

United States District Court,
N.D. California.

NORDIC NATURALS, INC,
Plaintiff.

v.

J.R. CARLSON LABORATORIES, INC., et al,
Defendants.

No. C 07-2385 PJH

June 6, 2008.

Behrooz Shariati, Jones Day, Palo Alto, CA, for Plaintiff.

William G. Gaede, III, McDermott Will & Emery LLP, Palo Alto, CA, for Defendants.

ORDER CONSTRUING CLAIMS

PHYLLIS J. HAMILTON, District Judge.

Plaintiff Nordic Naturals ("Nordic Naturals") manufactures and distributes flavored gelatin capsules containing fish oils and omega oils. Joar Opheim, inventor of two patents for flavored gelatin fish oil capsules-U.S. Patent No. 6,346,231, issued February 12, 2002 ("the '231 patent"), and U.S. Patent No. 6,652,879, issued November 25, 2003 ("the '879 patent")-assigned the patents to Nordic Naturals. Both patents are directed toward flavored capsules and a method of manufacture of flavored capsules. The '879 patent is a continuation of the '231 patent.

Nordic Naturals filed this action on May 2, 2007, alleging that defendants J.R. Carlson Laboratories, Inc. and Matagenics, Inc. infringed Nordic Naturals' patents by manufacturing flavored fish oil capsules and/or offering them for sale; and also asserting that defendants violated s. 43(a) of the Lanham Act by falsely representing that their fish oil capsules are "lemon-flavored." On June 5, 2007, defendants filed an answer and counterclaim, seeking a declaratory judgment of non-infringement and invalidity of the '231 patent and the ' 879 patent. The parties now seek a judicial construction of nine terms.

DISCUSSION

A. Legal Standard

Patent infringement analysis involves a two-step process. First, the court must determine as a matter of law the correct scope and meaning of disputed claim terms. Second, the properly construed claims are compared to the accused device to see whether the device contains all the limitations (literally or by equivalents) in the claims at issue. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 384, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996).

"[T]he claims of a patent define the invention to which the patentee is entitled the right to exclude." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed.Cir.2005) (citation and quotation omitted); see also Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1248 (Fed.Cir.1998) (claim construction "begins and ends" with the actual words of the claims). The terms used in the claims bear a "heavy presumption" that they mean what they say and have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art. CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed.Cir.2002) (citation omitted).

A patentee is presumed to have intended the ordinary meaning of a claim term in the absence of an express intent to the contrary. *See* York Prods., Inc. v. Central Tractor Farm & Family Ctr., 99 F.3d 1568, 1572 (Fed.Cir.1996). The ordinary and customary meaning of a claim term is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." Phillips, 415 F.3d at 1313. The person of ordinary skill in the art is "deemed to read the claim term not only in the context of the particular claim ... but in the context of the entire patent, including the specification." *Id.* The words in the claim may also be interpreted in light of the prosecution history, if in evidence. Teleflex, Inc. v. Ficosa North Am. Corp., 299 F.3d 1313, 1324-25 (Fed.Cir.2002) (citations omitted).

"[I]ntrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). Only if an analysis of the intrinsic evidence fails to resolve any ambiguity in the claim language may the court then rely on extrinsic evidence, such as expert declarations. *Id.* at 1583 ("In those cases where the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper").

B. The '231 Patent, the '879 Patent, and the Asserted Claims

Soft gelatin capsules are used to provide an easy-to-swallow means of taking fish oil. The technology at issue relates to flavoring gelatin capsules that contain fish oil or other substances having a flavor that certain people, particularly children, find unpleasant.

The '231 patent and the '879 patent relate generally to the use of flavorings in a soft gelatin capsule, in order to improve the palatability and taste of the capsule and its contents. The patents-in-suit teach the provision of fish oil in flavored gelatin capsules, in which the fish oil may also be flavored. The patents-in-suit also teach a method of manufacture of gelatin capsules.

the '231 patent

The claims in the '231 patent are generally directed to a gelatin capsule used for encapsulating a dose of fish oil. The claims recite the specific ranges of concentration for various components, with the purpose of providing a palatable capsule that protects the fish oil from spoiling. The '231 patent also describes and claims a method for manufacturing a gelatin capsule with specific concentrations of ingredients.

