

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* MARIAN ANNA VERHEUL-KOOT, CHANTAL NELLEKE  
KLEIJER, ROBERT JOHAN JOSEPH HAGEMAN,  
ROELOF ANDRE BORK, and MAUD GOETHALS<sup>1</sup>

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Appeal 2008-4946  
Application 10/993,348  
Technology Center 1600

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Decided: November 17, 2008

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Before SALLY G. LANE, MICHAEL P. TIERNEY and  
JAMES T. MOORE, *Administrative Patent Judges*.

MOORE, *Administrative Patent Judge*.

DECISION ON APPEAL

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STATEMENT OF CASE

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The Appellants appeal under 35 U.S.C. § 134 (2002) from a final  
rejection of claims 1-4, 7, 8, 10-20, 22, and 23.<sup>2</sup> We have jurisdiction under  
35 U.S.C. § 6(b) (2002).

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<sup>1</sup> The real party in interest is N.V. Nutricia. (App. Br. 1).

<sup>2</sup> Claims 5 and 6 have been objected to as being dependent upon a rejected  
base claim, but would be allowable upon rewriting the claims in independent

1           The Appellants' claims are directed to methods of treating a subject  
2 having pressure ulcers by administering a nutritional composition into the  
3 intestines. In the specification, pressure ulcers, also referred to as  
4 "decubitus" ulcers, are stated to "occur relatively often, especially in  
5 surgery patients and immobile persons ... that have to stay in bed for  
6 extended periods." (Specification p. 1). The specification also states that  
7 "[t]he nutritional condition of decubitus patients is often poor, as a result of  
8 insufficient nutrition following surgical operations, malnourishment, loss of  
9 components from wounds, immobility, physical disability or other  
10 impediments." (Id.).

11           Claims 1, 20, 22, and 23 are the only independent claims in the  
12 application.

13           The Appellants argue claims 1-4, 11-13 and 15-19 together.

14           The Appellants separately argue claims 7 and 8 together, claim 10,  
15 claims 14 and 23 together, claim 20, and claim 22.

16           The Appellants also separately argue claims 14 and 23 as a group.

17           Independent claim 1 reads as follows:

18           1. A method of treating a subject having pressure ulcers,  
19 comprising enterally administering to a subject in need thereof  
20 a composition comprising proteins, carbohydrates, fats, arginine  
21 or equivalents thereof, ascorbic acid equivalents and  $\alpha$ -  
22 tocopherol equivalents,  
23           wherein arginine or equivalents thereof are administered  
24 in a daily amount of 3-15 g,  
25           ascorbic acid equivalents are administered in a daily  
26 amount of 180-840 mg,

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form. (App. Br. 1; Final Rejection, Jan. 5, 2007, p. 9). Claims 9 and 21  
have been canceled. (App. Br. 1).

1             $\alpha$ -tocopherol equivalents are administered in a daily  
2 amount of 50-400 mg,  
3            and wherein the composition further comprises  
4 carotenoids administered in a daily amount of 0.8-16 mg.

5  
6 Claim 7 recites,

7            7,     The method according to claim 1, wherein the  
8 composition additionally contains copper, said copper being  
9 administered in a daily amount of 2-10 mg.

10  
11 Claim 10 recites,

12            10.    The method according to claim 1, wherein the  
13 carotenoids comprise 20-60% lutein, 1-30% lycopene, 5-25%  
14  $\alpha$ -carotene, 5-40%  $\beta$ -carotene, 1-15% cryptoxanthine and 1-  
15 15% zeaxanthine.

16  
17 Claim 14 recites,

18            14.    The method according to claim 1, wherein the  
19 composition contains 50-100 g/l of proteins, 60-180 g/l of  
20 carbohydrates and 20-40 g/l of fats, the fats comprising 0.05-  
21 0.5 g/l of DHA and having an  $\omega$ -6/ $\omega$ -3 ratio of between 2 and 5.

22  
23 Claim 20 recites,

24            20.    A method of treating pressure ulcers in a subject  
25 comprising enterally administering to said subject in need  
26 thereof a composition comprising proteins, carbohydrates, fats,  
27 arginine or equivalents thereof in a daily amount of 3-15 g,  
28            ascorbic acid equivalents in a daily amount of  
29 180-840 mg,  
30             $\alpha$ -tocopherol equivalents are in a daily amount of  
31 50-400 mg,  
32            and folic acid in a daily amount of 0.4-1.2 mg.

1 Claim 22 recites,  
2 22. A method of treating pressure ulcers in a subject  
3 comprising enterally administering to said subject in need  
4 thereof a composition comprising proteins, carbohydrates, fats,  
5 arginine or equivalents thereof in a daily amount of 3-15 g,  
6 ascorbic acid equivalents in a daily amount of  
7 180-840 mg,  
8  $\alpha$ -tocopherol equivalents are in a daily amount of  
9 50-400 mg,  
10 calcium in a daily amount of 500-1000 mg  
11 and phosphorus in a daily amount of 400-900 mg.  
12

13 (App. Br. 13-16)(Additional indentation added, *see* 37 CFR §1.75(i)).

14  
15 THE EVIDENCE  
16

17 The Examiner relies upon the following as evidence in support of the  
18 rejections:

19 Alexander	US 5,053,387	Oct. 01, 1991
20 Zaloga	US 5,656,588	Aug. 12, 1997
21 Henningfield et al.	WO 93/16595 A1	Sep. 02, 1993

22  
23 THE REJECTIONS  
24

25 The following rejections are before us for review:

- 26 1. Claims 1-4, 7, 8, 10-13, 15-20 and 22 stand rejected under 35 U.S.C.  
27 § 103(a) over the combination of Zaloga (US 5,656,588) and Henningfield  
28 (WO 93/16595).  
29 2. Claims 14 and 23 stand rejected under 35 U.S.C. § 103(a) (2004) over  
30 the combination of Zaloga, Henningfield, and Alexander (US 5,053,387).



