UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

SOURCEONE GLOBAL PARTNERS, LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	**Magistrate Judge Sidney I. Schenkier**
KGK SYNERGIZE, INC.,	)	
	)	**Case No. 08 C 7403**
Defendant.	)	
	)	
KGK SYNERGIZE, INC.,	)	
	)	
Counterclaim Plaintiff and Third-Party Plaintiff,	)	
	)	
v.	)	
	)	
SOURCEONE GLOBAL PARTNERS, LLC, d/b/a SOURCEONE GLOBAL PARTNERS, d/b/a SOURCEONE GLOBAL PARTNERS LLP, and f/k/a SOURCEONE, GLOBAL, LLC,	)	
	)	
Counterclaim Defendant.	)	

MEMORANDUM OPINION AND ORDER

The plaintiff, SourceOne Global Partners, LLC, d/b/a SourceOne Global Partners, d/b/a SourceOne Global Partners, LLP, and f/k/a Source One Global, LLC ("SourceOne"), has filed a thirteen-count complaint which seeks, among other things, declaratory and injunctive relief in connection with three patents—United States Patent Nos. 6,251,400 ("the '400 patent"), 6,239,114 ("the '114 patent"), and 6,987,125 ("the '125 patent"). All three patents are owned, in

whole or part, by defendant and counterclaimant, KGK Synergize, Inc. ("KGK").[1] In its counterclaim, KGK alleges, among other things, infringement of the '400, '114, and '125 patents.

All three patents pertain to compositions and methods for treating disease. The '400 patent application, entitled "Compositions and Methods of Treatment of Neoplastic Diseases and Hypercholesterolemia with Citrus Limonoids and Flavonoids and Tocotrienols" was filed on September 26, 1997, and issued on June 26, 2001. The '114 patent application, entitled "Compositions and Methods for Treatment of Neoplastic Diseases with Combinations of Limonoids, Flavonoids and Tocotrienols," was a continuation-in-part of the application that led to the '400 patent. The application for the '114 patent was filed on January 12, 2000, and the patent issued on May 29, 2001. The application for the '125 patent, entitled "Compositions and Methods of Treating, Reducing and Preventing Cardiovascular Diseases and Disorders with Polymethoxyflavones," was filed on March 17, 2000, and the patent issued on January 17, 2006.

The case is before the Court for construction of disputed claim language in these three patents.[2] In an order dated October 21, 2009, we directed the parties to agree on no more than ten terms and/or phrases to be submitted to the Court for claim construction, pursuant to Local Patent Rule 4.1(b) (doc. # 89). The parties have submitted seven claims with disputed terms for construction, and they have filed extensive briefs presenting their respective positions

[1]KGK is the sole owner of the '114 and '400 patents. KGK and the United States Government co-own the '125 patent. This Court previously held that SourceOne's claims in connection with the '125 patent may proceed in the absence of the Government as a party. *See SourceOne Global Partners, LLC v. KGK Synergize, Inc.*, 08 C 7403, 2009 WL 1346250 (N.D. Ill. May 13, 2009), *motion for reconsideration denied*, 2009 WL 1916380 (N.D. Ill. June 29, 2009).

[2]On February 27, 2009, by consent of all parties and pursuant to 28 U.S.C. § 636(c), the case was assigned to this Court for all proceedings, including entry of final judgment (doc. # 27).

concerning how each disputed claim term should be construed. In this memorandum opinion and order, we set forth the Court's construction of those terms and the rationale for each construction that we reach.[3]

I.

Claim construction is a matter of law decided by the Court. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 387 (1996). Claim terms "are generally given their ordinary and customary meaning." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). The ordinary meaning "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 . . . ." *Id.* at 1313. A 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.*

In some cases, the ordinary meaning of a claim term as understood by a person of ordinary skill in the art may be readily apparent to the Court, and claim construction "involves little more than the application of the widely accepted meaning of commonly understood words." *Phillips*, 415 F.3d at 1314. However, because the ordinary meaning "is often not immediately apparent, and because patentees frequently use terms idiosyncratically," the Court looks to "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.*

[3]The parties have agreed that the issues have been fully briefed and declined the Court's offer to hold a *Markman* hearing. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 387 (1996) (holding that expert testimony to assist a district court in claim construction is often helpful but not required).

After the claims themselves, the specification of the patent is "the single best guide to the meaning of a disputed term" and is usually dispositive. *Phillips*, 415 F.3d at 1315. A patent is "a fully integrated written instrument," consisting principally of the specification, which "describe[s] the manner and process of making and using" the patented invention. *Id.* The specification concludes with the claims, which consist of both limitations within the body of each claim as well as a preamble that introduces the subject matter of each claim. "A preamble to a claim may or may not be limiting, depending on the circumstances." *Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1366 (Fed. Cir. 2010).

In construing disputed claim terms, a court "should also consider the patent's prosecution history, if it is in evidence." *Phillips*, 415 F.3d at 1315. The prosecution history is part of the patent's intrinsic evidence. It consists of the complete record of proceedings before the United States Patent and Trademark Office ("PTO") and includes the prior art cited during the examination of the patent, providing evidence of how the inventor and the PTO understood the patent. *Id.* at 1317. District courts also are authorized to rely on evidence extrinsic to the patent, such as dictionaries, treatises, and inventor or expert testimony concerning "relevant scientific principles, the meaning of technical terms, and the state of the art." *Phillips*, 415 F.3d at 1314, 1317. Extrinsic evidence, however, is "unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1319.

II.

