

United States District Court,
N.D. California.

USE TECHNO CORPORATION and Futoshi Matsuyama,
Plaintiffs.

v.

KENKO USA, INC., et. al,
Defendants.

No. C-06-02754 EDL

July 24, 2007.

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Sri K. Sankaran, John Brogan, Kevin S. Ueland, Paul Robbennolt, Dorsey & Whitney LLP, Minneapolis, MN, Devin Alexander McRae, Dorsey & Whitney LLP, Palo Alto, CA, for Defendants.

ORDER RE: CLAIM CONSTRUCTION OF UNITED STATES PATENT 6,716,459

ELIZABETH D. LAPORTE, United States Magistrate Judge.

Before the Court is the parties' dispute over the proper construction of certain terms in United States Patents No. 6,716,459 ("the '459 patent").

I. BACKGROUND

Plaintiffs Use Techno Corporation and Futoshi Matsuyama (collectively, "Plaintiffs") have filed suit against Defendants Iovate Health Sciences USA, Inc., Jarrow Formulas, Inc., Jarrow Industries, Inc., Kenko USA, Inc., Soft-Gel Technologies, Inc., Chemco Industries, Inc., Ronald Udell and Siva Hari FN1 (collectively, "Defendants") for patent infringement. According to the complaint, Plaintiffs' business is related to "studying natural active chemical compounds and developing, patenting and licensing the application developed." Am. Compl. para. 1. Plaintiffs have identified corosolic acid as a specific extract of the Banaba plant (*Lagerstroemia speciosa* (Lin. or Pers.)) leaves that has been found to maintain healthy blood sugar levels in humans. *Id.* Plaintiffs are "engaged in the business of planting, harvesting, extracting, marketing, and selling corosolic acid extracts for the prevention and treatment of diabetes, obesity, constipation and skin diseases." *Id.* Plaintiff alleges that it owns the ' 459 patent and that Defendants are infringing the ' 459 patent by importing, making, using, offering for sale and selling products containing corosolic acid. Am. Compl. para. 61.

FN1. Plaintiffs' claims against Iovate Health Sciences USA, Inc., Jarrow Industries, Inc., Jarrow Formulas, Inc. and Siva Hari have either been settled or are in the process of settling. Ronald Udell has been

dismissed from this case. The remaining Defendants are Kenko USA, Inc., Soft-Gel Technologies and Chemco Industries, Inc.

The Court held a claim construction hearing for the '459 patent on June 27, 2007.

II. LEGAL STANDARD

The construction of a patent claim is a matter of law for the Court. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). A "bedrock principle" of patent law is that " 'the claims of a patent define the invention to which the patentee is entitled to the right to exclude.' " *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed.Cir.2005) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 1115 (Fed.Cir.2004)). The terms of a claim are generally given their ordinary and customary meaning, that 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, i.e., as of the effective date of the filing of the patent," which provides an "objective baseline from which to begin claim interpretation." *Phillips*, 415 F.3d at 1313 (citing *Innova*, 381 F.3d at 1116). A court should look at " 'those sources available to the public that 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). Those sources include "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms and the state of the art." *Id.* (quoting *Innova*, 381 F.3d at 1116); *see also CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed.Cir.2002).