1           4. Zaloga further describes that the composition may include the  
2 recommended dietary intakes of vitamins, and preferably higher than the  
3 recommended dietary intake of vitamins C, E, A, and zinc. (Id. 4:27-31).

4           5. Specifically, Zaloga describes an example of the composition  
5 comprising 20-30 g/l of arginine. (Id. 4:40-50).

6           6. Zaloga also describes an example of the composition comprising  
7 700 to about 1400 mg/day of vitamin C. (Id.).

8           7. The recommended dietary intake of vitamin C at the time of the  
9 invention was 50-60 mg/day. (Specification p. 5).

10          8. Therefore, Zaloga describes using a range of 50-1400 mg/day of  
11 vitamin C in the nutritional composition. (FF-4, 6, 7).

12          9. Zaloga also describes an example of the composition comprising  
13 50-400 IU of vitamin E (Zaloga 4:32-33), which is approximately 33-267  
14 mg.

15          10. Zaloga also describes an example of the composition comprising  
16 20-30 mg of zinc and further describes that the composition of the invention  
17 may include approximately 30-90 mg/day of zinc. (Id. 4:40-50).

18          11. Zaloga does not describes adding carotenoids, copper, folic acid,  
19 calcium, phosphorus or essential fatty acids to the composition.

20          12. Henningfield describes enterally administering a nutritional  
21 product for trauma and surgery patients comprising proteins, carbohydrates,  
22 fats, essential fatty acids, vitamins A, C, and E, copper, zinc, folic acid,  
23 calcium, phosphorus, and carotenoids. (Henningfield Title; p. 1:9, Table 2;  
24 p. 19).

1           13. Henningfield describes that severe injury or trauma, including  
2 surgery, is associated with loss of the body's nutrient stores. (Id. p. 1).

3           14. Henningfield describes that optimal recovery requires proper  
4 nutritional intake to avoid malnutrition-associated complications, including  
5 depletion of protein levels, immune incompetence, increased risk of  
6 infection and other complications associated with morbidity and mortality  
7 can result. (Id.).

8           15. Specifically, Henningfield describes that beta carotene “does not  
9 have the toxicity problems of vitamin A and may be the preferred form to  
10 add supplemental retinol to the diet.” (Id. p. 17).

11           16. Henningfield also describes that beta carotene “may enhance  
12 immune system function and functions as an antioxidant.” (Id.).

13           17. Henningfield describes administering 2 mg of copper, which  
14 Henningfield indicates is the daily recommended amount of copper. (Id. p.  
15 9, Table 2).

16           18. Additionally, Henningfield's claim language recites that the  
17 product composition will provide “at least 100% of the U.S. RDA” of  
18 copper. (Id. p. 24, Henningfield claims 21-22).

19           19. Henningfield describes using at least the RDA of zinc, which is  
20 taught to be 15 mg/day. (Henningfield p. 18; p. 24, Henningfield claims 21-  
21 22).

22           20. Additionally, in one embodiment, Henningfield describes using  
23 22.5 mg of zinc. (Id. p. 9, Table 2).

1           21. Henningfield also describes that the product composition provides  
2 “at least 100% of the U.S. RDA” of folic acid. (Henningfield p. 24, Claims  
3 21-22).

4           22. Henningfield further describes an embodiment of the invention  
5 using 600 mcg (0.6 mg) of folic acid, which Henningfield indicates is 200%  
6 of the RDA. (Henningfield, p. 9, Table 2).

7           23. Therefore, Henningfield discloses using folic acid in range of  
8 between 0.4-0.6 mg. (FF-21, 22).

9           24. Henningfield also describes using 1000 mg each of calcium and  
10 phosphorus in the composition. (Henningfield, p. 9, Table 2).

11           25. Henningfield describes adding essential fatty acids, i.e., linoleic  
12 (omega-6) and alpha-linolenic (omega-3), in a ratio ranging from 3.5:1 to  
13 5.5:1. (Henningfield p. 16).

14           26. Alexander describes a nutritional composition comprising protein,  
15 carbohydrates, vitamins C and E, arginine and further comprising omega  
16 fatty acids, including eicosapentanoic acid (“EPA”), docosahexanoic acid  
17 (“DHA”), and linolenic acid. (Alexander 3:56-68; 5:16-22).

18           27. Alexander describes enterally administering the composition as a  
19 method of treating traumatic injury, including major surgery and substantial  
20 burn, by improving immunologic response and reducing hypermetabolic  
21 response. (Id. 8:5-6; 3:41-55).

22           28. Alexander describes adding the omega-3 fatty acids EPA, DHA,  
23 and linolenic acid to the nutritional composition in amounts sufficient to  
24 reduce the hypermetabolic response associated with traumatic injury. (Id.).



1            wherein arginine or equivalents thereof are administered  
2            in a daily amount of 3-15 g,  
3            ascorbic acid equivalents are administered in a daily  
4            amount of 180-840 mg,  
5             $\alpha$ -tocopherol equivalents are administered in a daily  
6            amount of 50-400 mg,  
7            and wherein the composition further comprises  
8            carotenoids administered in a daily amount of 0.8-16 mg.

9  
10           (App. Br. 13)(Additional indentation added, see 37 CFR §1.75(i)).