The '231 patent has 18 claims. Nordic asserts claims 1-4 and 16 of the '231 patent against defendants.

The '231 patent claims

1. A fish oil capsule for palatable presentation of fish oil comprising:

a) a gelatin capsule, said gelatin capsule comprising gelatin, a gelatin softener, water, and a water soluble flavoring, wherein said water is present in said gelatin capsule in a concentration between about 6% and about 10%, and wherein said water soluble flavoring is present in a concentration between about 0.50% and about 1.50% of said gelatin capsule; and

b) a fish oil dose, said gelatin capsule encapsulating said fish oil dose, whereby said fish oil capsule is a palatable fish oil composition which promotes ingestion of the fish oil.

2. The fish oil capsule claimed in claim 1, wherein said water soluble flavoring is present in a concentration between about 0.5% and about 1.0% of said gelatin capsule.

3. The fish oil capsule claimed in claim 1, wherein said water soluble flavoring is chosen from the group consisting of berry, strawberry, chocolate, cocoa, vanilla, lemon, nut, almond, cashew, macadamia nut, coconut, blueberry, blackberry, raspberry, peach, lemon, lime, mint, orange, banana, chili pepper, pepper, cinnamon, and pineapple.

4. The fish oil capsule claimed in claim 2, wherein said water soluble flavoring is chosen from the group consisting of berry, strawberry, chocolate, cocoa, vanilla, lemon, nut, almond, cashew, macadamia nut, coconut, blueberry, blackberry, raspberry, peach, lemon, lime, mint, orange, banana, chili pepper, pepper, cinnamon, and pineapple.

5. The fish oil capsule claimed in claim 3, further comprising an oil soluble flavoring, wherein said oil soluble flavoring is dissolved in said fish oil dose.

6. The fish oil capsule claimed in claim 4, further comprising an oil soluble flavoring, wherein said oil soluble flavoring is dissolved in said fish oil dose.

7. The fish oil capsule claimed in claim 5, wherein said oil soluble flavoring is chosen from the group consisting of berry, strawberry, chocolate, cocoa, vanilla, lemon, nut, almond, cashew, macadamia nut, coconut, blueberry, blackberry, raspberry, peach, lemon, lime, mint, orange, banana, chili pepper, pepper, cinnamon, and pineapple.

8. The fish oil capsule claimed in claim 6, wherein said oil soluble flavoring is chosen from the group consisting of berry, strawberry, chocolate, cocoa, vanilla, lemon, nut, almond, cashew, macadamia nut, coconut, blueberry, blackberry, raspberry, peach, lemon, lime, mint, orange, banana, chili pepper, pepper, cinnamon, and pineapple.

9. The fish oil capsule claimed in claim 7, wherein said oil soluble flavoring is present in a concentration between about 0.5% and about 1.0% of said fish oil dose.

10. The fish oil capsule claimed in claim 8, wherein said fish oil dose comprises at least one Omega-3 fatty acid chosen from the group consisting of eicosapentanoic acid and docosahexanoic acid.

11. The fish oil capsule claimed in claim 9, wherein said fish oil dose comprises at least one Omega-3 fatty acid chosen from the group consisting of eicosapentanoic acid and docosahexanoic acid.