A court should first focus on intrinsic evidence in construing patent claims. Importantly, the context of the claim language is highly instructive. *Phillips*, 415 F.3d at 1314; *see also Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996) ("Although words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history.") (citation omitted); *Hoechst Celanese Corp. v. BP Chems. Ltd.*, 78 F.3d 1575, 1578 (Fed.Cir.1996) ("A technical term used in a patent document is interpreted as having the meaning that it would be given by persons experienced in the field of the invention, unless it is apparent from the patent and the prosecution history that the inventor used the term with a different meaning."). In addition, other claims of the patent, whether asserted or not, can also illuminate the meaning of a claim term. *Phillips*, 415 F.3d at 1314 (citing *Vitronics*, 90 F.3d at 1582). Claims, however, should be read in light of the specification. *Id.* at 1315; *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed.Cir.1995) (*en banc*), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996)). The specification " '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.' " *Phillips*, 415 F.3d at 1315 (quoting *Vitronics*, 90 F.3d at 1582). In addition to the specification, a court should also consider the patent prosecution history. *Phillips*, 415 F.3d at 1317; *see also Markman*, 52 F.3d at 980 ("Although the prosecution history can and should be used to understand the language used in the claims, it too cannot enlarge, diminish, or vary the limitations in the claims.") (internal quotation marks deleted) (citations omitted). However, the prosecution history, which provides insight into how the Patent and Trademark Office and the inventor understood the patent, "lacks the clarity of the specification and thus is less useful for claim construction purposes." *Phillips*, 415 F.3d at 1317.

Ordinarily, the Court should not rely on extrinsic evidence to assist in claim construction, because the public is entitled to rely on the public record of the patentee's claim (as contained in the patent claim, the

specification, and the prosecution history) to ascertain the scope of the claimed invention. *Vitronics*, 90 F.3d at 1583. Extrinsic evidence, such as expert testimony, dictionaries and treatises, should be used only if needed to assist in determining the meaning or scope of technical terms in the claims, or to understand the underlying technology, and may not be used to vary or contradict the terms of the claims. *Id.* (citing *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1216 (Fed.Cir.1995)); *Phillips*, 415 F.3d at 1318-19; *Markman*, 52 F.3d at 981. External evidence is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed.Cir.2004) (internal quotations omitted)). "Extrinsic evidence may be useful to the court, but it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of intrinsic evidence." *Id.* at 1319.

An accused infringer may overcome the heavy presumption that a claim term carries its ordinary and customary meaning, but "he cannot do so simply by pointing to the preferred embodiment or other structures or steps disclosed in the specification or prosecution history." *CCS Fitness*, 288 F.3d at 1366; *see also Phillips*, 415 F.3d at 1323 ("... we have repeatedly warned against confining the claims to those embodiments [contained in the specification]."). Neither the specification nor the title of the patent can be used to import limitations into the claims that are not found in the claims themselves. *Pitney-Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1312 (Fed.Cir.1999). While the claims must be read in view of the specification, limitations from the specification are not to be read into the claims. *Phillips*, 415 F.3d at 1323.

III. DISCUSSION

The '459 patent is entitled "Composition for Inhibiting Increase of Blood Sugar Level or Lowering Blood Sugar Level." This patent has two claims:

1. A composition for inhibiting an increase in, or lowering, a blood sugar level, in a human patient in need thereof, consisting essentially of:

a concentrate of ethanol or ethanol aqueous solution extract of leaves of *Lagerstroemia Speciosa*, Linn. or Pers. having a corosolic acid content of 0.01 to 15 mg per 100 mg of the concentrate.

2. The composition according to claim 1, wherein said ethanol solution contains 50 to 80 by weight of ethanol.

'459 patent at col. 6, lines 57-65. The parties ask the Court to construe the following eleven terms from the claims of the '459 patent.

Disputed claim language	Plaintiffs' construction	Defendants' construction
A composition for inhibiting an increase in, or lowering, a blood sugar level	The preamble of this patent is clear and unambiguous and therefore is not in need of construction.	A mixture made up of one or more ingredients that has the effect of preventing blood glucose from rising above a normal level, or lowering blood glucose to a normal level.

