United States District Court,
D. Delaware.

GLAXO GROUP LTD and Smithkline, Beecham Corporation d/b/a Glaxosmthkline,
Plaintiffs.
v.
TEVA PHARMACEUTICALS USA, INC,
Defendant.

Civil Action No. 07-713-JJF

April 30, 2009.

Jack B. Blumenfeld, James Walter Parrett, Jr., Karen Jacobs Louden, Morris, Nichols, Arsht & Tunnell, Wilmington, DE, for Plaintiffs.

John W. Shaw, Karen Elizabeth Keller, Young, Conaway, Stargatt & Taylor, Wilmington, DE, for Defendant.

MEMORANDUM ORDER

JOSEPH J. FARNAN, JR.**, District Judge.**

This is a patent infringement action brought by Plaintiffs Glaxo Group Ltd. and SmithKline Beecham Corporation d/b/a GlaxoSmithKline (collectively "GSK") against Defendant Teva Pharmaceuticals USA, Inc. ("Teva") alleging infringement of United States Patent No. 5,859,021 ("the '021 patent"), which pertains to combinations of antiviral agents effective for the treatment of human immunodeficiency virus ("HIV"). The parties briefed their respective positions on claim construction, and the Court conducted a *Markman* hearing on the disputed terms. This Memorandum Order provides constructions of the disputed terms.

Plaintiff asserts Claims 1-2, 4, 6, and 8-10 of the '021 patent. Briefly, the asserted claims pertain to a combination of (1) the (-)-enantiomer of an antiviral agent known as BCH-189 (the "first compound" in the claims) and (2) the well-known HIV antiviral agent AZT (the "second compound" in the claims). Representative claims of the '021 patent with the disputed terms highlighted are as follows:

1. A combination of anti-HIV compounds which ***comprises*** a mixture of first and second compounds wherein said first compound is (2R,cis)-4-amino-1-(2-hydroxy-methyl-1,3-oxathiolan-5-yl)-1 H-pyrimidin-2-one or a pharmaceutically acceptable salt, ester or salt of said ester of said first compound and said second compound is 3'-azido-3'-deoxythymidine or a pharmaceutically acceptable salt, ester or salt of said ester of said second compound with the proviso that said first and second compounds of said combination are present in a ratio wherein the ratio of said first compound to said second compound is from about 1:2 to about 1:1 by weight.

2. The combination of claim 1 which further ***comprises*** a ***pharmaceutically acceptable carrier*** for said first and second compounds.

4. A ***method for the treatment of a mammal, including man, suffering from or susceptible to infection by HIV*** which ***comprises*** administering a combination of anti-HIV drugs wherein said combination includes first and second compounds; said first compound being (2Rcis) -4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-1 H-pyrimidin-2-one or a pharmaceutically acceptable salt, ester or salt of said ester of said first compound and said second compound being 3'-azido-3'-deoxythymidine or a pharmaceutically acceptable salt, ester or salt of said ester of said second compound wherein the first and second compounds are administered in a ratio of said first compound to said second compound which is from about 1:2 to about 1:1.

8. The combination of claim 2 which is in the ***form of a dosage unit.***

For the reasons that follow, the Court construes the disputed terms as follows:

I. "Comprises" And "Includes" FN1

FN1. "As a patent law term of art, 'includes' means 'comprising.' " Sandisk Corp. v. Memorex Prods., 415 F.3d 1278, 1284 (Fed.Cir.2005). Accordingly, the Court addresses these terms together.

GSK's Proposed Construction	Teva's Proposed Construction
Does not exclude additional unrecited elements, or steps in the case of a method claim, but may not be used to alter the scope of the elements in the claim at issue.	Does not exclude additional unrecited elements, or steps in the case of a method claim, but may not be used to remove the limitations that are present.

" 'Comprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim." Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501 (Fed.Cir.1997); *see also* Kustom Signals, Inc. v. Applied Concepts, Inc., 264 F.3d 1326, 1332 (Fed.Cir.2001) ("The open-ended transition 'comprising' does not free the claim from its own limitations."). Because Teva's proposed construction, unlike GSK's proposed construction, ostensibly allows for unclear modifications of claim elements so long as those elements are not "removed," the Court will not adopt Teva's proposed construction. However, the Court will also not adopt GSK's proposed construction. In the Court's view, GSK's proposed construction places an undue-and perhaps misleading-emphasis on prohibiting alteration of claim elements.