12. A fish oil capsule for palatable presentation of fish oil comprising:

a) a gelatin capsule, said gelatin capsule comprising gelatin, a gelatin softener, water, and a water soluble flavoring, wherein said water is present in said gelatin capsule in a concentration between about 6% and about 10%, and said water soluble flavoring is present in said gelatin capsule in a concentration between about 0.25% and about 0.50%, and wherein said gelatin capsule comprises between 10 and 35 percent of said gelatin softener, and said gelatin softener comprises at least one polyol, said polyol chosen from the group consisting of glycerol and sorbitol; and

b) a fish oil dose, said gelatin capsule encapsulating said fish oil dose, whereby said fish oil capsule is a palatable fish oil composition which promotes ingestion of the fish oil.

13. The fish oil capsule claimed in claim 12, wherein said fish oil dose has a concentration of Omega-3 fatty acids above about 80%.

14. The fish oil capsule claimed in claim 13, wherein said water soluble flavoring is chosen from the group consisting of berry, strawberry, chocolate, cocoa, vanilla, lemon, nut, almond, cashew, macadamia nut, coconut, blueberry, blackberry, raspberry, peach, lemon, lime, mint, orange, banana, chili pepper, pepper, cinnamon, and pineapple.

15. The fish oil capsule claimed in claim 14, further comprising an oil soluble flavoring, wherein said oil soluble flavoring is dissolved in said fish oil dose.

16. A process for forming a fish oil capsule for palatable presentation of fish oil, comprising the steps of:

a) combining gelatin, a gelatin softener, water, and a water soluble flavoring;

b) forming a gelwatch by heating, melting and mixing said gelatin, said gelatin softener, said water and said water soluble flavoring;

c) forming a flavored capsule comprising a gelatin capsule encapsulating a fish oil dose with a portion of said gelwatch; and

d) drying said flavored capsule to produce a water concentration in said gelatin capsule which is between about 6% and about 10%, and a water soluble flavoring concentration in said gelatin capsule above about 0.25%.

17. The process described in claim 16, wherein the water soluble flavoring is present in a concentration of between about 0.25% and about 1.25% of said gelatin capsule, and wherein an oil soluble flavoring is dissolved in said fish oil dose.

18. The process described in claim 16, wherein the water soluble flavoring is present in a concentration of between about 0.25% and about 1.0% of said gelatin capsule, and wherein an oil soluble flavoring is dissolved in said fish oil dose.

The '879 patent is a continuation of the application that resulted in the ' 231 patent. The '879 patent discloses a flavored gelatin capsule that may be used to encapsulate a dose of a substance, including but not limited to fish oil, and recites specific ranges of components based on discoveries made by the inventor.

The '879 patent has 6 claims. Nordic Naturals asserts claims 1-6 of the ' 879 patent against defendants.

The '879 patent claims

1. A flavored gelatin capsule suitable for encapsulating a dose, said flavored gelatin capsule comprising gelatin, a gelatin softener, water, and a water soluble flavoring, wherein said water soluble flavoring is present in said flavored gelatin capsule in a concentration which is in the range between about 0.25% and about 1.5% of said flavored gelatin capsule, and wherein said water is present in said flavored gelatin capsule in a concentration in the range between about 6% and about 10% of said flavored gelatin capsule, whereby the palatability of a dose encapsulated in said flabored FN1 gelatin capsule is improved by the water soluble flavoring.

FN1. The parties agree that this is a typographical error, and that the correct word is "flavored."

2. The flavored gelatin capsule of claim 1 further comprising a dose encapsulated therein.

3. The flavered FN2 gelatin capsule of claim 1 wherein the water soluble flavoring comprises a flavor chosen from the group consisting of berry, strawberry, chocolate, cocoa, lemon, but, FN3 almond, cashew, macadamia nut, coconut, blueberry, blackberry, raspberry, peach, lemon, lime, mint, orange, banana, chili pepper, pepper, cinnamon, and pineapple.

FN2. The parties agree that the correct word is "flavored."

FN3. The parties agree that the correct word is "nut."

4. The flavored gelatin capsule of claim 1 wherein the gelatin sofener FN4 is present in a concentration in the range between 10% and 35% of said flavored gelatin capsule.

FN4. The parties agree that the correct word is "softener."