11           The Examiner found that Zaloga describes a nutritional composition  
12           that stimulates and improves wound healing in a patient suffering from  
13           wounds, such as surgical wounds, traumatic wounds, and decubiti ulcers,  
14           also known as pressure ulcers. (Final Rejection, Jan. 5, 2007, pp. 2-3). The  
15           Examiner also found that Zaloga describes that the nutritional composition  
16           may be administered enterally. (Id. 2-3). Specifically, the Examiner found  
17           that Zaloga describes that the nutritional composition comprises protein,  
18           carbohydrates, lipids, arginine, vitamin C (ascorbic acid) and vitamin E ( $\alpha$ -  
19           tocopherol). (Id.).

20           According to the Examiner, Zaloga differs from the claimed invention  
21           “in the absence of the exact amounts of individual components i.e., arginine,  
22           ascorbic acid etc.” (Id. 3). However, the Examiner determined that it would  
23           have been obvious for a person of ordinary skill in the art at the time of the  
24           invention “to optimize the amounts of the individual components of the  
25           nutritional composition of Zaloga, with an expectation to provide treatment  
26           for pressure ulcers.” (Final Rejection, Jan. 5, 2007, p. 3).

27           The Examiner also found that Zaloga does not describe that the  
28           nutritional composition includes carotenoids, (Id.).

1           However, the Examiner found that Henningfield describes a  
2 nutritional product containing proteins, carbohydrates, fats, arginine, vitamin  
3 C and vitamin E and further comprises carotenoids, folic acid, calcium and  
4 phosphorus. (Id. 3). The Examiner also found that Henningfield teaches the  
5 amounts of the components as a quantity per 60,000 lbs and in amounts per  
6 1500 Kcal. (Id.). According to the Examiner, Henningfield describes using  
7 the nutritional product in patients who have suffered severe injury or trauma,  
8 including surgery, to improve the immune response and to reduce the risk of  
9 infection and other malnutrition-associated complications. (Id. 3-4)(citing  
10 Henningfield p. 1).

11           The Examiner determined that it would have been obvious to a person  
12 of ordinary skill in the art at the time of the invention to add the nutritional  
13 components of Henningfield, i.e., carotenoids, copper, zinc, folic acid,  
14 calcium and phosphorus to the nutritional composition of Zaloga for treating  
15 patients with pressure ulcers. (Final Rejection, Jan. 5, 2007, p. 4).

16           According to the Examiner, both references teach administering nutritional  
17 compositions for tissue repair and recovery in surgery or trauma patients,  
18 with Zaloga specifically addressing the treatment of pressure ulcers. (Id.).  
19 Thus, the Examiner found that the references represent analogous art such  
20 that a skilled artisan would be motivated to combine their teachings. (Id.).

21           The Examiner further found that although Henningfield “does not  
22 teach the exact percentages of the individual components of the composition  
23 (as claimed),” Henningfield does teach “broad ranges of the components in  
24 the nutritional product and also suggests a range of caloric density required  
25 to meet the needs of patients suffering from post-surgical trauma, burns, etc.,

1 for wound healing and increased immunostimulation.” (Id.). Therefore, the  
2 Examiner determined that it would have been obvious to an ordinarily  
3 skilled artisan “to optimize the amounts” of components in the compositions  
4 of Henningfield with an expectation “to provide the optimum immune  
5 response in trauma or surgery patients for faster recovery.” (Id.).

6 *Arginine, Vitamin C and Vitamin E*

7 The Appellants assert that independent claims 1, 20, and 22 are not  
8 obvious over the prior art because one skilled in the art at the time of the  
9 invention would not “have had a reason to combine and modify Zaloga and  
10 [Henningfield] to obtain a method of administering a composition with the  
11 components and amounts as claimed....” (App. Br. 6, 10) (emphasis in  
12 original).

13 Specifically, the Appellants assert that the combined references do not  
14 teach “arginine or equivalents thereof, ascorbic acid equivalents and  $\alpha$ -  
15 tocopherol equivalents, wherein arginine or equivalents thereof are  
16 administered in a daily amount of 3-15 g, ascorbic acid equivalents are  
17 administered in a daily amount of 180-840 mg,  $\alpha$ -tocopherol equivalents are  
18 administered in a daily amount of 50-400 mg.” (Id. 6).

19 This argument is not persuasive.

20 The Examiner found that Zaloga, by itself, describes a nutritional  
21 composition for the treatment of pressure ulcers comprising arginine,  
22 ascorbic acid (vitamin C), and  $\alpha$ -tocopherol (vitamin E), as claimed by  
23 independent claims 1, 20 and 22. (Final Rejection, Jan. 5, 2007, pp. 2-3).  
24 Specifically, Zaloga describes an example composition comprising 20-30 g/l  
25 of arginine. (Zaloga 4:40-50). The fact that Zaloga’s range of arginine is

1 not the “exact amount” recited in claims 1, 20, and 22, i.e., 3-15 g, does not  
2 render the claims nonobvious.

3         Rather, as the Federal Circuit has stated, “[A] *prima facie* case of  
4 obviousness exists when the claimed range and the prior art range do not  
5 overlap but are close enough such that one skilled in the art would have  
6 expected them to have the same properties.” *In re Peterson*, 315 F.3d at  
7 1329. Thus, we find that Zaloga describes a range of arginine that is close  
8 enough to the claimed range such that the claimed range would have been  
9 obvious to a skilled artisan at the time of the invention. The Appellants have  
10 not established otherwise with persuasive evidence.

11         Regarding ascorbic acid, Zaloga describes that the composition may  
12 include the recommended dietary intake of vitamins and may preferably  
13 include higher than the recommended dietary intake of vitamin C. (Zaloga  
14 4:26-50). Appellants’ specification indicates that at the time of the  
15 invention, the recommended daily amount (“RDA”) of vitamin C was  
16 between 50-60 mg. (Specification p. 5). Zaloga describes an embodiment  
17 of the composition comprising 0.7-1.4 g/l (700-1400 mg/l) of vitamin C.  
18 (Zaloga 4:40-50). Therefore, Zaloga discloses a nutritional composition  
19 comprising vitamin C in the range of 50-1400 mg, a range which  
20 encompasses the claimed range of 180-840 mg.

21         As the Federal Circuit has noted, “[s]electing a narrow range from  
22 *within* a somewhat broader range disclosed in a prior art reference is no less  
23 obvious than identifying a range that simply overlaps a disclosed range.” *In*  
24 *re Peterson*, 315 F.3d at 1229-30. Moreover, when “the claimed ranges are  
25 completely encompassed by the prior art, the conclusion is even more

1 compelling than in cases of mere overlap.” *Id.* at 1330. Therefore, we find  
2 the Examiner did not err in finding that the claimed range of vitamin C is  
3 obvious in view of Zaloga.

4 As for vitamin E, Zaloga describes an embodiment of the  
5 composition comprising 50-400 IU of vitamin E. (Zaloga 4:32-33). Claims  
6 1, 20, and 22, however, recite the amount of vitamin E in mg. Using the  
7 conversion provided in the specification, “1 mg  $\alpha$ -tocopherol equivalent  
8 (TE) (= 1.5 IU of vitamin E),” 50-400 IU of alpha-tocopherol is  
9 approximately 33-267 mg. (Specification p. 3). Therefore, Zaloga describes  
10 a range of approximately 33-267 mg of vitamin E, which range overlaps the  
11 50-400 mg range recited in claims 1, 20, and 22. As we and the Federal  
12 Circuit have consistently held, “even a slight overlap in range establishes a  
13 *prima facie* case of obviousness.” *In re Peterson*, 315 F.3d at 1329.  
14 Therefore, the claimed range of vitamin E is obvious in view of Zaloga.

15 Consequently, we do not find that the Appellants have established  
16 error on the part of the Examiner.

17 We note that the Appellants have not directed us to evidence of  
18 secondary considerations, such as unexpected results.

### 19 *Carotenoids*

20 The Appellants next assert that “the proposed combination fails to  
21 render obvious claim 1” because Zaloga fails to disclose or suggest a  
22 composition containing carotenoids and Henningfield does not recognize  
23 administering carotenoids in the amount recited in the claims or with  
24 arginine, ascorbic acid, and  $\alpha$ -tocopherol in their recited daily amounts.  
25 (App. Br. 7). In the reply brief, the Appellants further assert that

1 Henningfield “does not give any reason for administering carotenoids to  
2 treat pressure ulcers as recited in claims 1 and 10.” (Reply Br. 3). The  
3 Appellants further assert that Henningfield “does not recognize the benefits  
4 of carotenoids” nor does the reference describe the “amount of carotenoids  
5 in treating pressure ulcers.” (Id.) (emphasis in original).

6 This argument is also unpersuasive.

7 The Appellants fail to consider the combination of references  
8 together, and misfocus on the references individually. “Non-obviousness  
9 cannot be established by attacking references individually where the  
10 rejection is based upon the teachings of a combination of references.” *In re*  
11 *Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) (citing *In re Keller*, 642  
12 F.2d 413, 425 (CCPA 1981)). Further, in determining obviousness, the  
13 references are read not in isolation but for what they fairly teach in  
14 combination with the prior art as a whole. *Id.*

15 Here, the rejection is based on the combination of Zaloga and  
16 Henningfield. The Examiner relied upon Zaloga’s teaching the use of a  
17 nutritional composition for treating pressure ulcers and other surgical,  
18 trauma and burn wounds, comprising protein, carbohydrates, lipids, arginine,  
19 vitamin C and vitamin E. (Final Rejection, Jan. 5, 2007, pp. 2-3). As  
20 discussed, *supra*, the claimed amounts of arginine, vitamin C and vitamin E  
21 in the composition are obvious in view of the ranges disclosed in Zaloga.

22 The Examiner further relied on Henningfield’s teaching to add  
23 carotenoids to a nutritional composition. (Id. 4). Henningfield describes  
24 that beta carotene “does not have the toxicity problems of vitamin A and  
25 may be the preferred form to add supplemental retinol to the diet.” (Id. 6-7;

1 Henningfield p. 17). Henningfield also states that beta carotene “may  
2 enhance immune system function and functions as an antioxidant.” (Id. 6-7;  
3 Henningfield p. 17).

4 As the Examiner explained, Henningfield, like Zaloga, describes a  
5 nutritional composition for tissue repair and recovery in surgical, trauma and  
6 burn patients comprising proteins, carbohydrates, fats, arginine, vitamin C  
7 and vitamin E. (Final Rejection, Jan. 5, 2007, p. 4). Therefore, Zaloga and  
8 Henningfield represent analogous art and a skilled artisan at the time of the  
9 invention would have been motivated to combine Henningfield’s beta  
10 carotene with Zaloga’s nutritional composition to supplement its retinol and  
11 antioxidant content without added toxicity.

12 As for the amount, the instant claim limitation recites “carotenoids  
13 administered in a daily amount of 0.8-16 mg.” (Claim 1). While the claim  
14 recites the amount of this component in milligrams, Henningfield provides  
15 the combined daily amount of beta-carotene and vitamin A palmitate  
16 activity, expressed as vitamin A activity, in international units, i.e., 10,000  
17 IU. (Henningfield Table 2, p. 9).

18 The Appellants have not argued that the claimed amount of  
19 carotenoids is distinguishable from this known IU of vitamin A activity, as  
20 described by Henningfield. Nor have the Appellants established that the  
21 Examiner erred in concluding that the claimed milligrams of carotenoids  
22 would have been obvious to a person of ordinary skill in the art at the time  
23 the invention was made who reviewed Henningfield’s description of the  
24 combined beta-carotene and vitamin palmitate activity. Therefore, we do

1 not find that the Appellants have established error on the part of the  
2 Examiner.

3 *Copper and Zinc*

4 Also in the reply brief, the Appellants assert that an additional  
5 “deficienc[y] of Zaloga” is that the reference does not disclose administering  
6 copper, as recited in dependent claim 7, i.e., “copper being administered in a  
7 daily amount of 2-10 mg.” (Reply Br. 1-2; Claim 7). Additionally, the  
8 Appellants assert that Zaloga is deficient for not disclosing the further  
9 limitation in claim 8 that “the composition additionally contains zinc in a  
10 molar zinc to copper ratio of between 7 and 14.” (Reply Br. 1-2; Claim 8).

11 This argument is not persuasive, The Examiner acknowledged that  
12 Zaloga does not describe adding copper to the composition. However, the  
13 Examiner found that Henningfield describes a composition comprising  
14 copper and zinc, as claimed. We see no error in this finding.

15 Specifically, Henningfield describes administering 2 mg of copper,  
16 which Henningfield indicates is the daily recommended amount of copper.  
17 (Henningfield p. 9, Table 2). Additionally, Henningfield states in the claim  
18 language that the product will provide “*at least* 100% of the U.S. RDA” of  
19 copper, therefore additional copper may be added. (Id. p. 24, Claims 21-  
20 22)(emphasis added). Therefore, Henningfield teaches using *at least* 2 mg  
21 of copper which overlaps, and renders obvious, the Appellants’ claimed  
22 range of 2-10 mg.

23 Similarly, Henningfield teaches using at least the RDA of zinc, which  
24 is taught to be 15 mg/day. (Henningfield p. 18; p. 24, Claims 21-22). In one  
25 embodiment, Henningfield describes using 22.5 mg of zinc. (Id. p. 9, Table

1 2). Therefore, Henningfield's disclosure of 15-22.5 mg of zinc along with  
2 the disclosure of using at least 2 mg of copper satisfies the claimed zinc to  
3 copper ratio of between 7 and 14, recited in claim 8.

4 Consequently, we do not find that the Appellants have established that  
5 the Examiner erred in rejecting dependent claims 7 and 8.

6 *Lutein, Lycopene,  $\alpha$ -Carotene,  $\beta$ -Carotene, Cryptoxanthine and*  
7 *Zeaxanthine*

8 The Appellants additionally assert that Henningfield does not  
9 disclose the further limitation of claim 10 "that the carotenoids comprise 20-  
10 60% lutein, 1-30% lycopene, 5-25%  $\alpha$ -carotene, 5-40%  $\beta$ -carotene, 1-15%  
11 cryptoxanthine and 1-15% zeaxanthine," as recited by claim 10. (Reply Br.  
12 3).

13 We agree that the Examiner, in rejecting claim 10, has not provided a  
14 sufficient rationale for determining that this dependent claim is obvious over  
15 the combined references.

16 In rejecting claims under 35 U.S.C. § 103, the Examiner bears the  
17 initial burden of presenting a *prima facie* case of obviousness. *See In re*  
18 *Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993). A determination that the  
19 claimed subject matter is *prima facie* obvious must be supported by  
20 evidence, as shown by some objective teaching in the prior art or by  
21 knowledge generally available to one of ordinary skill in the art that would  
22 have led that individual to combine the relevant teachings of the references  
23 to arrive at the claimed invention. *See In re Fine*, 837 F.2d 1071, 1074 (Fed.  
24 Cir. 1988).

1           Here, the Examiner has not addressed the specific carotenoids recited  
2 in claim 10, i.e., lutein, lycopene,  $\alpha$ -carotene,  $\beta$ -carotene, cryptoxanthine and  
3 zeaxanthine or their respective recited percentages. Thus, the Examiner has  
4 not directed our attention to sufficient evidence that establishes the  
5 obviousness of the claimed subject matter.

6           We accept the Appellants' argument as a representation made under  
7 their obligation under 37 CFR §1.56(b)(2) that they are unaware of any  
8 material information which, when properly combined with the teachings  
9 cited by the Examiner, refutes or is inconsistent with their argument for  
10 patentability of this claim.

11           Consequently, the Examiner has not established a *prima facie* case of  
12 obviousness for claim 10.

13           We therefore reverse this rejection as it applies to claim 10.

14           *Folic Acid*

15           The Appellants also assert that "the proposed combination fails to  
16 render obvious claim 20" because Zaloga neither discloses nor mentions  
17 folic acid and fails to disclose administering folic acid in a daily amount of  
18 0.4-1.2 mg, as recited by the claim. (App. Br. 7). Additionally, the  
19 Appellants assert that Henningfield does not recognize "whether  
20 administering folic acid in the recited amount with the claimed combination  
21 and amounts of arginine, ascorbic acid, and  $\alpha$ -tocopherol would result in an  
22 effective method." (Id.).

23           This argument is unpersuasive. As we have discussed, Zaloga  
24 describes an enterally administered nutritional composition comprising  
25 proteins, carbohydrates, fats, and the claimed amounts of arginine, ascorbic

1 acid and  $\alpha$ -tocopherol for treating a subject having pressure ulcers. Claim  
2 20 additionally recites “folic acid in a daily amount of 0.4-1.2 mg.” (Claim  
3 20). The Examiner relied on Henningfield for the teaching to add folic acid  
4 to the nutritional composition. Specifically, Henningfield states in the claim  
5 language that the product will provide “*at least* 100% of the U.S. RDA” of  
6 folic acid. (Henningfield p. 24, Claims 21-22)(emphasis added).  
7 Henningfield also describes an embodiment of the invention using 600 mcg  
8 (0.6 mg) of folic acid, which Henningfield indicates is 200% of the RDA.  
9 (Henningfield, p. 9, Table 2).

10 Therefore, Henningfield discloses folic acid in an amount of 0.4-0.6  
11 mg, which overlaps and renders obvious the range recited in claim 20. As  
12 the Examiner determined, one skilled in the art at the time of the invention  
13 would have been expected the resulting combination to be an effective  
14 method of supplementing a nutritionally deficient patient suffering from  
15 pressure ulcers because the references are analogous art and as a whole is  
16 concerned with treating patients suffering physical effects of malnutrition.  
17 Consequently, the Appellants have not established that the Examiner erred in  
18 rejecting claim 20.

19 *Calcium and Phosphorus*

20 The Appellants next assert that “the proposed combination fails to  
21 render obvious claim 22” because Zaloga does not disclose administering  
22 calcium in a daily amount of 500-1000 mg and phosphorus in a daily amount  
23 of 400-900 mg, as recited by the claim. (App. Br. 8). Additionally, the  
24 Appellants assert that Henningfield “does not suggest or give one skilled in

1 the art a reason to administer calcium and phosphorus with” arginine,  
2 ascorbic acid, and  $\alpha$ -tocopherol in the daily amounts recited. (App. Br. 8).

3 This argument is also unpersuasive for the reasons discussed, supra.  
4 Additionally, the Examiner relied upon Henningfield for the disclosure of  
5 using calcium and phosphorus in the nutritional composition. Henningfield  
6 describes using 1000 mg each of calcium and phosphorus. (Henningfield, p.  
7 9, Table 2). These disclosed amounts for calcium and phosphorus are close  
8 enough to the claimed ranges such that a skilled artisan would have expected  
9 them to have the same properties. Consequently, we do not find that the  
10 Appellants have established that the Examiner erred in rejecting claim 22.

11 *Hindsight*

12 The Appellants further assert that “[i]t is only with the benefit of  
13 hindsight of the present application, and with respect to the teachings of the  
14 present specification, that one can argue that one of ordinary skill in the art  
15 would combine and modify the teachings of the [prior art] to obtain the  
16 claimed invention.” (App. Br. 9).

17 This argument is also unpersuasive. As the Examiner determined, a  
18 skilled artisan at the time of the invention would have been motivated to  
19 combine Zaloga and Henningfield because the references represent  
20 analogous art directed to the treatment of conditions relating to nutritional  
21 deficiencies in trauma patients. Moreover, as the Court explained in *In re*  
22 *McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971), “Any judgment on  
23 obviousness is in a sense necessarily a reconstruction based upon hindsight  
24 reasoning ....”

1           The Court further clarified that such a reconstruction is proper if it  
2 relies on ordinary skill at the time of the invention and not on knowledge  
3 gained solely from the applicant's disclosure. *Id.* As discussed, *supra*, the  
4 cited combinations of references disclose the limitations of claims 1-4, 7, 8,  
5 11-13, 15-20 and 22 and it would have been obvious to one of ordinary skill  
6 in the art at the time of the invention to combine the references to make the  
7 claimed invention.

8           *Optimization*

9           The Appellants next assert that the Examiner erred in determining that  
10 it would be obvious to "optimize" the amount of ingredients disclosed in  
11 Zaloga and Henningfield because "there is nothing in either reference to  
12 indicate that the disclosed amounts are not already optimal." (App. Br. 9-  
13 10). In the reply brief, the Appellants assert that "neither publication  
14 discloses what parameters could be 'optimized' to obtain a method of  
15 treating a subject having pressure ulcers as recited in the claimed invention."  
16 (Reply Br. 2).

17           The Appellants also assert that the references do not even "suggest  
18 what particular components or amounts should be administered to  
19 specifically treat a subject having pressure ulcers." (*Id.*). According to the  
20 Appellants, therefore, the Examiner failed "to present a prima facie case of  
21 obviousness that would require the submission of unexpected results." (*Id.*  
22 3).

23           This argument is also not persuasive. Both Zaloga and Henningfield  
24 describe amounts of ingredients that overlap or are close enough to the  
25 claimed range of the ingredients recited in claims 1-4, 7, 8, 11-13, 15-20 and

1 22, such that the claimed ranges would have been obvious to a person of  
2 ordinary skill in the art. Therefore, the Examiner, relying on these  
3 references, has established a prima facie case of obviousness.

4 Moreover, the Examiner's determination that it would have been  
5 obvious for a skilled artisan at the time of the invention to optimize the  
6 amounts of the ingredients disclosed in Zaloga and Henningfield to reach the  
7 exact amounts recited in the claims relies on the skill and knowledge of the  
8 ordinary artisan and not on a particular suggestion in the reference to  
9 optimize. Consequently, we do not find that the Appellants have established  
10 error on the part of the Examiner.

11 Accordingly, we affirm the Examiner's rejections of claims 1-4, 7, 8,  
12 11-13, 15-20 and 22, and reverse the Examiner's rejection of claim 10.

13 II. The Rejection of Claims 14 and 23 under 35 U.S.C. § 103(a) over  
14 the combination of Zaloga, Henningfield, and Alexander.

15 Claims 14 and 23 stand rejected under 35 U.S.C. § 103(a) over  
16 Zaloga, Henningfield, and Alexander.

17 Claim 23 recites,

18 A method of treating pressure ulcers in a subject,  
19 comprising enterally administering to a subject in need thereof  
20 a composition comprising proteins, carbohydrates, fats, arginine  
21 or equivalents thereof in a daily amount of 3-15 g, ascorbic acid  
22 equivalents in a daily amount of 180-840 mg,  $\alpha$ -tocopherol  
23 equivalents in a daily amount of 50-400 mg, and EPA and DHA  
24 in a total daily amount of EPA and DHA of 0.1-1.0 g/day.

25  
26 (App. Br. 16).

27 The Examiner found that Alexander describes a nutritional  
28 composition comprising protein, carbohydrates, vitamins C and E, arginine

1 and further comprising omega fatty acids, including eicosapentanoic acid  
2 (“EPA”), docosahexanoic acid (“DHA”), and linolenic acid. (Non-Final  
3 Rejection, May 10, 2006, p. 8, incorporated by reference in Final Rejection,  
4 Jan. 5, 2007, p. 7). The Examiner also found that Alexander describes  
5 administering the composition as a method of treating traumatic injury,  
6 including major surgery and substantial burn, by improving immunologic  
7 response and reducing hypermetabolic response. (Id.).

8         According to the Examiner, Alexander suggests adding the omega-3  
9 fatty acids EPA, DHA, and linolenic acid to the nutritional composition in  
10 amounts sufficient to reduce the hypermetabolic response associated with  
11 traumatic injury. (Id.).

12         Therefore, the Examiner determined that it would have been obvious  
13 to a skilled artisan at the time of the invention to add EPA and DHA as  
14 taught by Alexander (in amounts sufficient to reduce a hypermetabolic  
15 response) in the nutritional composition of Zaloga because Alexander  
16 describes that adding these omega-3 fatty acids to a nutritional composition  
17 enhance the healing rate of a traumatic injury and Zaloga describes a  
18 nutritional composition to treat traumatic injury patients, including those  
19 with pressure ulcers. (Non-Final Rejection, May 10, 2006, p. 8,  
20 incorporated by reference in Final Rejection, Jan. 5, 2007, p. 7).

21         The Appellants, on the other hand, assert that one skilled in the art  
22 would not have had a reason to administer EPA and DHA in the amount  
23 recited because “neither Zaloga or [Henningfield] discuss administering  
24 EPA and DHA together in the amounts recited” or with the recited daily  
25 amounts of arginine, ascorbic acid, and  $\alpha$ -tocopherol. (App. Br. 11).

1           This argument is unpersuasive.

2           The Examiner relied on Zaloga's teaching a nutritional composition  
3 for treating pressure ulcers comprising arginine, ascorbic acid and  $\alpha$ -  
4 tocopherol such that the claimed amounts of these components recited in  
5 claim 1 (and repeated in claim 23) would have been obvious to a person of  
6 ordinary skill in the art at the time of the invention. The Examiner further  
7 relied on Alexander for the teaching that adding EPA and DHA to a  
8 nutritional composition comprising arginine, vitamin C and and vitamin E  
9 enhances the healing rate of traumatic injury and improves the immunologic  
10 response in such injury.

11           Alexander teaches the amount of omega-3 fatty acids in the  
12 composition is expressed as a percentage range of the total energy intake.  
13 The Appellants have not shown that the claimed amount of EPA and DHA,  
14 i.e., 0.1-1.0 g/day, is distinguishable from the disclosed 7-15% of the total  
15 energy intake, as described by Alexander (8:18-21). Similarly, the  
16 Appellants have not established that the Examiner erred in concluding that  
17 the claimed amount of EPA and DHA would have been obvious to a person  
18 of ordinary skill in the art at the time the invention was made who reviewed  
19 Alexander.

20           Therefore, we do not find that the Appellants have established error  
21 on the part of the Examiner.

22           Additionally, the Appellants assert that Alexander describes using  
23 omega-3 fatty acids "to attenuate or reduce hypermetabolic resting metabolic  
24 state resulting from a traumatic injury, especially a substantial burn injury,"  
25 whereas, "the claimed invention does not limit the method to burn patients

1 or patients exhibiting a hypermetabolic resting metabolic state.” (App. Br.  
2 5; Reply Br. 5). According to the Appellants, “one skilled in the art would  
3 even be dissuaded from adding omega-3 fatty acids to patients that do not  
4 expend a great deal of energy (e.g., elderly patients).” (Id.).

5 This argument is unpersuasive because the Appellants read Alexander  
6 too narrowly. Alexander describes a method of treating patients suffering  
7 from traumatic injury, which is not limited to burns, but also includes, e.g.,  
8 surgery patients. (Alexander 1:15-20).

9 Also, the Appellants fail to consider the level of ordinary skill in the  
10 art. Alexander describes that omega-3 fatty acids are useful to improve  
11 immunologic response and to enhance the healing rate of traumatic injury.  
12 (Non-Final Rejection, May 10, 2006, p. 8, incorporated by reference in Final  
13 Rejection, Jan. 5, 2007, p. 7; see also, Alexander 3:8-12).

14 The Appellants’ argument suggests that a skilled artisan at the time of  
15 the invention would not have appreciated that Alexander’s nutritional  
16 composition for hypermetabolic trauma patients would also be beneficial for  
17 trauma patients with pressure ulcers, where both patients are known to suffer  
18 from nutritional deficiencies. As stated in *In re Sovish*, 769 F.2d 738, 743  
19 (Fed. Cir. 1985), “This argument presumes stupidity rather than skill.”

20 Moreover, the assertion that a skilled artisan would be “dissuaded  
21 from adding omega-3 fatty acids to patients that do not expend a great deal  
22 of energy” is attorney argument and not evidence. (App. Br. 11; Reply Br.  
23 5). Consequently, we do not find that the Appellants have established that  
24 the Examiner erred in rejecting claim 23 as obvious.

25 Claim 14 recites,

1           The method according to claim 1, wherein the  
2           composition contains 50-100 g/l of proteins, 60-180 g/l of  
3           carbohydrates and 20-40 g/l of fats, the fats comprising 0.05-  
4           0.5 g/l of DHA and having an  $\omega$ -6/ $\omega$ -3 ratio of between 2 and 5.  
5

6 (App. Br. 15).

7           In addition to the findings, *supra*, the Examiner also found Alexander  
8           “suggests the optimum amounts of energy to be obtained from proteins, fats,  
9           and carbohydrates so as to enable improved immunological response. (Non-  
10          Final Rejection, May 10, 2006, p. 8, incorporated by reference in Final  
11          Rejection, Jan. 5, 2007, p. 7).

12          In the Answer, the Examiner states that Henningfield describes adding  
13          essential fatty acids, i.e., linoleic (omega-6) and alpha-linolenic (omega-3),  
14          in a ratio ranging from 3.5:1 to 5.5:1, i.e., between 3.5 and 5.5. (Final  
15          Rejection, Jan. 5, 2007, p. 3; *see also* Henningfield p. 16). As stated, *supra*,  
16          the Examiner determined that it would have been obvious for one of  
17          ordinary skill in the art at the time of the invention to include the omega  
18          fatty acids of Henningfield in the composition of Zaloga because a skilled  
19          artisan would have expected that an effective nutritional treatment for post-  
20          surgical and trauma patients would also be an effective nutritional treatment  
21          for patients suffering surgical wounds, traumatic wounds, and pressure  
22          ulcers.” (Final Rejection, Jan. 5, 2007, pp. 7-8).

23          The Appellants assert that Alexander does not provide one skilled in  
24          the art a reason to “administer a composition with the claimed components,  
25          amounts, or ratio (e.g.,  $\omega$ -6/ $\omega$ -3 ratio of between 2 and 5....).

26          This argument is unpersuasive for the same reasons discussed  
27          regarding claim 23.

1 Further, this argument is not persuasive because the Appellants have  
2 not argued that the claimed amounts, expressed in grams/liter, of protein,  
3 carbohydrates, and fats are distinguishable from the disclosed % of the total  
4 energy intake of these components described by Alexander. Specifically,  
5 Alexander describes a composition comprising, in terms of percent of total  
6 energy intake, 20-30 percent proteins, 65-70 percent carbohydrates, and 7-  
7 15% lipids. (Alexander 6:45-53).

8 The Appellants have not established that the Examiner erred in  
9 concluding that the claimed amounts of protein, carbohydrates, and fats  
10 would have been obvious to a person of ordinary skill in the art at the time  
11 the invention was made who reviewed Zaloga and Alexander. .

12 Additionally, as the Examiner stated, Henningfield discloses adding  
13 both omega-6 (linoleic) and omega-3 (linolenic) essential fatty acids in the  
14 nutritional composition, in a ratio between 3.5 and 5.5. This known ratio  
15 overlaps the claimed ratio of between 2 and 5, such that a *prima facie* case  
16 of obviousness exists. Also, as the Examiner found, Alexander describes the  
17 benefits of adding omega-3 fatty acids, including DHA and linolenic acid.

18 Therefore, we find no error in the Examiner's conclusion that it would  
19 have been obvious to a person of ordinary skill in the art at the time of the  
20 invention to substitute Henningfield's omega-3 linolenic acid with  
21 Alexander's omega-3 DHA. (See *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct.  
22 1727, 1740 (2007)(mere substitution of one known element for another is  
23 obvious). Consequently, the Appellants have not established error on the  
24 part of the Examiner.

25 Accordingly, we affirm the Examiner's rejections of claims 14 and 23.

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CONCLUSION OF LAW

On the record before us, the Appellants have not shown that the Examiner erred in rejecting claims 1-4, 7- 8, 11-13, 14-20 and 22-23.

The Appellants have not established that their claimed invention does more than combine known elements in a known fashion to achieve a predictable and expected result.

Regarding claim 10, we find that the Examiner did not provide sufficient evidence to support the rejection.

DECISION

The Rejection of claims 1-4, 7, 8, 11-13, 15-20 and 22 under 35 U.S.C. §103(a) as being unpatentable over the combination of Zaloga and Henningfield is AFFIRMED.

The Rejection of claim 10 under 35 U.S.C. §103(a) as being unpatentable over the combination of Zaloga and Henningfield is REVERSED.

The Rejection of claims 14 and 23 under 35 U.S.C. §103(a) as being unpatentable over the combination of Zaloga, Henningfield, and Alexander is AFFIRMED.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv) (2006).

AFFIRMED-IN-PART

ack

Appeal 2008-4946  
Application 10/993,348

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