Given that the term "comprising" is a term of art in patent law, the Court is unwilling to adopt a specialized definition for this term absent some evidence in the internal record suggesting that such a definition is appropriate. The Court finds no such evidence. Accordingly, for the term "comprising," the Court will adopt a standard jury instruction, such as the one prepared by the American Institute of Intellectual Property ("AIPLA"), FN2 or, alternatively, a standard instruction of similar ilk that the parties find agreeable. FN3

FN2. The AIPLA instruction for infringement of "comprising" claims explains that the "word 'comprising' means 'including the following but not excluding others" and instructs the jury that "the fact that [the Defendant]'s [[product] [method]] might include additional [[components] [method steps]] would not avoid

literal infringement ...." AIPLA's Model Patent Jury Instructions 15 (2008), http://www.aipla.org/Content/ContentGroups/Publications1/ Publications_available_ for_viewing1/2008_03_27_AIPLA_Model_Jury_Instructions.pdf

FN3. After the parties completed claim construction briefing and after the *Markman* hearing, Teva submitted a letter to the Court purportedly clarifying issues discussed during the *Markman* hearing. (*See* D.I. 57.) Briefly, Teva explained that, in its view, chemical mixtures containing racemic BCH-189 and AZT were within the scope of the claims. (*Id.* at 3.) GSK then submitted a response letter disputing this position. (*See* D.I. 62.) In the Court's view, the issues raised in the parties' late submissions are most appropriately addressed during an infringement or invalidity analysis undertaken based on the constructions issued in this Memorandum Order.

II. "Method For The Treatment Of A Mammal, Including Man, Suffering From Or Susceptible To Infection By HIV"

GSK's Proposed Construction	Teva's Proposed Construction
Method for managing human immunodeficiency virus infection in a person suffering from or susceptible to that disease.	Method for the treatment of a mammal which is infected with HIV or which is susceptible to becoming infected with HIV.

GSK contends, first, that the word "treating" should be defined as "managing" and, second, that this limitation, in spite of its plain language, refers only to the treatment of humans. (*See* D.I. 32 at 13-15.) The Court will not adopt GSK's construction.

With respect to whether "treating" should be defined as "managing," GSK's position appears to be, in effect, an attempt to limit the claims to "long term" treatment of HIV infection. Indeed, GSK argues, for instance, that "the prior art patents considered by the examiner and listed on the face of the ' 021 patent confirm that a person of ordinary skill in the art would understand that treatment of HIV means *long-term* management." (D.I. 32 at 14 (emphasis added).) Thus, in support of its construction, GSK points to, for example, passages in the specification suggesting that HIV requires long-term treatment. ('021 patent at 1:20-23 ("However, HIV infection of cells results in integration of the virus genome into the host chromosome, and so it has been necessary to continue AZT treatment for long periods of time.").) In addition, GSK cites a declaration in the prosecution history from a GSK researcher who carried out a 52-week study on the effectiveness of the claimed invention. (D.I.32, Exh. D.) Apparently, GSK contends that the 52-week study length confirms that the claims are limited to long-term management. (*See, e.g.,* D.I. 44 at 57:13-17 (GSK argues at the *Markman* hearing that the declaration included a chart that "itself represents the inhibition of HIV over the course of 52 weeks" and urges the Court to note that "it didn't stop at zero," "it didn't stop at a single dose" and that "[i]t kept going").) GSK further maintains that because the specification never suggests the possibility of a one-time treatment or that the claimed invention will cure HIV, the claims must be referring to long-term treatment. (*See* D.I. 32 at 13.)

However, "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.' " Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed.Cir.2004) (quoting Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1327

(Fed.Cir.2002)). The Court has reviewed all of GSK's arguments and evidence that "treatment" should be redefined as "management" so that the claims are then limited to "long-term" care of HIV infection. On so doing, the Court concludes that GSK's evidence falls well short of warranting this limitation.

As to GSK's position that the claims should be limited to the treatment of only people, the Court notes that this limitation refers generally to "mammals" and lists "man" as an exemplary "mammal." Furthermore, the specification explains that the amount of drug to be used will be "at the discretion of the attendant physician *or veterinarian*." ('021 patent at 4:26-32 (emphasis added).) Thus, the claims and specification exhibit a definitive intent for the invention to cover more than just the treatment of humans. In these circumstances, the Court requires compelling evidence to adopt GSK's proposed construction. GSK points out only that "HIV" means "*human* immunodeficiency virus" and that the "specification and prosecution history clearly focuses on the treatment of humans." (*See* D.I. 35 at 10.) In the Court's view, this evidence is not sufficient to effect the drastic alteration of the claim language that GSK seeks.

GSK attacks Teva's proposed construction as bearing too much similarity to the raw claim language. (*See* D.I. 35 at 9.) However, having concluded that the claims should not be limited in the manner suggested by GSK, the Court agrees with Teva that this is a case where the "claim language is simple enough ... such that it does not require further 'construction' ...." (D.I. 36 at 14 .)

Accordingly, the Court concludes that this term requires no further construction.

III. "Form Of A Dosage Unit"

GSK's Proposed Construction	**Teva's Proposed Construction**
Form suitable for administration to a human, e.g., a table, that includes a predetermined amount of each active ingredient.	Form suitable for administration to a mammal.

GSK contends, first, that this limitation should be limited to the treatment of humans only and, second, that the "dosage unit" should have a "predetermined amount of each ingredient." (*See* D.I. 32 at 16-17.) The Court will not adopt GSK's construction.

For the reasons stated immediately above, the Court will not limit this claim element to the treatment of only humans. (*See* Part II of this Memorandum Order.)