Language in a claim's preamble is appropriate for construction when it limits the claimed invention. A preamble generally limits the claimed invention if it "recites essential structure or steps, or if it is necessary to give life, meaning and vitality to the claim." *NTP, Inc. v. Research in Motion*, 418 F.3d 1282, 1305 (Fed.Cir.2005) (quoting *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808

(Fed.Cir.2002) ("Additionally, dependence on a particular disputed preamble phrase for antecedent basis may limit claim scope because it indicates a reliance on both the preamble and claim body to define the claimed invention. [citation omitted] Likewise, when the preamble is essential to understand limitations or terms in the claim body, the preamble limits claim scope. [citation omitted] Further, when reciting additional structure or steps underscored as important by the specification, the preamble may operate as a claim limitation. [citation omitted]"). However, preamble language is generally 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.*, 289 F.3d at 808 (quoting *Rowe v. Dror*, 112 F.3d 473, 478 (Fed.Cir.1997)). Here, the parties agreed at the hearing that the preamble language is limiting. They disagree, however, on whether the language needs to be construed.

The disagreement focuses on Defendants' proposed substitution of the word "preventing" for "inhibiting." Plaintiffs argue that the use of "preventing" is too limiting, and that the word "inhibiting," as used in the claim language, is clear and not in need of construction. The Court agrees that "preventing" is different from, and more restrictive than, the term "inhibiting." Defendants have made no showing, based on any intrinsic or extrinsic evidence, that "inhibiting" should be given a construction that is more restrictive than its ordinary meaning. For example, the specification does not contain the term "preventing," nor does the context of the claim language warrant use of this term. The specification includes language regarding keeping blood sugar at a normal level, but because the Court may not read limitations from the specification into the claims, the use of "preventing" would improperly impose limitations on the claim that are not found in the claims themselves. Finally, no party presented any prosecution history as to the meaning of "inhibiting" that would justify giving it a limited meaning.

In this context, inhibiting means slowing down or impeding, in whole or in part, a person's blood sugar level from increasing or going up higher than it otherwise would but for the method employed. *See* Pl.'s Reply at 2:14-16. This definition, however, only reiterates the plain meaning of "inhibiting," and therefore does not clarify or aid in understanding a disputed term. *See* *United States Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed.Cir.1997) ("Claims construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what a patentee covered by the claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy."). Accordingly, the Court declines to construe this language.

Disputed claim language	Plaintiffs' construction	Defendants' construction
in a human patient in need thereof	The preamble is clear on its face, and therefore the court should decline to construe it.	in a human diabetic patient who has an above-normal blood glucose level, or is expected to suffer an increase in blood glucose level above a normal level.

A "patient" is one who is suffering from any disease or behavioral disorder and is under treatment for it.

This disputed claim language also appears in the preamble. The parties agree that this phrase is limiting, but disagree that it needs to be construed. At the hearing, Defendants submitted documents from the prosecution history of United States Patent No. 6,485,760 and of the '459 divisional patent to demonstrate that Plaintiffs differentiated prior art by emphasizing that these patents envisioned use of the corosolic acid in human beings. *See* Declaration of Sri Sankaran Regarding Exhibits Used at Claim Construction Hearing ("Sankaran

Decl.") Ex. A at 7-8 ("It is respectfully submitted that it is and would be totally improper to conclude that one skilled in the art would learn or believe from Murakami that corosolic acid would be effective in treating blood sugar imbalances in human patients much less what a suitable dosage should be for this utility. That is, the disclosure of Murakami is limited to the results of in vitro tests using tumor cells and rats.... one skilled in the art would not try to and could not predict whether the concentrate would be effective to inhibit an increase in or reduction in human blood sugar level when an undisclosed dosage amount of concentrate is orally administered to a *human being*.") (emphasis in original); Ex. B at 2 ("Applicants note that claims drawn to methods of treating a human diabetic patient have been allowed in the priority application. The presently filed divisional application is directed to the patentable compositions used in the allowed methods."). Defendants argue that a human patient as referenced in the patent is a diabetic patient, one whose blood sugar level is elevated or is expected to be elevated. Plaintiffs object to this proposed construction because it is too restrictive; they argue that a "patient" could be someone who desires to inhibit from rising or to lower a blood sugar level without having a diabetes diagnosis or being at risk for diabetes, for example, to slow down weight gain. Plaintiffs point to the prosecution history of the '760 patent submitted by Defendants, which at one point references a human being, not a human patient. *See* Sankaran Decl. Ex. A at 8.