5. The flavored gelatin capsule of claim 2 wherein said dose comprises ingredients chosen from the group consisting of medicinal conponents FN5 and nutritive components.

FN5. The parties agree that the correct word is "components."

6. The flavored gelatin capsule fo FN6 claim 5 wherein the concentration of water-soluble flavoring present in said gelatin capsule is in the range between about 0.5% and about 1.5%.

FN6. The parties agree that the correct word is "of."

C The Disputed Terms and the Claims Construction

The disputed terms are "gelatin softener;" "water soluble flavoring;" "palatable" or "palatability;" "gelswatch;" "wherein said water soluble flavoring is present in said flavored gelatin capsule in a concentration which is in the range between about 0.25% and about 1.5% of said flavored gelatin capsule;" "wherein said water is present in said flavored gelatin capsule in a concentration in the range between about 6% and about 10% of said flavored gelatin capsule;" "flavored gelatin capsule;" and "wherein the gelatin softener is present in a concentration in the range between 10% and 35% of said flavored gelatin capsule."

1. water soluble flavoring (claims 1-4 and 16 of the '231 patent; claims 1, 3, and 6 of the '879 patent)

The parties agree that "water soluble" means "easily dissolved in water" or "dissolvable in water." Nordic Naturals proposes that "flavoring" be construed as "a substance or material used to alter the natural flavor, as opposed to the sweetness, of a food item." Defendants propose that "water soluble flavoring" means "a substance that has the capacity to affect the sense of taste and ... in the context of the claims, is present throughout the gelatin capsule shell in the concentration specified by the claims."

There are two main disputes with regard to "water soluble flavoring." The first dispute concerns whether "flavoring" includes or excludes sweeteners. The second concerns whether the term requires that the "water soluble flavoring" be present throughout the capsule in the concentration specified by the claims.

Although the patentee did not specifically define "flavoring," the purpose of the "flavoring" in the patents is clear. Both patents teach that "[t]he taste of many medicinal and nutritive components can be quite distinctive and potentially unpleasant[,] and that "[i]mprovement in the taste of certain drugs and nutritional supplements can lead to a higher compliance by consumers [,]" which, in turn, "will result in a greater commercial success for the drug and supplement manufacture and in increased health and well being particular consumers [sic]." '231 patent, Col. 1:12-18; '879 patent, Col. 1:18-24. The specification of the '231 patent clarifies that "[t]he flavoring of the capsule improves the taste and palatability of the capsule, and will subjectively improve the taste of the gelatin and a dose or contents contained within the flavored gelatin capsule." '231 patent, Col. 2, 17-21.

The specification of each patent provides examples of "suitable flavors known in the art"- "berry, strawberry, chocolate, cocoa, vanilla, lemon, nut, almond, cashew, macadamia nut, coconut, blueberry, blackberry, raspberry, peach, lemon, lime, mint, peppermint, orange, banana, chili pepper, pepper, cinnamon, and pineapple"-but also makes clear that the list is not exclusive. '231 patent, Col. 3:19-27; Col. 2, 22-27; '879 patent, Col. 2:28-33. Dependent claims 3, 4, and 14 of the '231 patent and dependent claim 3 of the '879 patent limit the "water soluble flavoring" to the flavorings listed in those claims, but independent claim 1 of the '231 patent and independent claim 1 of the '879 patent do not include that limitation.

In short, the purpose of the addition of the "flavoring" to the gelatin capsules and/or to the contents of the capsules is to make the fish oil capsules taste like something other than fish oil, which, according to the "Background of the Invention," many people find unpleasant. With the exception of the claims that limit the flavoring to one of a list of flavorings, the use of the term is unspecific, and is focused on the purpose of the patents-to make fish oil more "palatable" for human consumption. Whether that water soluble flavoring contains a sweetener or not is never specified. The specification supports the conclusion that the ordinary meaning of "flavoring" is tied to the sensation of "taste," and includes a broad range of materials that alter the "taste" of the gelatin capsule.