In support of the position that the "dosage unit" must have a "predetermined" amount of each active ingredient, GSK notes that the specification states that "[p]harmaceutical formulations suitable for oral administration may conveniently be presented as discrete units such as capsules, cachets or tablets each containing a predetermined amount of the active ingredient." ('021 patent at 5:17-21.) Based on this, GSK contends that the "specification clearly states that the 'form of a dosage unit' must contain a *predetermined* amount of each active ingredient." (D.I. 35 at 12 (emphasis added).) Unfortunately, this is not what the specification states. Rather, the specification merely states that one type of formulation (i.e., oral dosage forms) "may" be presented as units having a predetermined amount of the active ingredient. Thus, the statement in the specification relied upon by GSK is not a basis upon which to limit the claims. GSK further points to other exemplary dosage forms listed in the specification, such as ampoules, pre-filled syringes, and blister packs, and contends that "[t]here is not a single example" referring to dosage forms having something other than a predetermined amount of each active ingredient. (*See* D.I. 44:7-10; D.I. 35 at 13.)

However, GSK provides no evidence, such as expert witness testimony, that all of the disclosed dosage forms in fact contain a "pre-determined" amount of each active ingredient. Rather, GSK's evidence on this issue consists of little more than attorney argument and, perhaps, a dictionary definition. (*See* D.I. 32 at 16 (citing Webster's Third New Int'l Dictionary 676 (1986).) Attorney argument and extrinsic dictionary definitions carry little weight and are an insufficient basis upon which to introduce an extraneous limitation into claims. Indeed, "[i]t is improper for a court to add 'extraneous' limitations to a claim, that is, limitations added 'wholly apart from any need to interpret what the patentee meant by particular words or phrases in the claim.' " Hoqanas AB v. Dresser Indus., 9 F.3d 948, 950 (Fed.Cir.1993) (quoting E.I. Du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433 (Fed.Cir.1988).

Finally, GSK contends that Teva's construction "defies common sense" because it would allow a dosage unit to "contain an arbitrary and uncontrolled amount of the active ingredients." (*Id*. at 13.) However, in the Court's view, GSK fails to fully explain why the claims cannot, in fact, encompass dosage units in which there is variability in the relative amount of each active ingredient, such as where dosage units are prepared as a dry powder mixture containing rough amounts of each ingredient or as an aerosol in which the concentration of each agent varies with administration. FN4 Furthermore, the Court is concerned that GSK's proposed construction will not clarify the claims, but introduce ambiguity. Indeed, GSK's construction does not explain when or by whom the amounts of each active ingredient must be "predetermined," nor does it set forth the level of precision with which the amount of each active ingredient must be "predetermined."

FN4. GSK argued at the *Markman* hearing that failure to administer a "predetermined" amount of drug could lead to a "whole host of problems" and cited toxicity and resistance problems, identifying "peripheral neuropathy" as a particular example. (*See* D.I. 44 at 91:19-92:20.) However, this was not buttressed by any evidence and is therefore nothing more than attorney argument, which the cannot credit.

Accordingly, the Court will construe the claim term "form of a dosage unit" to mean, as Teva contends, a "form suitable for administration to a mammal."

IV. "Pharmaceutically Acceptable Carrier"

GSK's Proposed Construction	Teva's Proposed Construction
Material that is compatible with the other ingredients of the formulation and not deleterious to the recipient thereof for the life of the formulation.	Carrier that is compatible with the other ingredients of the formulation and not deleterious to the recipient thereof.

The parties propose essentially identical constructions, both of which are derived from a portion of the specification stating that "[t]he carrier(s) must be 'acceptable' in the sense of being compatible with other ingredients in the formulation and not deleterious to the recipient thereof." ('021 patent at 5:1-4.) GSK construction differs from Teva's only in that it tacks on the additional limitation that the carrier not be deleterious to the recipient "for the life of the formulation." The Court will not adopt this aspect of GSK's construction.

GSK offers very little support for this aspect of its construction. Briefly, GSK asserts that "[a] person of ordinary skill in the art would understand that any pharmaceutically acceptable carrier must be 'compatible' and 'not deleterious' during the formulation's life, however short or long it is expected to be." (D.I. 32 at 11.)

GSK then cites some passages from a textbook on pharmaceutical sciences explaining that incompatibility of ingredients in a pharmaceutical formulation can be a source of instability. (Id. (citing Remington's Pharmaceutical Sciences 1504-07 (18th ed.1990).)

In the Court's view, this is but another attempt by GSK-without any meaningful support from the internal record-to introduce another extraneous and vague limitation into the claims. The Court will not do this.

Instead, the Court will construe the claim term "pharmaceutically acceptable carrier" to mean, as Teva contends, a "carrier that is compatible with the other ingredients of the formulation and not deleterious to the recipient thereof."

NOW THEREFORE, IT IS HEREBY ORDERED that:

1. The Court will instruct the jury as to the meaning of the claim terms "comprises" and "includes" through a standard jury instruction such as the one provided by the AIPLA.

2. The term **"method for the treatment of a mammal, including man, suffering from or susceptible to infection by HIV"** requires no construction.

3. The term **"form of a dosage unit"** means a "form suitable for administration to a mammal."

4. The term **"pharmaceutically acceptable carrier"** means a "carrier that is compatible with the other ingredients of the formulation and not deleterious to the recipient thereof."

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