The Court is not convinced that this phrase needs construction. Defendants point to no intrinsic or extrinsic evidence to support limiting the term "patient" to the definition proposed by Defendants. The patentee could have specified in the claims that the human patient be diabetic, but chose not to and instead made the claim more broad. The specification contains numerous references to treatment of diabetes using corosolic acid. *See, e.g.* '459 patent at col. 1, lines 32, 45, 61; col. 2, lines 16. However, importing Defendants' restrictive proposed construction would improperly read limitations from the specification into the claim. Moreover, a person may be a "patient" without necessarily having a particular confirmed diagnosis or being under current treatment. Defendants' proposed construction would simply invite more questions about what constitutes "under treatment" in terms of frequency of contact with and type of treatment provider.

Indeed, Defendants' proposed construction of "patient" is subsumed within the plain language of the last portion of this claim phrase, "in need thereof." If a patient has or is expected to have an above-normal blood glucose level, then that patient would be "in need thereof" of the patent invention, which purports to inhibit an increase in or lower blood sugar levels. This is evident from the context of the claims themselves and from the specification. If a person has normal blood sugar level and no reason to try to prevent an increase in blood sugar, then he or she is not "in need thereof" under the patent, and would therefore not fall within the claim language.

Finally, this phrase is not beyond the understanding of a typical juror. The Court finds no reason to import a more restrictive construction of the phrase "in a human patient in need thereof" than its ordinary meaning. Accordingly, the Court declines to construe this phrase.

Disputed claim language	Plaintiffs' construction	Defendants' construction
blood sugar level	The concentration of glucose in blood	Agreed

The parties agree on the construction of this term. Therefore, the Court adopts the agreed construction of "blood sugar level."

Disputed claim language	Plaintiffs' construction	Defendants' construction
consisting essentially of	The invention necessarily includes the listed components and is open to unlisted ingredients that do not materially affect the basic and novel properties of the claim.	The transitional phrase, "consisting essentially of," signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the claim. Thus, as used in this claim, the transitional phrase should be read so as to exclude any ingredients that affect the ability of the claimed composition to prevent blood glucose level from rising above a normal level, or to lower blood glucose level to a normal level.

There is essentially no dispute as to the meaning of this phrase. The phrase "consisting essentially of" is a middle ground transitional phrase used to signal a partially open claim in a patent. *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed.Cir.1998) (A "consisting essentially of" claim occupies a middle ground between closed claims that are written in a "consisting of" format and fully open claims that are drafted in a "comprising" format.). At the hearing, the parties agreed that the first sentence of Defendants' proposed construction and Plaintiffs' proposed construction were essentially the same and constituted an accurate statement of the law. The second sentence of Defendants' proposed construction unduly restricts this transitional phrase and incorporates the flaws in its proposed construction of the first disputed term. Therefore, the Court adopts the following construction of "consisting essentially of:" "the invention necessarily includes the listed components and is open to unlisted ingredients that do not materially affect the basic and novel properties of the claim."

Disputed claim language	Plaintiffs' construction	Defendants' construction
concentrate	A compound extracted from the leaves of the Banaba plant (<i>Lagerstroemia speciosa</i> , Linn. or Pers.).	A substance which is extracted from the leaves of the <i>Lagerstroemia Speciosa</i> , Linn. or Pers., and which is concentrated.

There is essentially no dispute about the meaning of this term. At the hearing, Plaintiffs agreed that the words, "which is concentrated," should be included in the construction. In addition, for ease of reference, the parties agreed that the words "Banaba plant" should be used in addition to the plant's Latin name, "*Lagerstroemia speciosa*, Linn. or Pers." Further, there is no meaningful difference between "compound" and "substance," and at the hearing, the parties agreed to the use of the word "substance." Accordingly, the Court adopts Defendants' construction of this term as modified: "A substance which is extracted from the leaves of the Banaba plant (*Lagerstroemia speciosa*, Linn. or Pers.) and which is concentrated."