Applying these rules of claim construction, we now proceed to analyze the claim terms disputed by SourceOne and KGK. We begin with the '400 patent, and, in particular, Claim 1 of

that patent. Claim 1 reads as follows: "A pharmaceutical composition for treating breast cancer in a human subject, said composition comprising anti-neoplastic effective amounts of: a citrus limonoid selected from the group consisting of limonin and nomilin, and a tocotrienol" (*Id.*).[4] The parties dispute the proper construction of the phrase "a pharmaceutical composition for treating breast cancer in a human subject," which appears in the preamble to Claim 1 (doc. # 92: Joint Appendix ("J.A.") at 12, '400 patent, Col. 14, lines 11–17). The parties also disagree about whether the preamble should be considered a limitation of the claim.

A.

SourceOne contends that the preamble of Claim 1 serves as a limitation on the scope of the claim, while KGK argues that the preamble is not a limitation of the claim. There is a presumption against reading preamble language as a claim limitation "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" or "to give context for what is being described in the body of the claim." *Symantec Corp. v. Computer Assocs. Int'l, Inc.*, 522 F.3d 1279, 1288 (Fed. Cir. 2008); *see also Marrin v. Griffin*, 599 F.3d 1290, 1294-95 (Fed. Cir. 2010). Conversely, a preamble is also construed as a limitation "if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim." *Symantec*, 522 F.3d at 1288 (internal quotations omitted).

"In considering whether a preamble limits a claim, the preamble is analyzed to ascertain whether it states a necessary and defining aspect of the invention, or is simply an introduction to

[4]Citrus limonoids and flavonoids are found in citrus fruits or juices (J.A. at 6-7, '400 patent, Col. 1, lines 40-65; Col. 3, lines 10-25), while tocotrienols are found in palm oil and are a form of Vitamin E (J.A. at 7, '400 patent, Col. 4, lines 20-25).

the general field of the claim." *Hearing Components*, 600 F.3d at 1366 (internal quotations and citations omitted). "A term is often limiting when the patentee has relied on it during prosecution to distinguish prior art, as such reliance demonstrates that the feature disclosed in the preamble is necessary to the patentability of the claim." *Id.*

The prosecution history of the '400 patent persuades us that the preamble to Claim 1 limits the scope of the claim. In response to the application, the examiner issued restriction requirements to separate the claims pertaining to the treatment or prevention of cancer from those pertaining to the treatment or prevention of hypercholesterolemia (*i.e.*, high cholesterol) (J.A. at 78). Following the applicant's amendment to the patent application and election of the claims directed to the treatment of cancer, the examiner continued to reject the claims as overly broad, indefinite, and not sufficiently distinct from the prior art (J.A. at 119-23, 139-47). Eventually, the applicant and the examiner reached agreement to overcome the examiner's rejections (J.A. at 159). The examiner made his own amendments to the claims, which included expanding the preamble to Claim 1, limiting the claims to "[a] pharmaceutical composition for treating breast cancer in a human subject" (J.A. at 161–64).

This prosecution history – and the examiner's amendment, in particular – demonstrates that some of the words in the preamble to Claim 1 are "necessary to the patentability of the claim." *Hearing Components*, 600 F.3d at 1366. The preamble, which narrowed the claim to the treatment of cancer, and breast cancer in particular, was relied upon to distinguish the claimed invention from the prior art and to overcome the examiner's restriction requirements. KGK correctly points out that the examiner did not explain the reason that he narrowed the claim

to breast cancer (KGK's Surreply at 6). However, even where no explanation of the examiner's action is given, the Court "presume[s] that the PTO had a substantial reason related to patentability for including the limiting element added by amendment." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 33 (1997); *Schoenhaus v. Genesco, Inc.*, 440 F.3d 1354, 1359 (Fed. Cir. 2006). The burden is on KGK – the patent holder – to establish the reason for an amendment required during patent prosecution. *Warner-Jenkinson*, 520 U.S. at 33-34. KGK may not simply rely on the examiner's silence, as KGK seeks to do. *Id.* If the applicant did not wish to limit the claim scope to treating "breast cancer in a human subject," the applicant should have raised objections to the examiner's amendment before the claims issued as the '400 patent. We conclude that the preamble limits the scope of Claim 1 to the treatment of breast cancer in a human subject.

The words, "pharmaceutical composition," however, unlike the limiting terms, "for treating breast cancer in a human subject," are "simply an introduction to the general field of the claim." *Hearing Components*, 600 F.3d at 1366. They are "reasonably susceptible to being construed to be merely duplicative of the limitations in the body of the claim (and w[ere] not clearly added to overcome a rejection)." *Symantec*, 522 F.3d at 1288-89. While we "presume that the PTO had a substantial reason related to patentability for including the *limiting element* added" by the words "for treating breast cancer in a human subject," *Warner-Jenkinson*, 520 U.S. at 33 (emphasis added), the words "pharmaceutical composition" are not limiting. Rather, as explained further below, those words simply describe the components of the invention as listed in the claim limitations. Absent any indication in the specification or prosecution history

that "pharmaceutical composition" is more than descriptive of the limitations in the claims, we assume that these terms are not a separate limitation. *Symantec*, 522 F.3d at 1289. As in *Symantec*, all of the words of the preamble were added concurrently to overcome the same prior art, but the words "pharmaceutical composition" did not have their own independent significance. *Symantec*, 522 F.3d at 1289.

Thus, we find that it is proper to construe the words "for treating breast cancer in a human subject" to be a limitation to Claim 1, while the first words in the preamble, "pharmaceutical composition," merely introduce the claim.

B.

Having determined that the preamble limits the scope of Claim 1, we now construe the phrase "a pharmaceutical composition for treating breast cancer in a human subject."[5] SourceOne proposes construing this phrase as "a drug; *i.e.*, a substance used in the treatment or prevention of a disease intended to give medical aid to prevent or inhibit breast cancer in a human subject" (*see* doc. # 91: SourceOne's Br. at 9 and 12). By contrast, KGK proposes the following construction: "a formulation or preparation that is (a) suitable and safe for administration to mammals and (b) capable of preventing or inhibiting transformation of preneoplastic cells to tumor cells, or tumor cell proliferation, invasion or metastasis" (doc. # 101: KGK's Br. at 20). For the following reasons, we do not agree with either proposed construction.

[5]Although the parties discuss this phrase in two parts – "a pharmaceutical composition" and "for treating breast cancer in a human subject" – it is a basic tenet of patent law that "claims must be construed in a way that comports with the instrument as a whole," and that "preserves the patent's internal coherence." *Versa Corp. v. Ag-Bag Int'l Ltd.*, 392 F.3d 1325, 1336 (Fed. Cir. 2004) (quoting *Markman*, 517 U.S. at 389–90). Construing the disputed phrase in pieces would be more likely to lead to inconsistent or erroneous constructions; accordingly, we construe the disputed phrase as a whole, and in the context of the entire patent.

In construing the disputed terms, we look first to the '400 patent's specification. *See Phillips*, 415 F.3d at 1315. Initially, KGK's description of the claimed invention as a "formulation or preparation" rather than a single "substance," finds ample support in the specification. The '400 patent repeatedly refers to the invention as a formulation or preparation of various substances (*see, e.g.*, J.A. at 9, '400 patent, Col. 8, lines 44-67). Thus, the Court adopts the terms "formulation or preparation" as part of the construction.

Contrary to KGK's arguments, however, the '400 patent does not teach that the description of the formulation as "pharmaceutical" is "merely" a synonym for "purity and safety" or "suitable" (*see* KGK's Br. at 17). Nor does the '400 patent teach that the formulation is suitable and safe for "administration to mammals," because that would contradict the plain language which claims an invention "for treating breast cancer *in a human subject*." Moreover, contrary to SourceOne's contentions, the word "drug" should not be substituted for "pharmaceutical." Where KGK's proposed construction would improperly expand the scope of Claim 1, SourceOne's proposed construction would improperly narrow its scope. The '400 patent does not state that the "pharmaceutical composition" must be a "drug" rather than some other formulation consistent with the language in Claim 1, that it is "for treating breast cancer." SourceOne cites to numerous dictionary definitions in support of its proposed construction (*see* SourceOne's Br. at 9-10). However, one potential shortcoming of relying on dictionary definitions in particular is that it "focuses the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent." *Phillips*, 415 F.3d at 1321. The dictionary evidence cited by SourceOne – which is secondary to the language in the patent

itself – does not persuade us to ascribe to the term a meaning not set forth in the specification or prosecution history.[6]

Rather, as explained above, the meaning of "pharmaceutical" as used in Claim 1 is evident from the words of the claim itself, as well as from the specification. The "pharmaceutical composition," or the "pharmaceutical formulation or preparation" as construed by the Court, would be understood by a person of skill in the art as simply introducing and describing the components of the invention.[7] The limitations in Claim 1 "define[] a structurally complete invention," while the words "pharmaceutical composition" are "merely duplicative of" and "give context for" the limitations in the body of the claim. *Symantec*, 522 F.3d at 1288-89. The body of the claim states that the invention would be comprised of a certain formulation or preparation of citrus limonoids, citrus flavonoids, and/or tocotrienols that would be used to treat breast cancer. Thus, we find that "pharmaceutical" as used in Claim 1 of the '400 patent is merely descriptive and needs no further construction.[8]

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[6]SourceOne also argues that the claim should be limited to a "drug" because the invention is "directed at the treatment of breast cancer, a deadly disease which requires professional care and highly refined and purified drugs to treat" (doc. # 111: SourceOne's Reply at 8). This argument, however, further demonstrates how adding the term "drug" may alter or narrow the meaning of the claim – such as by implying something "highly refined and purified."

[7]The parties dispute the probative value of additional patents to the claim construction at issue. KGK attaches the prosecution history of U.S. patent application number 09/481,724 ('724 patent), and SourceOne attaches U.S. Patent No. 5,919,818 ('818 patent). The '724 patent application (abandoned before any patent issued) was a continuation-in-part application to the '400 patent, and the '818 patent was cited in the prosecution of the '400 patent. While these patents are of limited probative value, the Court notes that these patents support the Court's decision not to further construe the word, "pharmaceutical." In the '724 patent, the examiner noted that lemon juice, beet juice, and bee honey could all be "pharmaceutical compositions" (KGK's Br. at 15 n.15), while the '818 patent showed that pharmaceutical compositions may take numerous forms, such as tablets, capsules, powders, solutions, lotions, or creams (KGK's Br. at 18). This is further evidence that the words "pharmaceutical composition" merely describe a variety of potential formulations or preparations.

[8]The term "pharmaceutical composition" is also used in asserted Claims 2, 4, and 5 of the '400 patent. The parties do not argue that the term should be construed differently in those claims than in Claim 1. We find that the presumption that the same claim terms in the same patent carry the same construed meaning applies here. *See Omega Eng'g., Inc., v. Raytek Corp.*, 334 F.3d 1314, 1334 (Fed. Cir. 2003).

The limiting phrase, "for treating breast cancer in a human subject," further shows that "pharmaceutical composition" simply describes the subsequent limitations set forth in the claim. KGK and SourceOne agree that "treating" breast cancer should be read as "prevent[ing] or inhibit[ing]" breast cancer (SourceOne's Br. at 12; KGK's Br. at 19).[9] The parties disagree, however, on what meaning is imparted by use of the preposition "for," found in the phrase "for treating breast cancer." KGK argues that it means "capable of" (KGK's Br. at 19), while SourceOne contends that it means "intended to" (SourceOne's Br. at 12). SourceOne's construction as "intended to" is narrower, and would mean that the invention in Claim 1 would be used for the sole purpose of treating breast cancer, while KGK's construction as "capable of" is broader, and would mean that the invention covers any use within any art, so long as one of these uses could be treating breast cancer.

The prosecution history in this case is instructive in resolving the dispute about how the word "for" should be construed. The original patent application filed on September 26, 1997, included claims directed to hypercholesterolemia (high cholesterol) and neoplastic diseases (*e.g.*, cancer). However, as explained above, the examiner issued a restriction requirement, because he found that the claims directed to the treatment of cancer represented a distinct invention from the claims directed to the treatment of hypercholesterolemia (J.A. at 139–40). To continue prosecuting the application, the applicant elected to restrict the application to only those claims

[9]In its entirety, SourceOne argues that the word "treating" should be construed to mean as "used in the treatment or prevention of a disease intended to give medical aid to prevent or inhibit . . ." The words before "to prevent," however, are redundant. The disputed phrase already indicates that the invention is for treating a disease – breast cancer – which inherently connotes a "medical" use. Courts eschew redundant constructions, so we decline to adopt SourceOne's excess verbiage. *See Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp.*, 587 F.3d 1339, 1348 (Fed. Cir. 2009) (finding that the patent drafters could not have intended to claim "soluble calcium sulfate anhydrite" because the word "anhydrite" would be redundant).

that were directed to the treatment of cancer (J.A. at 140). Then, following an interview on August 24, 1999 (J.A. 159), the examiner further limited Claim 1, issuing an amendment to the preamble which specified that the invention is for the treatment of *breast* cancer in particular (J.A. 162–64).

A patent applicant disclaims, or surrenders, protection of certain subject matter if during prosecution, the applicant's statements constitute "a clear and unmistakable" surrender of subject matter. *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1342 (Fed. Cir. 2009) ("since, by distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover, he is by implication surrendering such protection."). Here, the applicant's election to pursue only those claims directed to the treatment of cancer was a "clear and unmistakable" disclaimer, or surrender, of the claims directed to the treatment of any diseases other than cancer. Further, the limitation added by the examiner's amendment and not contested by the patent applicant– that the claims were directed to breast cancer, specifically – was a "clear and unmistakable" disavowal of claims directed to other types of cancer. As explained above, the Court presumes that the PTO had a substantial reason related to patentability for including the limiting element added by amendment. *Warner-Jenkinson*, 520 U.S. at 33.

If we were to construe the disputed phrase in Claim 1 as KGK requests – as merely a formulation *capable of* treating breast cancer – the limitation of Claim 1 to cancer, and to breast cancer, in particular, would be meaningless. Under KGK's preferred construction, Claim 1 would cover not only other types of cancer, but also other diseases, such as hypercholesterolemia. We decline to construe the claim this way, because it would

impermissibly allow KGK to reclaim what was disclaimed during the prosecution in order to secure the patent. *See Edward Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1334 (Fed. Cir. 2009) ("[The patentee] cannot now reclaim what it disclaimed during prosecution and throughout the specification . . . ."). Therefore, in accordance with the prosecution history, the Court construes the disputed phrase of the '400 patent as "a pharmaceutical formulation or preparation *intended to* prevent or inhibit breast cancer in a human subject."[10]

Finally, we note that KGK proposes that the phrase "breast cancer" should be construed as "transformation of preneoplastic cells to tumor cells, or tumor cell proliferation, invasion or metastasis." However, changing the readily understood word, "cancer," to the more complex phrase, "transformation of preneoplastic cells to tumor cells, or tumor cell proliferation, invasion or metastasis," would unnecessarily complicate the meaning of Claim 1. While the specification of the '400 patent states that "[p]referred compositions of the invention are those which specifically or preferentially prevent transformation of preneoplastic cells to tumor cells, and prevent or inhibit tumor cell proliferation, invasion and metastasis," (J.A. at 6, '400 patent, Col. 1, lines 21–28), these "preferred compositions" are not the "exclusive" compositions. *See Symantec*, 522 F.3d at 1290-91 (holding that it was improper to limit the claims to cover only the preferred embodiment when the specification did not so limit the claims). Furthermore, "the

[10]Because the intrinsic evidence – the prosecution history – convinces the Court that the meaning of the word "for" is "intended to," we do not address SourceOne's numerous dictionary definitions of the word. *See Phillips*, 415 F.3d at 1319 ("[U]ndue reliance on extrinsic evidence poses the risk that it will be used to change the meaning of claims in derogation of the 'indisputable public records' . . . ."). We note that in any event, the proffered dictionary definitions are of little help here. For example, *New Collegiate Dictionary* states that "for" may be defined not only as "used as a function word to indicate *purpose*" and "used as a function word to indicate an *intended* goal," as proposed by SourceOne, but also "used as a function word to indicate *suitability* or fitness," as proposed by KGK (SourceOne's Br. at Ex. 1) (emphasis added). In addition, *Random House Unabridged Dictionary* defines "for" as both "with the object or purpose of" and "appropriate or adapted to" (SourceOne's Br. at Ex. 6). Neither SourceOne nor KGK offers a principled basis to pick one dictionary definition over another.

ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Phillips*, 415 F.3d at 1314. We find that the customary meaning of "breast cancer" that would be understood by a person of ordinary skill in the art at the time of invention and in view of the intrinsic evidence is sufficient to cover all applicable phases of breast cancer development and avoids the confusion to the finder of fact that could result from adopting KGK's proposal.

Based on the foregoing analysis, the Court construes the phrase, "a pharmaceutical composition for treating breast cancer in a human subject," as "a pharmaceutical formulation or preparation intended to prevent or inhibit breast cancer in a human subject." With this construction, Claim 1 of the '400 patent reads: "A pharmaceutical formulation or preparation intended to prevent or inhibit breast cancer in a human subject, said composition comprising anti-neoplastic effective amounts of: a citrus limonoid selected from the group consisting of limonin and nomilin, and a tocotrienol."

III.

Next, we address the claim construction of disputed terms in the '114 patent, which is entitled "Compositions and Methods for Treatment of Neoplastic Diseases with Combinations of Limonoids, Flavonoids and Tocotrienols." The '114 patent is a continuation-in-part of the application of the '400 patent. The parties dispute certain phrases found in Claims 1 and 17 in the '114 patent.

A.

In its entirety, Claim 1 recites:

> A pharmaceutical composition comprising a synergistic combination of at least two compounds selected from the group consisting of a limonoid, a flavonoid and a tocotrienol for treating a mammal at risk of or suffering from cancer, said composition exhibiting synergistic anti-proliferative activity against at least one form of cancer.

(J.A. at 394, '114 patent, Col. 10, lines 19–24). The parties dispute the construction of the preamble in Claim 1, "a pharmaceutical composition," as well as the limitations "for treating a mammal at risk of or suffering from cancer" and "said composition exhibiting synergistic anti-proliferative activity against at least one form of cancer."

1.

Both parties propose the same constructions for "pharmaceutical composition" in the '114 patent – and make the same arguments in support – as they did for the identical words in the '400 patent (*see* SourceOne's Br. at 14; KGK's Br. at 22). Initially, we do not construe these words as a limitation to Claim 1 in the '114 patent. Unlike the case with the '400 patent, those words were part of the claims in the original application for the '114 patent (*see* J.A. at 428). However, as in the '400 patent, there is no indication that the phrase "pharmaceutical composition" is anything other than "simply an introduction to the general field of the claim." *Hearing Components*, 600 F.3d at 1366. The prosecution history of the '400 patent is relevant and instructive as to the construction of similar terms because the '114 patent is a continuation-in-part of the '400 patent. *See Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1368 (Fed. Cir. 2007). And, there is nothing in the prosecution history of either patent to indicate that

the words "pharmaceutical composition" are a "necessary and defining aspect of the invention." *Hearing Components*, 600 F.3d at 1366.

As for construction of "pharmaceutical composition," our analysis for the '400 patent applies equally here. Common claims terms should be interpreted consistently across patents in the same patent family. *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1293 (Fed. Cir. 2005). In the '400 patent, we determined that the specification and words of the claim showed that "composition" meant "formulation or preparation." The specification and claims in the '114 patent show that the term has the same meaning here (*see, e.g.*, J.A. at 394, '114 patent, Col. 10, lines 19-24). Similarly, as in the '400 patent, the word "pharmaceutical" needs no further construction. It simply introduces and describes the limitations in the body of the claim which require that the invention be composed of a combination of a limonoid, flavonoid, and a tocotrienol.

2.

The second disputed phrase in Claim 1 of the '114 patent is "for treating a mammal at risk of or suffering from cancer." SourceOne proposes construing this phrase to mean "for giving medical aid to a mammal at risk of developing or suffering from cancer" (SourceOne's Br. at 16). KGK proposes construing this phrase to mean "suitable for administering to a mammal at risk of or suffering from cancer and capable of preventing or inhibiting transformation of preneoplastic cells to tumor cells, or tumor cell proliferation, invasion or metastasis" (KGK's Br. at 22). As an initial matter, we adopt SourceOne's use of the word "developing" to clarify the meaning of the claim language, "at risk of . . . cancer." Although the

word "developing" does not appear in KGK's proposed construction, KGK agrees with that meaning (*see* KGK's Br. at 22–23 ("[The formulations] may be used for those individuals who are 'at risk' for *developing* cancer.") (emphasis added)). We agree that the addition of this word will add clarity to the claim without altering its meaning or scope.

The parties dispute the meaning of the rest of the phrase. SourceOne seeks the more narrow construction of "for treating" as "for giving medical aid," while KGK proposes the broader "capable of preventing or inhibiting."[11] In the '400 patent, however, the parties agreed that the term "treating" meant "inhibiting or preventing." As explained above, identical claims terms in the same patent family should be construed consistently, and the parties have not provided the Court with any reason to deviate from the previously agreed upon construction of "treating."

Likewise, we again construe the preposition, "for," as "intended for," as opposed to the far broader words "capable of." As a continuation-in-part of the application that led to the '400 patent, the claims of the '114 patent must be construed in light of the restriction requirement in the prosecution history of the '400 patent. *Omega Eng'g., Inc., v. Raytek Corp.*, 334 F.3d 1314, 1333 (Fed. Cir. 2003). As explained above, the patentee made a "clear and unmistakable" disclaimer of claim scope in its prosecution of the '400 patent, giving up all claims directed to the treatment of diseases other than cancer, such as hypercholesterolemia. *Id.* "[W]e presume, unless otherwise compelled, that the same claim term in the same patent or related patents carries the same construed meaning." *Id.* at 1334. Moreover, "[w]hen multiple patents derive

[11]SourceOne again points to extrinsic evidence – dictionary definitions – to support its proposed construction. Because the Court is able to construe the claim in light of the intrinsic evidence, we do not analyze the numerous dictionary definitions provided by SourceOne (SourceOne's Br. at 16).

from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation." *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 980 (Fed. Cir. 1999). Consequently, the Court construes the word "for" to mean "*intended* to," as it did in construing that same word in the '400 patent.

Similarly, as we did with respect to the '400 patent, we reject KGK's complex definition of "cancer." *See Terlep v. Brinkmann Corp.*, 418 F.3d 1379, 1382 (Fed. Cir. 2005) (holding that claim construction is "a way of elaborating the normally terse claim language in order to understand and explain, but not to change, the scope of the claims"). Consistent with our construction of the same term in the '400 patent, we find that the customary meaning of "cancer" that would be understood by a person of ordinary skill in the art at the time of invention and in view of the intrinsic evidence is sufficient to cover all applicable phases of cancer development and avoids the confusion to the finder of fact that could result from adopting KGK's needlessly long and complex proposed construction.

We also find that it is unnecessary to insert the word "development" before "at least one form of cancer" as SourceOne has done in its proposal because it is not essential to the proper construction of the claim, and may impermissibly narrow the meaning of cancer to include less than all of its phases.[12] The words, "at least one form of cancer," need no further construction. Thus, we construe the phrase "for treating a mammal at risk of or suffering from cancer" to mean "intended to treat a mammal at risk of developing or suffering from cancer."

[12]The Court further notes that SourceOne did not deem it necessary to add the term "development in its proposed construction of cancer in the '400 patent.

3.

The third disputed phrase within the claim is "said composition exhibiting synergistic anti-proliferative activity against at least one form of cancer." "[S]aid composition" refers to the preceding "pharmaceutical composition comprising a synergistic combination of at least two compounds consisting of a limonoid, a flavonoid and a tocotrienol . . ." SourceOne proposes reading the disputed phrase as "the combination of two or more substances preventing or inhibiting the development of at least one form of cancer to a greater degree than would the same amount of any one of the individual substances" (SourceOne's Br. at 18). KGK proposes construing the phrase as "said combination of two or more substances prevents or inhibits transformation of preneoplastic cells to tumor cells, or tumor cell proliferation, invasion or metastasis; and an amount of the combination causes a greater effect than is caused by the same amount of any individual substance" (KGK's Br. at 23).

First, we address the disputed word "cancer," which appears in the claim for the second time. "[T]he same word appearing in the same claim should be interpreted consistently." *Acromed Corp. v. Sofamor Danek Group, Inc.*, 253 F.3d 1371, 1382 (Fed. Cir. 2001) (quoting *Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1345 (Fed. Cir. 1998)); *see also Phillips*, 415 F.3d at 1314 ("Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims."). Consistent with our construction of the previous phrase, we conclude that the word "cancer" requires no construction.

Next, we look at each party's respective proposal to construe "exhibiting synergistic anti-proliferative activity." Both parties agree that the claim is limited to a combination of two or more substances that prevent or inhibit cancer. Their proposals differ, however, in that SourceOne maintains that the combination must "inhibit[] or prevent[]" cancer "to a greater degree" than an individual substance, while KGK proposes that the combination must simply "cause[] a greater effect" on cancer than an individual substance. KGK's construction is much broader because it could refer to any effect on cancer rather than the effect of preventing and inhibiting cancer. KGK's construction would impermissibly broaden the meaning of the claim beyond its stated limitation to prevent or inhibit cancer. Thus, we adopt the more accurate language in SourceOne's proposal, and we construe the phrase to mean "said combination of two or more substances preventing or inhibiting at least one form of cancer to a greater degree than would a same amount of any one of the individual substances."

As a whole, we construe Claim 1 as follows: "A pharmaceutical formulation or preparation comprising a synergistic combination of at least two compounds selected from the group consisting of a limonoid, a flavonoid and a tocotrienol intended to treat a mammal at risk of developing or suffering from cancer, said combination of two or more substances preventing or inhibiting at least one form of cancer to a greater degree than would a same amount of any one of the individual substances."

B.

The second claim with disputed terms in the '114 patent, Claim 17, recites:

> A method of treating an individual at risk of or suffering from cancer, comprising; administering to an individual *a pharmaceutical composition*

> comprising a synergistic combination of at least two compounds selected from the group consisting of a limonoid, a flavonoid and a tocotrienol, *said composition exhibiting synergistic anti-proliferative activity against at least one form of cancer*.

(J.A. at 395, '114 patent, Col. 11, lines 23–30) (emphasis added). The parties dispute two phrases in Claim 17: "a pharmaceutical composition;" and "said composition exhibiting synergistic anti-proliferative activity against at least one form of cancer." Both of these phrases also appear in Claim 1. As explained above, claim terms should normally be construed consistently throughout a patent. *Phillips*, 415 F.3d at 1314. Indeed, both parties propose the same construction for these phrases as they did for Claim 1 (*see* KGK's Br. at 21-23; SourceOne's Br. at 14-18), and we see no reason for the Court to construe the identical phrases differently in Claim 17 than it did in Claim 1. Therefore, we give the same construction to the identical phrases in Claim 17 as in Claim 1.

IV.

Finally, we address the claim construction of the disputed terms in three independent claims in the '125 patent, entitled "Compositions and Methods of Treating, Reducing and Preventing Cardiovascular Diseases and Disorders with Polymethoxyflavones." Claims 1 through 3 of the '125 patent recite:

> Claim 1: A composition for reducing apolipoprotein B production comprising an apolipoprotein reducing amount of a polymethoxyflavone selected from the group consisting of limocitrin-3,5,7,4'-tetraethylether (8,3-dimethoxy-3,5,7,4'-tetraethoxyflavone), limocitrin-3,7,4'-trimethylether-5-acetate, and mixtures thereof.
>
> Claim 2: A composition for reducing apolipoprotein B production comprising an apolipoprotein reducing amount of a polymethoxyflavone selected from the group consisting of sinensetin, tetra-O-methyl-scutellarein, and mixtures thereof.

> Claim 3: A composition for reducing apolipoprotein B production comprising an apolipoprotein reducing amount of a polymethoxyflavone selected from the group consisting of 5-desmethylnobiletin (5-hydroxy-7,7,8,3',4'-pentamethoxyflavone), tetra-O-methylisocutellarein (5,7,8,4'-tetramethoxyflavone), sinensetin (5,6,7,3',4'-pentamethoxyflavone), quercitin tetramethylether (5-hydroxy0-3,7,3',4'-tribenzyl ether, quercetin pentamethylether (3,5,7,3',4'-pentamethyloxyflavone), quercetin-5,7,3',4'-tetramethyl ether-3-acetate, 5,7,3',4'-tetramethylether (3-hydroxy-5,7,3',4'-tetramethoxyflavone), and mixtures thereof.

(J.A. at 672, '125 patent, Col. 10, lines 24–47).

The parties dispute two phrases found in all three independent claims. The first disputed phrase is "a composition for reducing apolipoprotein B production," which appears in the preamble of Claims 1 through 3. The second phrase is similar: "an apolipoprotein reducing amount," which appears as a limitation of Claims 1 through 3.

A.

The first disputed phrase is "a composition for reducing apolipoprotein B ['apoB'] production."[13] The parties agree that this phrase is a claim limitation (KGK's Br. at 8-10; SourceOne's Br. at 19-20). SourceOne proposes construing this phrase to mean "a composition intended to reduce the production of apolipoprotein B" (SourceOne's Br. at 19). KGK proposes a different construction: "a composition having the ability to reduce the production of apolipoprotein B" (KGK's Br. at 8).

As was the case for the previous patents, the parties dispute whether the word "for" implies an intent, as SourceOne contends, or a capability, as KGK contends. The intrinsic evidence, including the prosecution history of the '125 patent, persuades us that SourceOne's proposed construction is correct.

[13]ApoB is the principal protein of low-density lipoprotein ("LDL"), also known as "bad" cholesterol.

The original patent application claimed methods and compositions of an effective amount of polymethoxyflavone that could reduce substances that contribute to cardiovascular diseases or disorders, such as apoB, cholesterol, low density lipoprotein, or very low density lipoprotein (J.A. at 705-06). In an office action dated September 9, 2002, the examiner rejected the original claims as obvious in view of prior art that teaches that polymethoxyflavones may be used in a composition for reducing the level of substances that contribute to cardiovascular diseases or disorders (J.A. at 747).

Subsequently, on March 4, 2003, the applicant canceled all of the original claims and replaced them with ten new claims drawn solely to methods and compositions "for reducing apolipoprotein B production comprising providing an apolipoprotein B reducing amount of a polymethoxyflavone" (J.A. at 752-54). The applicant argued that the prior art "fails to teach compositions or methods for reducing the levels of Apolipoprotein [sic] B production by providing an apolipoprotein B reducing amount" of the composition (J.A. at 757).

On May 20, 2003, the PTO examiner again rejected the applicant's claims for obviousness (J.A. at 764). The examiner explained that the prior art teaches that flavonoids, including polymethoxyflavones, inhibit LDL cholesterol and apoB synthesis, thus reducing apoB levels and lowering the risk of cardiovascular disease (J.A. 765). On August 20, 2003, the applicant canceled most of the prior claims and added six new claims drawn solely to methods and compositions "for reducing apolipoprotein B production comprising providing an apolipoprotein B reducing amount of a polymethoxyflavone" (J.A. at 772-76). The applicant argued that the prior art does not teach that the specifically claimed polymethoxyflavones in the

application are a method for reducing levels of apoB (J.A. 779-80). On September 9, 2003, the examiner again rejected these claims (J.A. at 786), and the applicant appealed (J.A. at 789-804). On July 7, 2004, the applicant canceled the previous claims and added three new claims. These claims recited compounds making up the polymethoxyflavone that were not recited in the prior art (J.A. at 821-25). These claims were allowed and are currently the preamble in Claims 1 through 3 in the '125 patent (J.A. at 829).

The prosecution history shows that the applicant made a "clear and unmistakable" disclaimer of the claim scope in order to achieve patentability, by giving up the reduction of substances other than apoB. KGK's proposed construction of the disputed terms as "having the ability to reduce" apoB production, however, could embrace compositions that are not directed to reduction of apoB. That is an impermissible construction because KGK cannot now recapture claim scope that was given up during prosecution: specifically, the reduction of substances other than apoB. *See Edward Lifesciences*, 582 F.3d at 1334 ("[The patentee] cannot now reclaim what it disclaimed during prosecution and throughout the specification. . . ."). Various language in the specification selected by KGK to support its proposed construction – that polymethoxyflavones are "inhibitors" of apoB production and "result in" the reduction of apoB, and that "an object of" the invention is to provide compositions and methods to reduce, prevent, and/or treat cardiovascular diseases (KGK's Br. at 8-9 and n.2) – is not inconsistent with a construction drawn solely to reducing apoB.

By contrast, SourceOne's proposed construction of the disputed phrase gives meaning to the limitations in the claims required by the PTO examiner. The examiner ultimately approved

claims that were drawn solely to methods and compositions for reducing apoB, and thus, construction of the phrase must be limited to this scope.

Accordingly, we construe the phrase to mean "a composition *intended for* reducing the production of apolipoprotein B."

B.

The second disputed phrase of the '125 patent is "an apolipoprotein reducing amount." SourceOne proposes to construe that phrase to mean "an amount that reduces apolipoprotein B" (SourceOne's Br. at 20). KGK proposes to construe the phrase to mean "an amount that is sufficient to reduce the production of apolipoprotein B" (KGK's Br. at 10). For the reasons discussed below, the Court finds that KGK's proposal is the proper construction of the phrase.

In aid of its proposed construction, SourceOne cites the portion of the specification which states that administering the compound "results in a reduction in the amount of substances in the blood," such as apoB (J.A. at 670, '125 patent, Col. 5, lines 2–7; SourceOne's Br. at 21). SourceOne contends that this portion of the specification implies that the compound is designed to "eliminate quantities of apolipoprotein B that are already present in the blood" (SourceOne's Br. at 21). SourceOne further contends that because the word "production" is already present in the preceding phrase of the claim, it is inappropriate to add that term to the current phrase at issue (SourceOne's Reply at 5).

We disagree. The phrase "an apolipoprotein B reducing amount" is a limitation of claims that includes the previously construed preamble, "a composition for reducing apolipoprotein B production." SourceOne argued in favor of construing the preamble to mean that the

composition is intended for reducing production of apoB, which the Court adopted. It would be internally inconsistent for the Court to construe the first limitation following that preamble to mean that the composition is intended to reduce not production but rather quantities of apolipoprotein B already present in the blood.

We also note that statements in the specification explicitly describe the claimed compositions as having a reducing effect on the *production* of apoB. For example, several compounds were "found to be active as inhibitors of apolipoprotein B (apo-B)[14] production . . . ." (J.A. at 669, '125 patent, Col. 4, lines 61–63), and the compounds tested "have a dose-response inhibitory effect on apo-B production" (J.A. at 672, '125 patent, Col. 9, lines 37–38). Thus, the phrase should be construed as reducing production of apoB, rather than simply reducing apoB.

The rest of KGK's proposed construction, however, is not supported by the language of the patent and is not necessary to give meaning to the claim limitation. KGK proposed construing the phrase "an apolipoprotein reducing amount" as "an amount that *is sufficient* to reduce the production of apolipoprotein B." The words "is sufficient" are unnecessary to give meaning to the phrase, and thus, we construe the phrase as: "an amount that reduces the production of apolipoprotein B."

CONCLUSION

In summary, the claims of the three patents-in-suit are construed as follows:

The '400 patent:

> Claim 1: "*A pharmaceutical formulation or preparation intended to prevent or inhibit breast cancer in a human subject*, said composition comprising anti-

[14] The parties refer to apolipoprotein B as "apoB," while the patent itself lists it as "apo-B."

neoplastic effective amounts of: a citrus limonoid selected from the group consisting of limonin and nomilin, and a tocotrienol."

The '114 patent:

Claim 1: *A pharmaceutical formulation or preparation* comprising a synergistic combination of at least two compounds selected from the group consisting of a limonoid, a flavonoid and a tocotrienol *intended for treating a mammal at risk of developing or suffering from cancer, said combination of two or more substances preventing or inhibiting at least one form of cancer to a greater degree than would a same amount of any one of the individual substances.*

Claim 17: A method of treating an individual at risk of or suffering from cancer, comprising: administering to an individual *a pharmaceutical formulation or preparation* comprising a synergistic combination of at least two compounds selected from the group consisting of a limonoid, a flavonoid and a tocotrienol, *said combination of two or more substances preventing or inhibiting at least one form of cancer to a greater degree than would a same amount of any one of the individual substances.*

The '125 patent:

Claim 1: *A composition intended for reducing the production of apolipoprotein B* comprising *an amount that is sufficient to reduce the production of apolipoprotein B* of a polymethoxyflavone selected from the group consisting of limocitrin-3,5,7,4'-tetraethylether (8,3-dimethoxy-3,5,7,4'-tetraethoxyflavone), limocitrin-3,7,4'-trimethylether-5-acetate, and mixtures thereof.

Claim 2: *A composition intended for reducing the production of apolipoprotein B* comprising *an amount that is sufficient to reduce the production of apolipoprotein B* of a polymethoxyflavone selected from the group consisting of sinensetin, tetra-O-methyl-scutellarein, and mixtures thereof.

Claim 3: *A composition intended for reducing the production of apolipoprotein B* comprising *an amount that is sufficient to reduce the production of apolipoprotein B* of a polymethoxyflavone selected from the group consisting of 5-desmethylnobiletin (5-hydroxy-7,7,8,3',4'-pentamethoxyflavone), tetra-O-methylisocutellarein (5,7,8,4'-tetramethoxyflavone), sinensetin (5,6,7,3',4'-pentamethoxyflavone), quercitin tetramethylether (5-hydroxy0-3,7,3',4'-tribenzyl ether, quercetin pentamethylether (3,5,7,3',4'-pentamethyloxyflavone), quercetin-5,7,3',4'-tetramethyl ether-3-acetate, 5,7,3',4'-tetramethylether (3-hydroxy-5,7,3',4'-tetramethoxyflavone), and mixtures thereof.

The disputed claim terms are construed in accordance with the conclusions set forth in this Memorandum Opinion and Order.

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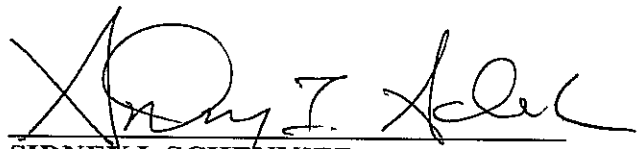

SIDNEY I. SCHENKIER
United States Magistrate Judge

Dated: June 3, 2010