Moreover, the representations made to the Patent and Trademark Office during the prosecution of what

became the '231 patent are inconsistent with Nordic Naturals' assertion that "flavoring" does not include sweeteners. Specifically, Nordic Naturals distinguished over the prior art by stating that the specific prior art reference "does not anticipate adding flavorants or sweetening agents to the gelatin capsules, which is a key point in all of the claims, and particularly claims 4-6." *See* Inventor's Amendment A, June 15, 2000, at 6. The only way to reconcile the representation that "a key point of all the claims" is the addition of "flavorants or sweetening agents," and the fact that the '231 patent refers only to "flavoring" but not to sweeteners, is to construe "flavoring" as including sweeteners.

The second dispute involves defendants' proposal that the "water soluble flavoring" must be "present throughout the gelatin capsule shell in the concentration specified by the claims." Nordic Naturals contends that claims 1-15 of the '231 patent require only that the proper materials be present in the proper proportions, with no requirement that they be uniformly mixed or present throughout the capsule. Nordic Naturals asserts that the capsule shell may be uniformly formed, but may just as easily be comprised of layers or sections of materials, provided that the proportions and percentages in the claims are met.

Both patents-in-suit teach the combining of the "gelswatch" ingredients. *See, e.g.*, '231 patent, Col. 2:45-30; Col. 3:11-27; '879 patent, Col. 2:52-57; Col. 3:19-35. Indeed, every description in the Detailed Description of the Preferred Embodiments in both patents describes the mixing of the gelswatch ingredients. In addition, claim 16 of the '231 patent—the only claim that recites a process for forming a fish oil capsule—teaches "combining gelatin, a gelatin softener, water, and a water soluble flavoring;" "forming a gelswatch by heating, melting an [sic] mixing said gelatin, said gelatin softener, said water, and said water soluble flavoring;" "forming a flavored capsule;" and "drying said flavored capsule" to produce a specified water concentration. '231 patent, claim 16.

The prosecution history confirms that the claims of the patents-in-suit require that the gelswatch ingredients be distributed throughout the gelatin capsule in the stated concentrations. For example, Nordic Naturals noted that "[w]ater content is significant in flavored shells because ... water soluble flavors are employed. Too little water ... results in a distorted unpleasant taste, probably due to uneven distribution of ... flavoring materials." Inventor's Amendment A, June 15, 2000, at 5. In addition, "[o]verly dried shells were ... found to be unpalatable since the water soluble flavoring is unevenly distributed." Inventor's Amendment C, Oct. 17, 2000, at 7. The inventor stated to the Examiner that the "harder capsules" were "unpleasant to the taste because the flavor was not evenly distributed in the capsule." Inventor's Declaration, October 17, 2000, at 3.

"Water soluble flavoring" means "a substance easily dissolved in water, which is used to alter the natural flavor of a food item, and which is present throughout the gelatin capsule shell in the concentration specified by the claims." "Flavoring" as used in the patents-in-suit does not exclude sweeteners.

2. flavored gelatin capsule (claims 1-6 of the '879 patent)

The parties agree as to the meaning of "gelatin capsule." The only dispute concerns the construction of "flavored," which the parties agree depends on the construction of "flavoring" in the term "water soluble flavoring," discussed above.

Nordic Naturals proposes that a "flavored gelatin capsule" is a gelatin capsule "whose natural taste has been altered by a Flavoring," as "flavoring" is defined above. Defendants propose that a "flavored gelatin capsule" is a gelatin capsule "in which flavoring is present throughout the gelatin capsule shell in the concentration specified by the claims."

"Flavored gelatin capsule" means "a gelatin capsule in which flavoring is present throughout, in the concentration specified by the claims." "Flavoring" is "a substance used to alter the natural flavor of a food item" and does not exclude sweeteners.

3. wherein said water soluble flavoring is present in said flavored gelatin capsule in a concentration which is in the range between about 0.25% and about 1.5% of said flavored gelatin capsule (claims 1 and 2 of the '231 patent; claim 1 of the '879 patent)

4. wherein said water is present in said flavored gelatin capsule in a concentration in the range between about 6% and about 10% of said flavored gelatin capsule (claim 1 of the '231 patent; claim 1 of the '879 patent)

5. wherein the gelatin softener is present in a concentration in the range between 10% and 35% of said flavored gelatin capsule (claim 4 of the '879 patent)

The primary disputes with regard to these three terms involve whether the "flavoring" or "water" or "gelatin softener" must be present in the gelatin capsule in the exact concentration specified in the claims, rather than in an approximate concentration; and whether the flavoring must be present throughout the capsule. Nordic Naturals proposes that in terms 3 and 4, "about" be construed as "approximately" or "to within acceptable manufacturing tolerances;" and that in all three terms, "present in" be construed as "present as part of the capsule, as opposed to the fill." Defendants do not believe there is any necessity to separately construe "present in" or "about."

Thus, Nordic Naturals proposes that term 3 be construed as "wherein said water soluble flavoring is present as part of said flavored gelatin capsule in a concentration which is in the range between .25% and 1.5% of said flavored gelatin capsule, within acceptable manufacturing tolerances." Defendants propose that the term be construed as "a flavoring substance that is soluble in water and is present throughout the entire gelatin capsule in the concentration of .25% to 1.5%."

Similarly, Nordic Naturals proposes that term 4 be construed as "wherein said water is present as part of said flavored gelatin capsule in a concentration in the range between 6% and 10% of said flavored gelatin capsule, within acceptable manufacturing tolerances ." Defendants propose that the term be construed as "wherein water is included throughout the gelatin capsule in the concentration from 6% to 10%."

Finally, Nordic Naturals proposes that term 5 be construed as "wherein the gelatin softener is present as part of said flavored gelatin capsule in a concentration in the range between 10% and 35% of said flavored gelatin capsule." Defendants propose that the term be construed as "wherein the gelatin softener, also called a plasticizer, is included throughout the gelatin capsule in the concentration of 10% to 35%."

The court finds that "about" in terms 3 and 4 should be construed as "approximately," or "within acceptable manufacturing tolerances." Claim 1 of the '879 patent describes the concentration range as "between about 0.23% and about 1.5%," while claim 4 of the '879 patent describes the concentration range as "between 10% and 35%." In so doing, the patentee distinguished between concentration ranges that were exact and those that were "approximate." *See Ortho-McNeil Pharm. Labs., Ltd., 476 F.3d 1321, 1327-28 (Fed.Cir.2007)* (specifically identified ratio of "1:5" was "meant to encompass compositions very close to that ratio," while ratio of "about 1:5" as part of stated range "point[ed] to a broad range of ratios"). Thus, it is necessary to

separately construe the qualifier "about" when construing two terms that use "about" and a third similar term that does not.

The court finds further that "present in" means "present throughout the capsule in the stated concentration ranges." The claims in both patents-in-suit set forth a limited acceptable range of the overall percentage of total ingredients present in the gelatin capsules. This "present in ... concentration" term appears in independent claims 1 and 12 of the '231 patent (and some dependent claims) and in claim 1 of the '879 patent and dependent claims 4 and 6) in the following form (from claim 1 of the '231 patent—"[water soluble flavoring] is present in said flavored gelatin capsule in a concentration which is in the range between [stated range].")

The intrinsic record requires that "water soluble flavoring" be present throughout the entire capsule; and the claim language limits Nordic Naturals' claims to the stated ranges of water, water soluble flavoring, and gelatin softener, whether exact or approximate. The specification makes clear that the ingredients used to make the gelatin capsules, including any "flavoring," are heated and thoroughly mixed together. *See '231 patent, Col. 3:28-34.* Moreover, the specification contains no language stating that the "flavoring" or "water" or "gelatin softener" need only be present in "part" of the gelatin capsule.

The prosecution history confirms that the patents require that the components listed be distributed throughout the gelatin capsule in the stated concentrations. The inventor represented to the Examiner that the acceptable ranges of water and water soluble flavoring were not expressly stated in the prior art, and were critical to ensure an even distribution of flavoring throughout the gelatin capsule. *See Inventor's Amendment A, June 15, 2000, at 5; Inventor's Amendment B, Oct. 17, 2000, at 7; Inventor's Declaration, Oct. 17, 2000, at 3; Inventor's Amendment C, Apr. 1, 2001, at 2-3.*

This construction does not require, as Nordic Naturals suggests, that there be a "uniform distribution" of the flavoring, water, and gelatin softener, but rather simply that these components are mixed into the gelswatch so that they are present throughout the gelatin capsule in the specified concentrations.

"Wherein said water soluble flavoring is present in said flavored gelatin capsule in a concentration which is in the range between about 0.25% and about 1.5% of said flavored gelatin capsule" means that the flavoring "is present throughout the gelatin capsule in a concentration in the range between .25% and 1.5% of the flavored gelatin capsule, within acceptable manufacturing tolerances."

"Wherein said water is present in said flavored gelatin capsule in a concentration in the range between about 6% and about 10% of said flavored gelatin capsule" means that the water "is present throughout the gelatin capsule in a concentration in the range between 6% and 10% of the flavored gelatin capsule, within acceptable manufacturing tolerances."

"Wherein the gelatin softener is present in a concentration in the range between 10% and 35% of said flavored gelatin capsule" means that the gelatin softener "is present throughout the gelatin capsule in a concentration in the range between 10% and 35%."

6. **gelatin softener** (claims 1 and 16 of the '231 patent; claims 1 and 4 of the '879 patent)

The parties agree that a person of ordinary skill in the art would understand "gelatin softener" to be a "plasticizer." Nordic Naturals proposes that the term be construed as "a compound used to make a gelatin

capsule more flexible, specifically including glycerol, sorbitol, and other polyols;" while defendants propose that the term be construed simply as "a softener or plasticizer."

Nordic Naturals contends that in order to sufficiently describe what constitutes a softener or plasticizer, with respect to gelatin capsules, it is necessary to provide examples of such softeners-such as "glycerol, sorbitol, and other polyols." Defendants assert, however, that those examples are unnecessary to the claim. For the reasons stated at the hearing, the court finds that the claims of the patents support a construction that includes examples of types of "gelatin softeners."

"Gelatin softener" means "a plasticizer such as glycerol, sorbitol, and other polyols."

7. palatable, palatability (claims 1 and 16 of the '231 patent; claim 1 of the '879 patent)

Nordic Naturals proposes that "palatable" means "having a pleasant or acceptable taste," and that "palatability" is "the property of being palatable." Defendants propose that "palatable" should be construed in its ordinary meaning as "acceptable to the taste," and that "palatability" should be construed as "the quality of acceptance or acceptability to the taste."

Nordic Naturals concedes that the proposed constructions are similar, as each requires that the taste be "acceptable." Nordic Naturals argues, however, that the addition of "pleasant" as in "acceptable *or* pleasant" is consistent with the use of the term "palatable" in the patent.

Nordic Naturals asserts that one of the main goals of the invention is to provide a soft gelatin capsule that is pleasant to the taste in order to persuade people to consume the capsule and its contents. Nordic Naturals also notes that in the prosecution of the patent, the inventor notes that a reference cited by the Examiner "results in a distorted unpleasant taste" (citing Inventor's Amendment A, June 15, 2000, at 5).

Defendants contend that plaintiff's proposed construction of "having a pleasant or acceptable taste" is an attempt to impose additional limitations into the claims. Defendants also assert that Nordic Naturals has cited nothing in the intrinsic record and no extrinsic evidence to support its proposed construction.

The specification and claims of the patents-in-suit make clear that the purpose of the invention is to produce a fish oil capsule that has a taste that is "palatable" to the ordinary consumer. For example, the '231 patent specification states in the "Background of the Invention" that

[t]he taste of many medicinal and nutritive components can be quite distinct and potentially unpleasant. Improvements in the taste of certain drugs and nutritional supplements can lead to a higher compliance by consumers.... As a consequence of this United States market aversion to the taste of fish oils, many residents of the United States are less willing to ingest fish oils and will therefore not benefit from the nutritional and medicinal qualities of fish oils.

'231 patent, Col. 1:12-30, 25-30. To this end, the "Summary of the Invention" explains that the "flavoring of the capsule" as taught in the '231 patent will "improve[] the taste" of the capsule and will also "subjectively improve the taste of the gelatin and a dose or contents contained within the flavored capsule ." '231 patent, Col. 2:17-21.

The purpose of the invention is to eliminate the "unpleasant" taste of the fish oil. While the flavoring, as

explained in the "Preferred Embodiments" may "provide[] an unexpected increase in the palatability of the composition ... by generating a flavored bouquet ..., whereby the consumer is greatly encouraged to ingest the composition ... in a favorable response to his or her olfactory appreciation of the bouquet," '231 patent, Col. 3:67-4:7, the purpose of the patent is not to enable the product of a fish oil capsule with a "pleasant" taste, but rather on that does not have an unpleasant taste-in other words, one that has an "acceptable" taste. Thus, the construction "acceptable" or "not unpleasant" more closely conveys the purpose of the patent as described in the specification.

"Palatable" means "having an acceptable or not unpleasant taste;" **"palatability"** means "the quality of having an acceptable or not unpleasant taste."

8. **gelswatch** (claim 16)

In the Joint Claims Construction Statement, Nordic Naturals proposed that "gelswatch" means "a mass of mixed shell ingredients ready for use in the encapsulation of the fill material, typically formed in sheets or ribbons;" while defendants proposed that "gelswatch" means "a mixture of gelatin, gelatin softener, water, and any additional components of the gelatin capsule shell."

In its opening brief, Nordic Naturals indicated that it was willing to agree to defendants' construction. This agreement was confirmed by counsel for Nordic Naturals at the claims construction hearing.

"Gelswatch" means "a mixture of gelatin, gelatin softener, water, and any additional components of the gelatin capsule shell."

9. **flavored** (claims 1 and 3 of the '879 patent)

In the joint claims construction statement, Nordic Naturals proposes that "flavored" has its ordinary meaning, related to the definition of "flavoring" construed above. That is, Nordic Naturals proposes that "flavored" means "having one's natural taste altered by a flavor." Defendants also propose the ordinary meaning of "flavored," referring to their arguments in the discussion of "flavoring."

Although every word used in a claim has a meaning, not every word requires a construction. United States Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1568 (Fed.Cir.1997). In the present case, neither side has provided a reason for the court to construe "flavored" differently than "flavoring," and it appears to the court that the only distinction between the two words is that each serves a different grammatical function.

"Flavored" means "the taste or flavor having been affected" or "the natural taste having been altered by a flavor."

D. Nordic Naturals' Motion to Strike the Steele Declaration

Nordic Naturals filed a separate motion to strike the Declaration of Donald R. Steele, which defendants filed on February 18, 2008 with their opposition to Nordic Naturals' opening claims construction brief. As the basis for its motion, Nordic Naturals asserts that defendants failed to disclose Mr. Steele's identity or his opinions prior to the February 18, 2008, filing.

As stated at the hearing, the court finds that the motion must be GRANTED, as the Steele Declaration was

filed in violation of Patent Local Rules 4-2 and 4-3.

IT IS SO ORDERED.

N.D.Cal.,2008.

Nordic Naturals, Inc. v. J.R. Carlson Laboratories, Inc.

Produced by Sans Paper, LLC.