Disputed claim language	Plaintiffs' construction	Defendants' construction
a concentrate of ethanol or ethanol aqueous solution extract of leaves of <i>Lagerstroemia speciosa</i> , Linn. or Pers.	No construction necessary because the proper approach is to define the terms of the phrase	A substance which is extracted from the leaves of <i>Lagerstroemia speciosa</i> , Linn. or Pers., using ethanol or a solution of ethanol and water, and which is concentrated.

There is essentially no dispute about the meaning of this phrase. Because several terms in this phrase will be construed, construction of this phrase is not necessary. At the hearing, Defendants raised their concern that this phrase could be interpreted to include the use of a hot water solution or some other solution to obtain the extract. The plain language of the patent, however, includes only a concentrate of ethanol or ethanol aqueous solution, so no further construction of this phrase on that point is necessary.

Disputed claim language	Plaintiffs' construction	Defendants' construction
ethanol	The chemical compound represented by the empirical formula C ₂ H ₆ O and variously represented by the molecular formula EtOH, CH ₃ CH ₂ OH and C ₂ H ₅ O.	The chemical compound represented by the empirical formula C ₂ H ₆ O and variously represented by the molecular formula EtOH, CH ₃ CH ₂ OH and C ₂ H ₅ OH.

There is essentially no dispute about the meaning of this claim term. Defendants' construction, however, contains the correctly formatted notations for ethanol. Therefore, the Court adopts Defendants' construction of this term.

Disputed claim language	Plaintiffs' construction	Defendants' construction
ethanol aqueous solution	Ethanol dissolved in water	A solution of ethanol and water

There is no real dispute about the meaning of this term. As the parties agreed at the hearing, the Court adopts Defendants' construction.

Disputed claim language	Plaintiffs' construction	Defendants' construction
a corosolic acid content of 0.01 to 15 mg per 100 mg of the concentrate	No construction necessary because the proper approach is to define the terms of the phrase	having corosolic acid content between .01 and 15 mg per 100 mg of the total substance.

There is essentially no dispute about the meaning of this claim phrase. Plaintiffs argue that Defendants' construction does not add anything to or otherwise clarify the plain language of the phrase. This phrase, which reflects the plain language in the specification, needs no further construction, especially because terms within this phrase will be construed separately.

Disputed claim language	Plaintiffs' construction	Defendants' construction
corosolic acid	A member of the chemical family of triterpenoids or triterpines including 2-a-Hydroxyursolic acid; Hydroxyursolic acid; and 2, 3-Dihydroxyurs-12-en-28-olc acid having the structural formula [contained in the formula shown in column two of the patent] .	Corosolic acid is one of the triterpenoids having the structural formula shown in column 2 of the patent.

There is essentially no dispute about the meaning of this term. At the hearing, Plaintiffs clarified that they included the additional language regarding triterpines in their proposed construction to reflect information

from experts regarding corosolic acid. This language, however, is not found in the specification. Moreover, at the hearing, Plaintiffs agreed that it is not necessary to have the language regarding triterpenes in a construction of this term. In addition, the specification itself contains a definition of corosolic acid, and Plaintiffs have provided no reason to deviate from that. *See* '459 patent at col. 2 at ll. 48-63. Therefore, the Court adopts Defendants' construction as follows: "Corosolic acid is one of the triterpenoids having the structural formula shown in column 2, lines 50-63 of the patent."

Disputed claim language	Plaintiffs' construction	Defendants' construction
ethanol solution contains 50 to 80 by weight of ethanol	An ethanol and water solution which contains, by weight, between 50 percent ethanol and 80 percent ethanol	Agreed

The parties agree on the construction of this term. Therefore, the Court adopts Plaintiffs' construction.

IT IS SO ORDERED.

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