agreed with this statement, but disagreed that a POSA would be able to make the invention without undue experimentation. Much of Dr. Thio's declaration, however, discussed the "heightened efficacy requirement" of additive or synergistic effects, an efficacy standard that Gilead is not claiming in this litigation (Dkt. No. 107-2 at 6-8). She stated that a POSA "would have been required to conduct significant experimentation, including clinical studies, to determine whether a treatment using the claimed co-formulation did in fact satisfy the therapeutically effective requirements set forth by Dr. Perno." Id. at 8.

It is clear, however, that a POSA would have known how to conduct such studies, as evidenced by Dr. Perno's declaration and the HIV Treatment Guidelines that discuss the exact same requirements. The Court therefore is unconvinced that a POSA would have had to conduct "undue experimentation" to replicate the invention, and therefore rejects, at this stage, Mylan's argument that the claims are invalid for lack of enablement. Telectronics, Inc., 857 F.2d at 785.

For all of the reasons stated, and because the intrinsic and extrinsic evidence supports Gilead's proposed construction, the Court **CONSTRUES** "treatment of the symptoms or effects of an HIV

infection" to mean "treatment of the symptoms or effects of an HIV infection that is therapeutically effective."

IV. CONCLUSION

For the reasons discussed, the Court **CONSTRUES** the contested claim terms and phrases as follows:

1. "Fixed dose combination" is non-limiting, and need not be construed;
2. "Less than [X%] degradation of [the TDF] over a 24-hour period" means "less than [X%] degradation of [the TDF] over one or more 24-hour periods;" and,
3. "Treatment of the symptoms or effects of an HIV infection" means "treatment of the symptoms or effects of an HIV infection that is therapeutically effective."

Further, the Court adopts the parties' agreed claim constructions and **CONSTRUES** the following terms and phrases as follows:

1. "Chemically stable" is non-limiting, and need not be construed;
2. "Pharmaceutical dosage form" means "a pharmaceutical dosage form for human administration;"
3. "Less than [10%/5%] degradation of the [TDF] or [FTC] after six months" in the '397 patent means "less than

[10%/5%] degradation of one or both of the [TDF] or [FTC] after six months;"

4. "Less than [10%/5%] degradation of the [TDF] and [FTC] after six months" in the '264 patent means "less than [10%/5%] degradation of each of the [TDF] and [FTC] after six months;"

5. "Degradation" means "loss in % label strength;"

6. "Dosage form is oral" means "an oral dosage form for human administration;"

7. "Less than 1% of impurities related to [TDF] and [FTC]" means "less than 1% of impurities related to each of [TDF] and FTC];" and,

8. "40○C./70% relative humidity" means "40○C./70% relative humidity."

It is so **ORDERED**.

The Court directs the Clerk to transmit copies of this Order to counsel of record.

DATED: May 12, 2015.

/s/ Irene M. Keeley
IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE