BL O/220/13

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PATENTS ACT 1977

APPLICANTS Ajit Lalvani, Kartar Singh Lalvani & Robert Taylor

ISSUE Whether patent applications numbers GB0804968.6 & GB0807735.6 comply with Sections 1(1)(b), 14(5)(c), & 76(2).

HEARING OFFICER Dr. Stephen Brown

DECISION

1. Introduction

1 This decision concerns two patent applications by the same applicants. Application GB0804968.6 was filed on 18th March 2008, with the title "Composition for bone health maintenance", and was published on 23rd September 2009 as GB2458467. Application GB0807735.6 was filed on 29th April 2008, with the title "Composition for postnatal health and lactation", and was published on 4th November 2009 as GB2459657.

2 During substantive examination the examiner objected that the claims of both applications did not satisfy the requirements of the Patents Act on the same grounds. Namely, that they lacked an inventive step, introduced added subject matter and were not supported.

3 While the two applications differ in content, it was agreed to deal with both at a single hearing given their identical legal grounds. Thus a single hearing addressing both cases was held before me on 10th October 2012. Representing the applicants at the hearing were Mr Keith Bridgeman and Mr Robert Taylor of Vitabiotics Ltd. Also present were the examiner, Ms Fiona Warner, and hearing assistant, Mr Gareth Prothero.

4 During the hearing, some further legal issues arose that the applicants felt they had not had the opportunity to adequately prepare for beforehand. These issues were set out in a letter from the examiner dated 8th November 2012 and the applicants were given the opportunity to address these further issues. This they did so in a letter dated 4th December 2012 and at a supplementary hearing held on 28th March 2013. This hearing was attended by the same people as the first. All the further submissions, both written and oral, including an

additional letter of 30th October 2012 from the applicants, have been taken into account in the following decision.

2. The applications

2.a GB0807735.6 ("The Lactation patent")

5 The description of this application explains that milk production during breastfeeding places a significant physical demand on a mother's body, and that the quality of a mother's milk is, to a large extent, dependent on her nutritional intake. The invention therefore provides a composition directed towards use by lactating women.

6 The most recent claims were filed on 12th July 2012. They include two independent claims, which are as follows:

1. A pharmaceutical composition that is specifically for lactation, which consists essentially of Calcium, DHA (Docsahexaenoic Acid) and EPA (Eicosapentaenoic Acid), Betacarotene, Vitamin D3, Vitamin E, Vitamin C, Vitamin B1 (Thiamine), Vitamin B2 (Riboflavin), Vitamin B3 (Niacin), Vitamin B6, Folic Acid, Vitamin B12, Pantothenic acid, Biotin, Vitamin K, Iron, Magnesium, Zinc, Iodine, Copper, and Selenium.

2. A pharmaceutical that is specifically for lactation, comprising Calcium, DHA (Docosahexaenoic Acid) and EPA (Eicosahexaenoic Acid), Betacarotene, Vitamin D3, Vitamin E, Vitamin C, Vitamin B1 (Thiamine), Vitamin B2 (Riboflavin), Vitamin B3 (Niacin), Vitamin B6, Folic Acid, Vitamin B12, Pantothenic acid, Biotin, Vitamin K, Iron, Magnesium, Zinc, Iodine, Copper, and Selenium, in which according to weight, Calcium, DHA (Docosahexaenoic Acid) and EPA (Eicosahexaenoic Acid), form 70% to 85% of the composition.

2.b GB0804968.6 ("The Bone health patent")

7 The description of this application explains that a trend away from dairy foods has resulted in an increased incidence of bone health problems, and identifies certain categories of people in need of bone health nutrients, such as women diagnosed with low bone density or osteoporosis, all women of 45 years or older who are concerned about osteoporosis, and breastfeeding women. The invention then provides a composition directed towards use by these people.

8 The most recent claims were also filed on 12th July 2012. They too include two independent claims, which are as follows:

1. A pharmaceutical composition for bone health maintenance, for combined, sequential or simultaneous administration, in any form, which consists essentially of Calcium, Soy Isoflavone, Boron, Omega-3 fatty acids that are specifically derived from fish oil, Magnesium, Zinc, Vitamin D3, Manganese, Selenium, Copper, and Vitamin C.

2. A pharmaceutical composition for bone health maintenance, for combined, sequential or simultaneous administration, in any form, comprising Calcium, Soy Isoflavone, Boron, Omega-3 fatty acids that are specifically derived from fish oil, Magnesium, Zinc, Vitamin D3, Manganese, Selenium, Copper, and Vitamin C, in which according to weight, Calcium, Soy Isoflavone, Boron and Omega-3 fatty acids that are specifically derived from fish oil, form 70% to 80% of the composition.

3. Inventive step

3.1 The law and its interpretation

9 The relevant part of the Patents Act with respect to inventive step is set out in sections 1 and 3:

1.-(1) A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say –

(a) The invention is new;

(b) It involves an inventive step;

……..

3. An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art by virtue only of section 2(2) above (and disregarding section 2(3) above)."

10 In addition to the above there is also the case law established in the UK in *Windsurfing*[1]. This long established approach involves a four step test which was reformulated by Jacob LJ in *Pozzoli*[2] as follows:

(1)(a) Identify the notional "person skilled in the art";

(1)(b) Identify the relevant common general knowledge of that person;

(2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;

(3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;

(4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

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[1] *Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd, [1985] RPC 59*
[2] *Pozzoli SPA v BDMO SA* [2007] EWCA Civ 588

11 Additionally, there is also the decision in *SABAF*[3] which is the leading authority on how to decide whether or not a combination of known things can be considered inventive. While the decision in SABAF[3] concerned a collocation of features of a mechanical device (a gas burner), it has long been accepted that the decision is one of general application to any invention defined in terms of a combination of features.

3.2 Preliminary issue - EPO vs. UK jurisprudence

12 Before considering the inventiveness of the claims, I must address a preliminary issue raised by the applicants regarding the relative effects of the jurisprudence of the UK national courts and that of the Boards of Appeal of the European Patent Office[4] (henceforth 'the EPO').

13 At the first hearing Mr Bridgeman submitted that, in his view, following the recent decision of the Supreme Court in *Human Genome*[5], the decisions of the EPO are now binding on me, even in preference to UK case law. Specifically, he argued that I am bound to follow the so-called 'problem-solution' approach used by the EPO when addressing issues of inventive step. Mr. Bridgeman drew my attention to paragraph 87 of *Human Genome*[5], where Lord Neuberger said:

> *Further, while national courts should normally follow the established jurisprudence of the EPO, that does not mean that we should regard the reasoning in each decision of the Board as effectively binding on us. There will no doubt sometimes be a Board decision which a national court considers may take the law in an inappropriate direction, misapplies previous EPO jurisprudence, or fails to take a relevant argument into account. In such cases, the national court may well think it right not to apply the reasoning in the particular decision. While consistency of approach is important, there has to be room for dialogue between a national court and the EPO (as well as between national courts themselves). Nonetheless, where the Board has adopted a consistent approach to an issue in a number of decisions, it would require very unusual facts to justify a national court not following that approach.*

14 I am afraid that I cannot see how Lord Neuberger's comments here have quite the universal effect that Mr Bridgeman submits. While the last sentence of the above paragraph indicates that decisions of the EPO should be followed where they have adopted a consistent approach to an issue, I note that the first sentence explicitly states that each EPO decision should not be regarded as binding. I simply cannot see any clear instruction in the decision in Human Genome[5] that states that henceforth all decisions of the EPO should be given precedence over those of the UK courts, or that UK case law should no longer be followed. That would be such a fundamental change in the practice of UK

[3] *SABAF SpA v MFI Furniture Centres Ltd* [2005] RPC 10
[4] Case Law of the Boards of Appeal; Sixth Edition, 2010.
[5] *Human Genome Sciences Inc v Eli Lilly and Company* [2011] UKSC 5

law that I feel sure that if that is what Lord Neuberger had intended to say, he would have done so with unavoidable clarity.

15 The 'problem-solution' approach to inventiveness has indeed been used consistently by the EPO for some time, thus it meets the criteria set out in the last sentence of paragraph 87 of *Human Genome*[5]. However, there is a tension between this sentence and the first one of the same paragraph which makes it clear that I am not bound by the decisions of the EPO. Inventive step is an area where the guidance of the UK courts is very well established and continues to be consistently applied. In contrast, the decision in Human Genome[5] concerned industrial applicability under Articles 52 and 57 of the EPC. This is an area of law in which, as Lord Neuberger noted at paragraph 88, "there has been little helpful domestic guidance". Thus on balance, I do not think that the decision in Human Genome[5] provides a clear and unequivocal enough basis for me to depart from the comprehensive guidance of the UK courts in the area of inventive step.

16 On the issue of collocation, I think it is also worth noting that in his judgment in SABAF[3], Lord Hoffmann considered the corresponding EPO Examination Guidelines with regard to inventions defined by a combination of features, and said (at paragraph 18):

> *Although this statement was made by reference to the pre-1977 UK law, the same principles are applied by the European Patent Office. The judge referred to the EPO Guidelines for Substantive Examination, where the following statement of principle appears in the current (December 2003) edition in Ch.IV:*
>
> > *9.5 Combination vs. juxtaposition or aggregation*
> >
> > *The invention claimed must normally be considered as a whole. When a claim consists of a 'combination of features', it is not correct to argue that the separate features of the combination taken by themselves are known or obvious and that 'therefore' the whole subject-matter claimed is obvious. However, where the claim is merely an 'aggregation or juxtaposition of features' and not a true combination, it is enough to show that the individual features are obvious to prove that the aggregation of features does not involve an inventive step. A set of technical features is regarded as a combination of features if the functional interaction between the features achieves a combined technical effect which is different from, e.g. greater than, the sum of the technical effects of the individual features. In other words, the interactions of the individual features must produce a synergistic effect. If no such synergistic effect exists, there is no more than a mere aggregation of features . . .*
> >
> > *Chapter IV, Annex 2.1 Obvious and consequently non-inventive combination of features:*

The invention consists merely in the juxtaposition or association of known devices or processes functioning in their normal way and not producing any non-obvious working inter-relationship.

17 Lord Hoffmann went on to say (at paragraph 24):

In my opinion the approach of the Court of Appeal is contrary to well established principles both in England and in the European Patent Office, as stated in the quotation from Lord Tomlin and the EPO Guidelines to which I have referred. I quite agree that there is no law of collocation in the sense of a qualification of, or gloss upon, or exception to, the test for obviousness stated in s.3 of the Act. But before you can apply s.3 and ask whether the invention involves an inventive step, you first have to decide what the invention is. In particular, you have to decide whether you are dealing with one invention or two or more inventions. Two inventions do not become one invention because they are included in the same hardware. A compact motor car may contain many inventions, each operating independently of each other but all designed to contribute to the overall goal of having a compact car. That does not make the car a single invention.

18 It seems clear to me from these passages that the approach to collocation adopted in SABAF[3] was intended to be fully consistent with EPO practice in this area, and I can see no reason to depart from it either.

19 So, in summary, I reject Mr Bridgeman's interpretation of the decision in *Human Genome*[5] and consider myself still bound by the precedents of the UK Courts while remaining no more than very strongly persuaded by the decisions of the EPO[4] in the area of inventive step. Thus I must follow the Windsurfing/Pozzoli[2] test in preference to the 'problem-solution' approach favoured by the EPO and Mr Bridgeman. However, I will briefly check my conclusions against the latter approach to determine if any different outcomes might have occurred.

3.3 Arguments and Analysis

3.3a Applying the Windsurfing/Pozzoli test to GB0807735.6 ("The Lactation patent")

I. Step 1(a): Identify the notional "person skilled in the art"

20 In her pre-hearing report (for the first hearing) the examiner stated that this person could be considered to be a team of people comprising a nutritionist, a pharmacist and a formulation scientist. In my opinion, this is a valid suggestion and I note that the applicants did not dispute it. To this I would add that I consider such a team to be one working in the field of dietary health supplements.

II. Step 1(b): Identify the relevant common general knowledge of that person

21 I believe that the common general knowledge of such a team would include awareness of nutritional supplements on the market, product information sheets, established scientific literature relating to health and nutrition, as well as other suitable reference materials and textbooks in their field. I also think that this common general knowledge would extend to how to formulate a nutritional or dietary supplement from a list of known or commonly available ingredients, including an awareness of how to determine standard dosages of such ingredients. Also, many of the constituents of claims 1 and 2 are vitamins, which by definition are essential nutrients that have long been known to be used in dietary supplements.

22 Additionally, the examiner has identified the following prior art, all of which was available before the filing date of the application:

Martindale – The Complete Drug Reference Thirty-fifth edition, Pharmaceutical Press, Ed. S C Sweetman (2007) ISBN 10 0 85369 687 X ('Martindale')

"Vitabiotics Pregnacare Original" (the applicants' own prior art product - henceforth 'the Pregnacare product');

D1: US2002/0102330 A1 (Schramm et al.)

D2: US2003/0216351A1 (Hermelin et al.)

D3: US2005/0037065A1 (Kirschner et al.)

D4: EP0705539A2 (Friesland)

23 Martindale is an established drugs reference guide which contains an entry for each of the twenty two constituents of claims 1 and 2, and makes clear the significance of their role in human health. At both hearings the applicants argued that Martindale was not relevant prior art as it contains references to tens of thousands of substances. Thus there would be no reason for the skilled person to home in on the twenty two constituents specified in claims 1 and 2.

24 This is, I think, to misunderstand the legal use to which the book can be put. In my opinion, it shows that it was common general knowledge at the filing date of the application that each constituent specified in the claims *could* be used in the management of human health. Whether or not choosing the exact twenty two constituents specified in the claims represents an inventive step is a more complex question.

25 The applicants similarly argued that documents D1-D4 disclose multi-substance panaceas with a vast range of ingredients. A skilled person would either dismiss them as nonsense or would have no reason to pick out the ingredients of the current application from all the other substances present. Again, I think this misunderstands the legal impact of their disclosures. Together with the Pregnacare product, I believe that this prior art provides sufficient evidence that each of the individual constituents specified in the claims was known to be of use as a dietary supplement at the filing date of the application. They thus

represent the 'state of the art' referred to in step 3 of the Windsurfing/Pozzoli[2] test.

III. Step 2: Identify the inventive concept of the claim in question or if that cannot readily be done, construe it:

26 In order to identify the inventive concept I must first construe the claims. At first sight, the construction of claims 1 and 2 seems reasonably straight forward. However, there are a few significant issues that need to be addressed.

27 It is accepted legal precedent that the correct approach to claim construction is that set out in *Kirin-Amgen*[6]. Here Lord Hoffman held that when applying a "purposive construction", the question is always what the person skilled in the art would have understood the patentee to be using the language of the claim to mean.

28 Firstly, each of independent claims, 1 and 2, requires a composition "specifically for lactation". I note that the word "specifically" has been introduced during the examination rounds, and that the original claims specified a composition "for postnatal health and lactation". Though not discussed at the hearings, it would seem from the arguments advanced during the examination rounds that the applicants consider that its introduction has the effect of excluding from consideration any prior art documents that disclose compositions that are for use not only during lactation, but also for other uses (as they are not "specifically for use in lactation"). In other words, the applicants consider that in order to anticipate these claims, a prior art composition must be described exclusively as being for use during lactation and for no other purpose.

29 I am afraid that I do not agree with this construction. The everyday meaning of the words "specifically for lactation" does not have the inevitable consequence of excluding any use other than lactation. Furthermore, I do not believe that the person skilled in the art would interpret the words any differently either. Therefore, I do not think that the word "specifically" here can reasonably be construed as having any particular limiting effect on claims 1 and 2. Thus I believe that these claims are effectively directed towards to a composition "for lactation".

30 Secondly, there is the question of whether or not the claims should be construed as relating to medical use. This is a significant point as it affects the relevance of the prior art that may be used to argue the issue of inventive step. Section 4A of the Act states that:

4A.-(1) A patent shall not be granted for the invention of-

(a) a method of treatment of the human or animal body by surgery or therapy, or

[6] *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2005] RPC 91

(b) a method of diagnosis practised on the human or animal body.

(2) Subsection (1) above does not apply to an invention consisting of a substance or composition for use in any such method.

(3) In the case of an invention consisting of a substance or composition for use in any such method, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if the use of the substance or composition in any such method does not form part of the state of the art.

(4) In the case of an invention consisting of a substance or composition for a specific use in any such method, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if that specific use does not form part of the state of the art.

31 Thus a claim to a substance or composition for a particular *medical use* is only anticipated by the prior use of that substance or composition for that particular medical use. The Examination Guidelines for Patent Applications relating to Medical Inventions at the UK Intellectual Property Office[7] explain this point in more detail than I feel it is necessary to do here.

32 However, if I decide that the claims are directed towards a non-medical use then it is a long established UK legal precedent[8] that they should be construed as a composition *per se*, 'suitable for', but not restricted to, their stated use. While this precedent was first established under a previous patents act, its principles have been upheld under the present act, for example in *FNM v Drammock International*[9], and thus I am confident that they remain good law.

33 Throughout the application process the examiner has maintained that the claims cannot be construed as relating to medical use as 'for lactation' is not a therapeutic use. To support this position she referred to the EPO's decision T24/91[10], where it was held that the term therapy can be considered as follows:

....The meaning of the term "therapy" is not restricted to curing a disease and removing its causes. Rather, this term covers any treatment which is designed to cure, alleviate, remove or lessen the symptoms of, or prevent or reduce the possibility of contracting any disorder or malfunction of the human or animal body.

34 At both hearings, Mr. Bridgeman disagreed with the examiners position, arguing that the claims did relate to medical use since it is well known that lactation can cause a variety of medical issues and that their invention was

[7] Examination Guidelines for Patent Applications relating to Medical Inventions at the UK Intellectual Property Office (August 2008) – see paragraphs 78, 80-83, and 103.
[8] Adhesive Dry Mounting Co Ltd v Trapp (1910) 27 RPC 341.
[9] FNM v Drammock International & Anor [2009] EWHC 1294 (Pat) – especially paragraphs 56-73.
[10] THOMPSON/Cornea OJEPO [1994] 512, paragraph 2.7.

formulated to help with these issues. In support of this view Mr Bridgeman and Mr Taylor directed me towards various passages between pages 4 and 10 of the description which detail the relevance of the various constituents including the recommended daily allowances for many of them.

35 Upon review of these passages, however, it seems to me that the majority of the constituents are not directed towards any particular therapeutic use. Rather they are directed towards what might be termed maintenance of the health of the mother and baby. For example, it is stated at page 5 that iodine "...levels help maintain healthy thyroid function"; calcium is (at page 6) "...to maintain healthy bones"; and that zinc (also at page 6) is "...fundamental to many bodily processes and cell division". On the other hand, it is true that some of the stated reasons might be considered therapeutic. Specifically, these are: iron, which is stated (at page 5) to be at a level "to prevent anaemia in both mother and developing child"; and vitamin K (at page 7), which can "prevent excessive bleeding" in babies.

36 However, while I accept that there is mention of a small number of therapeutic conditions that could be treated by the composition of the invention, in their present form the claims are not clearly directed towards any of these conditions. Rather the claims are directed towards 'lactation'. This is a physical state that occurs naturally in breastfeeding mothers and, in my opinion, cannot be considered a disorder or malfunction of the human body as per the definition of 'therapy' referred to in T24/91[10]. This conclusion is reinforced by the last two paragraphs of the description at page 2, which state:

> *This formulation has therefore been devised in order to provide specific follow on support during the postnatal period. It is also formulated to account for the need for a general postnatal supplement for 3-9 months following childbirth, to replace depleted nutrients and assist the body following pregnancy, even if the mother is not breast-feeding.*
>
> And
>
> *The invention concerns a pharmaceutical composition for postnatal health and lactation, that provides nutrients at meaningful and effective levels to safeguard a mothers [sic] diet during this period.*

37 Ignoring the contradictory reference to the composition being of use even if the mother is not breastfeeding, the emphasis here is clearly on providing a supplement that 'safeguards' a breastfeeding mother's diet.

38 So in summary of the preceding 8 paragraphs, there is no clear indication in the claims that the composition is directed towards preventing, curing, treating, or alleviating the symptoms of any particular condition. I therefore construe them as not relating to medical use. I must also add that although the claims are directed to a "pharmaceutical composition", these words alone are not enough to persuade me otherwise in light of the above analysis.

39 Thirdly, in their letter of 4th December 2012, the applicants argue that the claims should be construed as limited by their stated use (i.e. 'for lactation'), even

should I conclude that this is a non-medical use. They refer to the EPO decision in G02/88[11] in support of this argument. The final paragraph of this decision states that:

> *A claim to the use of a known compound for a particular purpose, which is based on a technical effect which is described in the patent, should be interpreted as including that technical effect as a functional technical feature, and is accordingly not open to objection under Article 54(1) EPC provided that such technical feature has not previously been made available to the public.*

40 While this paragraph certainly seems relevant, it is apparently at odds with the UK legal precedent first set out in *Adhesive Dry Mounting*[8]. I note that the decision in *FNM v Drammock International*[9] comments on this point, stating at paragraphs 68 & 69 that:

> *First, the decision in MOBIL itself is squarely predicated on the claim being in use form. As the Enlarged Board pointed out elsewhere in the decision, at [2.1] and [5], a use claim is a claim to a physical activity, which is different from, and more circumscribed than, a product claim, which is a claim to a physical entity. As the Board put it at [5]:*
>
> > *"… a claim to a particular use of a compound is in effect a claim to the physical entity (the compound) only when it is being used in the course of the particular physical activity (the use) …"*
>
> *Secondly, so far as I am aware, the EPO continues to allow use claims where the only novelty lies in the purpose of the use, but not to allow product claims in such circumstances: see Case Law of the Boards of Appeal of the European Patent Office (5th ed) at paragraph 5.3.3 (pages 119-120). Counsel for FNM was unable to cite any decision either in this country or in the EPO in which a product claim had been allowed on such a basis.*

41 Thus it appears that what G02/88[11] actually teaches is that non-medical claims should be construed as limited by their stated use only when they are *method* claims. In claims that relate to non-medical products or compositions the word 'for' is still to be construed as meaning 'suitable for', following the principles first laid out in *Adhesive Dry Mounting*[8].

42 Next, Claim 1 also requires a composition which "consists essentially" of twenty two different ingredients, as set out above. It is established legal precedent, both in UK law and before the EPO, that this phrase is to be construed as meaning that unspecified components could be present in the claimed composition as long as the characteristics of the claimed composition are not materially affected by the presence of these unspecified components. I see no reason to depart from that interpretation here or to dwell on it further, other than to note that it is explained more fully in the Office's Manual of Patent Practice[12].

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[11] Mobil Oil Corp. [1990] OJEPO 93
[12] The Manual of Patent Practice - paragraph 14.123.1.

43 Claim 2 also requires a composition that is “for lactation”, however, in this instance “comprising” (cf. “consisting essentially of” as in claim 1) the same twenty two ingredients, but where calcium, DHA and EPA form 70% to 85% by weight of the composition. In line with the conventional construction of the word “comprising” in patent claims, I take this as meaning that other ingredients may be present in the claimed composition.

44 Thus, as I have construed it, I believe that the inventive concept of independent claim 1 can be regarded as a composition consisting essentially of those constituents listed in the claim, suitable for, but not restricted to, use during lactation.

45 Similarly, the inventive concept of independent claim 2 can be summarized as a composition comprising the twenty two constituents listed in that claim, such that 70% to 85% by weight is formed of calcium, DHA and EPA, in a composition suitable for, but not restricted to, use during lactation.

IV. Step 3: Identify what, if any, differences exist between the matter cited as forming part of the “state of the art” and the inventive concept of the claim or the claim as construed

46 The applicants do not dispute that the ‘Pregnacare’ product, and its composition, was in the public domain prior to the filing date of the application. I also note that it is listed as a multivitamin and mineral preparation in Martindale[13]. As the name suggests, it is directed towards use by pregnant women, and this also has not been disputed by the applicants.

47 The applicants did however argue that being for the use of pregnant women was not the same thing as being suitable for use by lactating women as pregnancy and lactation are distinct biological phases. While this is true to an extent I am afraid that I cannot accept the applicants’ conclusion that ‘Pregnacare’ is thus not a relevant disclosure. It is well known that the female body prepares for lactation during the latter stages of pregnancy, for example by the production of colostrum. Thus, in my opinion, the ‘Pregnacare’ product would be relevant prior art for a skilled person developing a dietary supplement that is suitable for use by lactating women.

48 The ‘Pregnacare’ product includes all of the ingredients of claims 1 and 2 of the present application, with the exception of calcium, DHA, and EPA. Furthermore, it contains vitamin D (and not specifically vitamin D3 as required by claims 1 and 2), and “natural mixed carotenoids” (and not specifically beta carotene as required by claims 1 and 2).

49 With regards to claim 2, it should be noted that since there is no disclosure of DHA, EPA or calcium, it follows that there is no disclosure that these constituents form 70 to 85% by weight of the composition.

[13] At page 2700, column 1.

V. Step (4): Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

50 During the application process the examiner argued that each of claims 1 and 2 was no more than a non-inventive collocation of known constituents. She also argued that claims 1 and 2 represented a non-inventive selection of further constituents over those used in the 'Pregnacare' product. Both at the hearings and in writing, the applicants have countered that the cited prior art is not relevant, that the examiner has used *ex post facto* analysis, and that she has also misapplied the "could/would approach" as set out in the Case Law of the EPO Boards of Appeal[4]. I agree that all of these are important points and I shall now consider each of them.

V.1. Collocation

51 The examiner has maintained throughout that the claims relate to no more than a collocation of known ingredients. Naturally the applicants disagree. As mentioned above, the UK law relating to collocation is set out in *SABAF*[3]. In paragraph 24 of that decision Lord Hoffmann held that:

> *But before you can apply section 3 and ask whether the invention involves an inventive step, you first have to decide what the invention is. In particular, you have to decide whether you are dealing with one invention or two or more inventions. Two inventions do not become one invention because they are included in the same hardware. A compact motor car may contain many inventions, each operating independently of each other but all designed to contribute to the overall goal of having a compact car. That does not make the car a single invention.*

52 In paragraph 26 he went on to add:

> *The EPO guidelines say that "the invention claimed must normally be considered as a whole". But equally, one must not try to consider as a whole what are in fact two separate inventions. What the Guidelines do is to state the principle upon which you decide whether you are dealing with a single invention or not. If the two integers interact upon each other, if there is synergy between them, they constitute a single invention having a combined effect and one applies section 3 to the idea of combining them. If each integer "performs its own proper function independently of any of the others", then each is for the purposes of section 3 a separate invention and it has to be applied to each one separately. That, in my opinion, is what Laddie J meant by the law of collocation.*

53 At the second hearing Mr. Bridgeman argued that SABAF[3] was not a relevant precedent since it only concerned two inventions placed side by side in their entirety. In contrast the 'lactation patent' concerns 22 different constituents

mixed together. I think this is interpreting the precedent too narrowly. From his language, as quoted above, I believe that Lord Hoffmann was clearly setting out a general principle of how to determine how many inventions are actually present in a claim. To paraphrase him, I believe that what SABAF[3] teaches is that: 22 inventions do not become one invention because they are included in the same pill. The key question is whether or not there exists any synergistic effects between any of the twenty two individual constituents.

54 Mr. Bridgeman also argued that all biochemical substances act synergistically when present in a human body at the same time. Thus there is bound to be synergy between the 22 constituents when consumed. This is a very interesting assertion. If I accept it I will in effect be exempting all compositions that are consumed by humans, or other animals, from explicitly having to apply the SABAF[3] precedent. The mere act of consumption will imply synergy.

55 I might be more minded to reach such a conclusion if there were corroborating evidence in the application as filed. However, having carefully considered the application, I cannot find any evidence of any synergy. Page 3 of the description lists the amounts of constituents present in an "optimal formulation". Pages 3 to 6 also list the relevant daily dosage of each constituent for use in one capsule per day. Pages 6 to 11 recite the relevance of each constituent, in other words, the particular role that each has in the formulation. There is no suggestion anywhere in the description that any of the constituents interact with each other in any way.

56 I thus conclude that even if there is a degree of interaction between the 22 constituents when present in a human body it is unintentional and incidental to the operation of the claimed composition. It seems quite clear to me from reading pages 6 to 11 of the description that the applicants intended each of the individual constituents to perform its own function independently of the others. It thus seems correct that, following SABAF[3], I should assess each constituent as a separate invention and determine whether or not it is known or obvious individually. Further, as I have already concluded above that the claims of the 'lactation patent' are not medical use claims, I need only to assess whether each constituent is suitable for use by lactating women. I will now consider each of the constituents of claim 1 in turn:

i. <u>DHA (Docosahexaenoic Acid) and EPA (Eicosapentaenoic Acid)</u>

57 Both of these substances were very well known constituents of fish oil, itself a widely known dietary supplement, before the filing date of the application[14].

58 D2 discloses a nutritional supplement for supporting women prior to and during lactation – this much is declared in paragraph [0002]. Paragraph [0012] states that "Many body tissues require EPA and DHA. DHA is especially important in

[14] Martindale says at p1225 (column 2) that "Fish oils and other omega-3 fatty acid preparations have been widely promoted as dietary supplements and a wide range of preparations of varying composition and potency is available".

the retina and in the cerebral cortex of the brain. Half of the DHA in a foetus's body accumulates in the brain before birth, and half after birth, an indication of the importance of fatty acids to the fetes during pregnancy and then to the young infant during lactation".

59 D3 provides a soft gel nutritional supplement for pregnant or lactating women (see paragraphs [0041 to [0043]). At paragraph [0003] it states that "Essential fatty acids (arachadonic acid, eicosapentaenoic acid and docosahexaenoic acid) are essential for proper development of a foetus and for proper biological functioning of the mother. Stored fatty acids supplies are biochemical building blocks that support most of the body's biochemical pathways."

60 Thus, it was known to use both DHA and EPA in compositions for use by lactating women.

ii. Calcium

61 The use of calcium as a dietary supplement was also very well known before the filing date of the application[15]. Also paragraph [0009] of D1 states that "Calcium is critical for proper foetal development, and is essential for the production of milk by women. The administration of calcium to a pregnant or lactating woman also acts to prevent early osteoporosis in the woman as a result of a calcium drain in the woman during pregnancy or lactation". It is also disclosed as an ingredient of eight different commercially available formulations for use during lactation at paragraphs [0021] to [0028] of D3. Specfically, Nestabs CBF (RTM), Materna (RTM), Enfamil Natalins RX (RTM), Prenate Ultra (RTM), Niferex-PN (RTM), Niferex-PN Forte (RTM), Advanced formula Zenate (RTM), and Precare (RTM).

iii. Vitamin D3

62 It is well known that vitamin D3 is one of the major forms of vitamin D, which is listed as present in the 'Pregnacare' product. Page 6 of the description of the 'lactation patent' specifies that vitamin D3 is "necessary for the absorption and utilisation of calcium". This property of vitamin D was generally very widely known well before the filing date of the application, and would certainly have formed part of the common general knowledge of the skilled person[16].

63 Vitamin D3 is also disclosed as an ingredient in two different commercially available formulations for use during lactation at paragraphs [0028] and [0033] of D2 (Prenate Ultra (RTM) and Natafort (RTM)). Thus the use of vitamin D3 in a composition for use by lactating women is known.

[15] The role of calcium in the body and its use in supplements is discussed in Martindale at pages 1510 to 1513.

[16] For instance, Martindale states, at page 1825, column 2: "Vitamin D compounds are fat-soluble sterols, sometimes considered to be hormones or hormone precursors, which are essential for the proper regulation of calcium and phosphate homeostasis and bone mineralisation".

iv. Betacarotene

64 D3 mentions Betacarotene as a possible ingredient at paragraph [0084]. This document is directed to a nutritional supplement for lactating women - see paragraph [0041]. Betacarotene is also specified in claim 3 of D4 as an ingredient in a food for pregnant and lactating women.

v. Other constituents

65 All of the other constituents are present in the 'Pregnacare' product. As reasoned above this product is relevant prior art. Thus the remaining constituents for the composition of claim 1 were at least obvious to try in a dietary supplement for use during lactation. Thus I am forced to conclude that claim 1 relates to no more than a non-inventive collocation of known or obvious constituents.

66 Additionally, I note that each constituent was known, or at least obvious to try, in dietary supplements specifically for use during lactation. Thus even if I had construed claim 1 as relating to medical use I would still have concluded that it was obvious as a collocation.

67 I will now turn to claim 2. This claim specifies exactly the same constituents as claim 1 but additionally requires that calcium, DHA and EPA form 70 to 85% by weight of the composition. I note that this range was not explicitly stated in the application as filed and thus, unsurprisingly, I can find no indication in the application of any synergy or other effect arising from it. I am thus forced to conclude that it represents no more than an arbitrary compositional choice, representing conventional dosages of each specified constituent. As such, I cannot see how this range can confer the required inventive step. Thus claim 2 also appears to be obvious.

68 I am reassured that this conclusion is consistent with the decision in Actavis v Merck[17]. While this precedent was not raised at the hearings, its teaching is very clear. Paragraph 32 states that:

69 "…nearly always such dosage regimes will be obvious – it is standard practice to investigate appropriate dosage regimes. Only in an unusual case such as the present (where… treatment for the condition with the substance had ceased to be worth investigating with any dosage regime) could specifying a dosage regime as part of the therapeutic use confer validity on an otherwise invalid claim."

[17] Actavis v Merck [2008] EWCA Civ 444

70 Thus, Actavis v Merck[17] teaches that dosages are inventive only in unusual circumstances. The conclusion I have reached above in respect of claim 2 is fully consistent with this teaching.

71 While, as reasoned above, I remain bound by the UK law, I note that the EPO Guidelines for Substantive Examination on combination inventions state that the interactions between the individual features (in this case twenty two individual constituents) must produce a synergistic effect. If no such synergistic effect exists, then there is no more than a mere aggregation of features, in which case, according to the EPO Examination Guidelines "...it is enough to show that the individual features are obvious in order to prove that the aggregation of features does not involve an inventive step". Thus, even if I were to follow the EPO's approach I believe that I would arrive at the same conclusion, namely that both claims 1 and 2 are obvious.

V.2. Dependent claims

72 I shall now turn briefly to the dependent claims. Claim 3 specifies approximate average daily dosages of each constituent, and claim 4 specifies ranges of daily dosages. The description provides no evidence that these doses are in any way unusual. I am thus forced to conclude that these dosages would be obvious for the skilled person to try.

73 Claim 5 requires that the DHA and EPA are administered together in a separate tablet or capsule. The only reference to this feature would seem to be in the paragraph bridging pages 11 and 12 of the description as filed. However, I can find no suggestion of any synergistic effect of such a two part administration combining with the individual effects of the ingredients. Thus assessing this administration technique separately, I conclude that it would be obvious to a formulation scientist that the oil-based constituents, such as DHA and EPA, might be kept separate from the non-oil-based constituents. I thus find claim 5 obvious.

74 Claims 6 and 7 each require that certain constituents of the preceding claims are optional. In particular, claim 6 specifies that pantothenic acid, biotin, magnesium, copper and selenium are optional, and claim 7 specifies that betacarotene, vitamin D3, vitamin E, pantothenic acid, biotin, vitamin K, magnesium, zinc, copper and selenium are optional. As I have found above that the composition of claim 1 lacks an inventive step as a collocation of known or obvious elements, it follows that any sub-set of constituents will also be obvious.

75 Claim 8 specifies that "Omega-3 fatty acids generally" are used instead of DHA and EPA. The scope of this claim is less than clear as it does not indicate which omega-3 fatty acids are used or what is meant by the word 'generally'. Nonetheless, the use of omega-3 fatty acids in dietary supplements was well known at the filing date. Thus this claim is also obvious.

76 Claim 9 specifies that the pharmaceutical composition "does not comprise more than 300mg of amino acids in a protein or amino acid complex form". Putting aside the lack of clarity of this claim (it could be taken as requiring no amino acids are present), the dietary requirement of essential amino acids was well known before the filing date[18] and I do not think that the stated dosage can be regarded as in any way inventive following the same reasoning as for claims 2 to 4, above. Thus claim 9 is obvious.

77 Claim 10 specifies that the composition includes one or more carriers or excipients. This is a purely conventional feature of most pharmaceutical compositions and dietary supplements. Claim 10 is therefore also obvious.

V.3. Relevance of other approaches

78 The examiner has also objected that the claims represent non-inventive selections of constituents, following the approach of the Court of Appeal in *Dr Reddy's Laboratories*[19]. For their part, the applicants argued that the selection invention approach is not relevant to the present application as it relates to instances where an invention falls within the broadest scope of an earlier disclosure but is not specifically disclosed or exemplified in that earlier document. Having reviewed the decision in *Dr Reddy's Laboratories*[19], it is my opinion that it adds nothing helpful to the decision in this case, over and above what I have concluded using the collocation approach. I thus do not need to consider the selection invention approach any further.

79 The applicants' preferred methodology is the so-called 'problem-solution' approach favoured by the EPO. This is set out in the Case Law of the Boards of Appeal[4], Chapter I, Part D, paragraphs 4 to 5. On this basis, the applicants submit that the question to be determined is not whether the skilled person could have carried out the invention, but whether he would have done so in the hope of solving the underlying technical problem. Even though I have concluded, above, that I am not bound by the decisions of the EPO, I will for the sake of completeness address these arguments. If nothing else it will allow me to check that my decision is broadly compatible with the decisions of the EPO except where UK case law clearly forces me to be otherwise.

80 When following the 'problem-solution' approach it is first necessary to identify the technical field of the invention, or its intended purpose. I believe that page two of the description makes this clear where, in lines 24 to 26, it states:

> *The invention concerns a pharmaceutical composition for postnatal health and lactation, that provides nutrients at meaningful and effective levels to safeguard a mother's diet during this period.*

81 Thus, drawing on the discussion of construction above, I view the field to be 'dietary supplements suitable for use by lactating women'.

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[18] See for instance Martindale, at page 1762, column 1.

[19] *Dr Reddy's Laboratories (UK) Ltd v Eli Lilly & Co Ltd* [2010] RPC 9.

82 The second step in the approach is to identify the closest prior art. This is relatively easy in this case, I believe it is the applicants' own 'Pregnacare' product. As discussed above, this product is suitable for use by lactating women and contains all but 5 of the constituents specified in the claims of the current application.

83 The next step is to determine what underlying technical problem is solved by the differences vis-à-vis the closest prior art. To help answer this, I will first consider each of the 5 different constituents of claim 1 in turn:

i. DHA (Docosahexaenoic Acid) and EPA (Eicosapentaenoic Acid)

84 The relevance of these constituents is discussed at pages 8 to 10 of the description as filed. The first paragraph of page 9 states that "DHA....is the most important fatty acid required for healthy brain and eye development of the foetus". The second paragraph of page 9 states that "DHA and EPA are especially vital during pregnancy and breast-feeding as they form the building blocks of the baby's eyes and brain. DHA is the most important fatty acid required for healthy brain and eye development of the foetus".

85 However, these properties were not previously unknown – as discussed above, they have already been disclosed in the prior art cited by the examiner. Thus I believe that the skilled person would find it obvious to try adding these two constituents to produce a dietary supplement suitable for use by lactating women. Additionally, given the prior art, they would have a very good expectation of success when doing so.

ii. Calcium

86 The description at page 8 states that calcium is "vital for strong bones. The body has an extra requirement when lactating in order to support nutritious breastmilk" and "A high calcium diet when breastfeeding ensures healthy foetal bone development with minimised risk of bone loss in the mothers jaw". Again, this appears to be a previously known effect, and calcium is a well known ingredient in food supplements for lactating women as shown by the prior art cited by the examiner. Thus I also believe that the skilled person would have a good expectation of success when including calcium in a dietary supplement for use by lactating women.

iii. Vitamin D3

87 The only reference to this constituent in the description is at page 6, which specifies that it is "necessary for the absorption and utilisation of calcium". As discussed above, this property of vitamin D3 was widely known before the filing date of the application.

iv. Betacarotene

88 The only reference to this constituent in the description is also at page 6, where it states that betacarotene "is converted to Vitamin A as required by the body. It is important for cellular development and immune system function". As with each of the other constituents discussed above, this is not a new technical effect - it is well known generally that betacarotene is a precursor to vitamin A. For example, it is mentioned In Martindale at page 1770, column 3.

89 Overall, I can find no indication of any unknown or unexpected technical effects arising from the inclusion of any of the constituents of the claimed composition not already present in 'Pregnacare'. This makes identifying the underlying technical problem solved by the invention somewhat problematic. The best I can determine is 'finding an alternative composition which is suitable for use during lactation'.

90 If this is indeed the only 'problem' solved then the selection of any further constituents would appear to be arbitrary – i.e. any constituents suitable for use by lactating women would do. Moreover, as discussed above, the 'new' ingredients are all things which the skilled person would find obvious to try and have a good expectation of success when doing so. Thus I do not think that applying the problem-solution approach taken by the EPO would lead me to any different outcome.

91 At the hearings, the applicants were also keen to emphasise that prior art documents D1 to D4 and Martindale are not relevant as they are not "for the same purpose" as the present invention. To support this point they refer to the decision in G02/88[11] and the discussion in Chapter I (Patentability), Part D (Inventive step), paragraph 3.1 (Determination of closest prior art in general) of the Case Law of the Boards of Appeal[4].

92 As reasoned above, I am bound to follow the principles laid out in *Adhesive Dry Mounting*[8], and *SABAF*[3] over those in the Case Law of the Boards of Appeal[4]. Furthermore, as discussed above, the conclusion in G02/88[11] relates to method claims, not to non-medical product claims. Notwithstanding these issues, I note that the latter decision concerned the discovery of a new technical effect of a previously known substance, whereas, as I have concluded above, I can find no new technical effect in the present application. Thus again, following the approach of the EPO would not appear to lead me to a different conclusion.

93 So in summary, I have decided that the claims of GB0807735.6 ("the Lactation patent") are not to be construed as relating to medical use. Rather I have construed them as relating to a composition, consisting of those constituents listed in the relevant claims, suitable for use during lactation. On this basis I have applied two separate lines of reasoning, that applied to collocations and the problem-solution approach favoured by the EPO, and arrived at the same conclusion both times. Namely that none of the claims exhibit an inventive step. Thus they all fail section 1(1)(b) of the Act.

3.3b Applying the Windsurfing/Pozzoli test to GB0804968.6 ("The Bone health patent")

I. Step 1(a): Identify the notional "person skilled in the art"

94 As with GB0807735.6, I consider that this person could be considered a team of people comprising a nutritionist, a pharmacist and a formulation scientist, working on the design and formulation of dietary health supplements.

II. Step 1(b): Identify the relevant common general knowledge of that person

95 As before, I believe that the common general knowledge of such a team would include awareness of nutritional supplements on the market, product information sheets, established scientific literature relating to health, and nutrition, as well as reference materials and textbooks. Again, I suggest that their common general knowledge would extend to a knowledge of how to formulate a nutritional or dietary supplement from a list of known or commonly available ingredients, including being aware of recommended dosages.

96 In addition, the examiner identified the following prior art, all of which was available before the filing date of the application:

Martindale

Vitabiotics Osteocare Original (the applicants' own prior art product, henceforth 'Osteocare')

D5: US2003/190369A1 (Lovett)

D6: DE20310493U1 (Orthomol)

D7: DE202004013660U1 (Orthomol)

D8: The Journal of Clinical Endocrinology & Metabolism, Vol. 88 (10), 2003, Chen et al., "Soy Isoflavones have a Favorable Effect on Bone Loss in Chinese Postmenopausal Women with Lower Bone Mass: A Double-Blind, Randomized Controlled Trial".

D9: American Journal of Clinical Nutrition, Vol. 85 (3), 2007, "n-3 Fatty acids are positively associated with peak bone mineral density and bone accrual in healthy men: the NO_2 Study", pages 803-807.

97 Martindale contains an entry for each of the constituents of claims 1 and 2, making clear the significance of each in human health. Thus, it shows that it was common general knowledge at the filing date of the application that each constituent specified in the claims *could* be used in the management of human health.

98 Also, as I will discuss below, documents D5-D9 and the Osteocare product provide evidence that each of the individual constituents specified in the claims was known for use in dietary supplements at the filing date of the application. These disclosures thus represent the 'state of the art'.

III. Step 2: Identify the inventive concept of the claim in question or if that cannot readily be done, construe it:

99 As before, in order to identify the inventive concept I first need to consider some issues of claim construction. While I think that the claims can be understood reasonably clearly from the everyday meaning of the language they use, there are a few issues that need further comment.

100 Independent claims 1 and 2 each require "A pharmaceutical composition for bone health maintenance", and so, as with the claims of the 'lactation patent', the question arises as to whether or not these claims should be construed as directed towards a medical use.

101 The first paragraph of page 1 of the description states "This invention concerns a composition of biochemical and nutraceutical constituents for use in the maintenance of bone health, and the prevention of Osteoporosis" (my emphasis added). The description also states (under the heading "Disclosure of the Invention" at page 2), that "This invention concerns a novel dual tablet and capsule formulation aimed at supplementing the diet in order to provide constituents that will optimise the health of the bones". From a consideration of the claims and these passages of the description, I conclude that while prevention of osteoporosis is clearly a therapeutic use, the description also suggests other uses that are non-therapeutic, in particular, supplementing the diet to optimise bone health.

102 The claims themselves are clearly directed towards the "maintenance of bone health" and make no mention of osteoporosis. As such I conclude that the claims are directed towards a non-therapeutic use - i.e. keeping already healthy bones in a healthy condition and not the treatment or prevention of any particular disorder.

103 I also note that the claims are directed towards a composition "for combined, simultaneous or sequential administration, in any form", and construe this as requiring that the various constituents need not be administered as a single formulation, but could be administered separately and not necessarily at the same time, and in different forms.

104 Thus I construe the inventive concept of claim 1 to be a composition for combined, sequential or simultaneous administration in any form, consisting essentially of those constituents listed in the claim, suitable for, but not restricted to, use in maintaining bone health.

105 Similarly, I construe the inventive concept of claim 2 to be a composition comprising the twelve constituents listed in that claim, such that 70% to 80% by

weight comprises omega-3 fatty acids derived from fish oil, in a composition suitable for, but not restricted to, use in maintaining bone health.

IV. Step 3: Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed

106 'Osteocare' is the applicants' own product. I am satisfied that it was available before the filing date of the application[20], and note that this has not been disputed by the applicants. They have also not disputed that the composition of this product was in the public domain prior to the filing date, or that it was available as a product directed towards the promotion of bone health, as the name suggests.

107 The 'Osteocare' product includes all of the ingredients of claims 1 and 2 of the present application, with the exception of vitamin C, soy isoflavone, and omega-3 fatty acids derived from fish oil. With regard to claim 2, it should be noted that since there is no disclosure in the prior art product of omega-3 fatty acids derived from fish oil, and soy isoflavone, then there is no disclosure that these constituents, combined with calcium and boron, form 70 to 80% by weight of the composition.

V. Step (4): Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

V.1. Collocation

108 Claim 1 specifies a combination of twelve different constituents. Following the approach set out in SABAF[3], I can see no evidence in the application as filed of any synergy between them. The paragraph bridging pages 2 and 3 specifies an 'optimal formulation', and pages 3 to 6 set out the recommended daily dosages, and relevance of each constituent. However, although the alleged individual role of each constituent is indicated, there is nothing to suggest any interaction between them, and this conclusion is reinforced by the fact that the claims allow for the "combined, simultaneous or sequential administration, in any form" of the various constituents. In my opinion this outweighs the 'implicit synergy' argument due to the constituents being present in a human body, as asserted by Mr. Bridgeman and as discussed above in relation to the 'lactation patent'.

109 Therefore, I need to assess each constituent as a separate invention and determine whether or not it is known or obvious. I have already construed the claims as directed towards a non-therapeutic composition, suitable for use in

[20] 'Osteocare' is mentioned in Martindale as a calcium supplement at page 2660, column 1.

bone health maintenance, but not restricted to such use. I shall now consider each of the constituents of claims 1 and 2 in more detail:

i. Soy isoflavone

110 Page 7, table 4, of document D5 discloses an exemplary vitamin supplement including vitamin C and soy isoflavones. Paragraph [0056] states that "Soy isoflavonoids promote bone mass and protect antioxidant vitamins from oxidate damage".

111 Document D7 specifies the use of isoflavones in a nutritional supplement for use in cardiovascular disease, and for promoting bone formation (according to the WPI and EPODOC English language abstracts available from the EPO). Although this document has not been officially translated, a machine translation of paragraph [0014][21] specifies that isoflavones derived from plants, such as soya, are preferred.

112 I also note that D8 provides clear evidence that the beneficial effect of soy isoflavone on bone density was known at the filing date of the application. For instance, the abstract states "In conclusion, soy isoflavones have a mild, but significant, independent effect on the maintenance of hip BMC [bone mineral content] in postmenopausal women with low initial bone mass".

113 In light of the above, I conclude that it was known that soy isoflavone was suitable for use in compositions for the maintenance of bone health.

ii. Vitamin C

114 Paragraph [0054] of D5 states that "Vitamin C (ascorbic acid) is important for collagen and connective tissue formation, as well as for the maintenance of healthy gums". It is listed as an ingredient in each of the exemplary vitamin supplements of this document, which are for enhancing bone strength. It is also listed as an ingredient in the bone health promoting vitamin product of D7, for instance in the example at paragraph [0067].

iii. Omega-3 fatty acids derived from fish oil

115 The use of omega-3 fatty acids derived from fish oil are disclosed in the vitamin product of D7, which is directed towards promoting bone formation. Fish oil and omega-3 fatty acids are also specified in a micronutrient combination for use in the dietary treatment of rheumatoid arthritis and/or osteoporosis in D6, as set out in the WPI and EPODOC English language abstracts available from the EPO. Furthermore, I note that D9 concludes (at page 806) that "n-3

[21] Using Google Translate.

[omega-3] fatty acids, especially DHA, are positively associated with bone mineral accrual and, thus, with peak BMD [bone mass density] in young men".

iv. Other constituents

116 All of the other constituents are present in the 'Osteocare' product. As noted above, the applicants have not disputed that this product was directed towards the promotion of bone health. I thus conclude that each of the individual ingredients of the claims was known for use in dietary supplements at the filing date. I am thus forced to conclude that claim 1 relates to no more than a non-inventive collocation of known ingredients.

117 I should also add that since each of the constituents of claim 1 was known at the filing date to be used in compositions specifically for 'bone health', then even if I had construed the claim as directed towards a medical use, I would still have found it to be obvious as a collocation.

118 Claim 2 requires a composition comprising the same twelve ingredients as claim 1, though where the calcium, soy isoflavone, boron and omega-3 fatty acids form 70 to 80% by weight of the composition. However, there is nothing in the description to suggest that these proportions are based on anything other than standard amounts. Since the individual amounts of these constituents do not appear to be inventive it follows that their combination in claim 2 is also obvious as a collocation.

V.2. Dependent claims

119 Turning now to the dependent claims, claim 3 specifies exact dosages of each of the twelve constituents of claims 1 and 2. Claim 4 specifies dosage ranges of each constituent. Again, there is nothing in the description to suggest that these are based on anything other than standard amounts. Since the individual dosages for each constituent do not appear to be inventive it follows that their combination is also obvious as a collocation.

120 Claim 5 requires that two tablets are provided, with the omega-3 fatty acids, soy isoflavone and some of the vitamin D3 provided in a separate capsule. Although this feature is referred to in the paragraph bridging pages 6 and 7 of the description, its inventive significance is not disclosed. In light of this, it is my opinion that the skilled man, identified above, would be well aware of the advantage of keeping certain constituents separate depending on their hydrophobicity. I thus find claim 5 obvious too.

121 Claims 6 and 7 specify that some of the constituents of claim 1 are optional. In particular, claim 6 specifies that magnesium, zinc, vitamin D3, manganese, selenium, copper and vitamin C are optional. Claim 7 specifies that manganese, selenium, copper, and vitamin C are optional. Again, as I have found above that the composition of claim 1 lacks an inventive step as a

collocation of known constituents, it follows that any sub-set of constituents will also be obvious.

122 Claim 8 specifies that the composition "does not comprise more than 300mg of amino acids in a protein or amino acid complex form". The dietary requirement of essential amino acids was well known before the filing date[22] and I do not think that the stated dosage can be regarded as inventive. Thus I find claim 8 to be obvious.

123 Claim 9 specifies that vitamin D is used instead of vitamin D3. Claim 10 specifies that DHA and EPA are used "instead of omega-3 fatty acids generally". I consider that the skilled person would find each of these variations obvious. Vitamin D3 is a common form of vitamin D and, as I have noted above, DHA and EPA are well known constituents of fish oil.

124 Claim 11 requires that flax seed oil or linseed oil is used instead of omega-3 fatty acids "from a marine source". However, linseed oil was known as a source of essential fatty acids prior to the filing date[23]. I therefore consider that this claim is also obvious.

125 Finally, claim 12 specifies that the composition includes carriers or excipients. This is a purely conventional feature of most pharmaceutical compositions and dietary supplements. Claim 12 is therefore also obvious.

V.3. Relevance of other approaches

126 As with the 'lactation patent', I do not think that the selection invention approach adds anything useful in this case so I will not consider it.

127 With this application the applicants have also repeatedly argued that the case law of the EPO[4] should be followed. Thus for completeness I will again briefly apply the 'problem-solution' approach.

128 Firstly, I identify the technical field of the invention as 'dietary supplements suitable for maintaining bone health'. Next, I identify the closest prior art as the applicants' own ''Osteocare'' product. Again, determining the underlying technical problem that is solved by the invention is problematic as I can find no indication of any unknown or unexpected technical effects arising through the inclusion of any of the constituents of the claimed composition not already present in 'Osteocare''.

129 With regards to Soy isoflavone, the only reference in the description that might be regarded as suggesting a technical effect is at page 6, where it specifies that it is "....included to provide healthy bone density". However, this effect was already disclosed in documents D5, D7 & D8, as discussed above.

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[22] See for instance Martindale, at page 1762, column 1.
[23] See Martindale, p2116, column 3.

130 Vitamin C is referred to at page 6 of the application as "...a major antioxidant that contributes to bone matrix formation through its role in the development of collagen". Again, both roles were known at the filing date.

131 The description states, at page 5, that omega-3 fatty acids from fish oil are "...a source of the essential fatty acids DHA (Docosahexaenoic acid) and EPA (Eicosapentaenoic acid), which have been shown to play an important role in bone health". This would seem to be an acknowledgement that the role of DHA and EPA in bone health is already known. In any case, the use of omega-3 fatty acids derived from fish oil are disclosed in documents D6 and D7, as discussed above.

132 Thus in my opinion the 'problem solved' is simply that of 'finding an alternative composition which is suitable for maintaining bone health'. Again, this implies that the selection of any further constituents is arbitrary. Additionally, it is my view that the 'new' ingredients are all things which the skilled person would find obvious to try and have a good expectation of success when doing so. Thus I do not think that applying the problem-solution approach taken by the EPO would lead me to any different outcome.

133 So in summary, I have decided that the claims of GB0804968.6 ("The Bone health patent") are not to be construed as relating to medical use. Rather I have construed them as relating to a composition, consisting of those constituents listed in the relevant claims, suitable for use in maintaining bone health. On this basis I have again applied two separate lines of reasoning and arrived at the same conclusion both times. Namely, that none of the claims exhibit the required inventive step.

4. Medical use and support

134 Although I have decided that the claims of each application are not to be construed as relating to medical use, I will briefly consider the issues raised were they to be so construed. I do this because it is possible that the applicants could amend their claims such that they might relate more closely to therapeutic use. In my opinion, one key issue, were I to construe the claims as relating to medical use, would be support.

4.1 The law

135 Section 14 of the Patents Act sets out various requirements that must be met by a patent specification. The most relevant pieces are the parts of section 14(5) which state:

The claim or claims shall -

(a) define the matter for which the applicant seeks protection;

(b) be clear and concise;

(c) be supported by the description; …

136 In addition, I am bound to follow the precedents laid out in relevant UK case law. On the issue of support for medical use claims, one key case is Prendergast's Applications[24]. In this case Mr. Justice Neuberger held that:

"...where you have a claim for the use of a known active ingredient in the preparation of a medicament for the treatment of a particular condition, the specification must provide, by way of description, enough material to enable the relevantly skilled man to say this medicament does treat the condition alleged...pure assertion is insufficient."

137 This requirement is necessary to stop the speculative filing of applications on any, and all, combinations of substances and medical conditions. Neuberger J. went on to say:

"It was not practical to lay down what the tests should be in each case but it was clear that, in general, relatively rudimentary tests would suffice. It was not necessary for an applicant to have carried out full rigorous detailed and conclusive tests."

138 This precedent applies to so-called 'second medical use claims' (sometimes also referred to as 'Swiss-type' claims) – i.e. where a known therapeutic ingredient is put to a new medical use. At the first hearing, the applicants argued that *Prendergast*[24] did not apply to either of the two current applications as the combination of ingredients was new in each case. Specifically, they argued that the claims of their applications related to 'first medical use'.

139 If that is indeed the case then the decision by this Office in *Hoffman*[25] is relevant. In this decision the hearing officer stated, at paragraph 88, that:

Whilst the judgment in Prendergast's Applications concerned claims of the "Swiss-type", I see no reason why it should not apply in equal measure to claims of the "first medical use" type. Such claims are to known substances which have been found for the first time to have a use in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practiced on the human or animal body. Thus, as with "Swiss-type" claims, it appears to me that support for first medical use claims depends on the applicant including in his application enough material to enable the relevantly skilled person to say that the substance has, for example, the therapeutic activity alleged by the applicant. Ms Richardson seemed to accept that the judgment in Prendergast's Applications was also relevant to the question of support for first medical use claims.

[24] Prendergast's Applications [2000] RPC pg. 446
[25] *Hoffman - La Roche's Application* BL O/192/04

4.2 Arguments and analysis

140 The applicants have argued that the claims of each application should be construed as relating to first medical use as the claimed compositions are themselves new, and so have not previously been used in medicine. Notwithstanding that I have concluded, above, that the claims are not to be construed as relating to any form of medical use, I will, if only for the sake of argument, explore this proposition in order to see where it might lead us.

141 *If* the claims of either application are indeed construed as relating to first medical use, then the decision in *Hoffman*[25] appears relevant. However, the applicants argue that as this decision was before the Office it is not binding on me and therefore I should not follow it. While they are correct in the first part of their argument I cannot see how the second part follows it logically. While this Office's decisions are indeed non-binding on me I should at least consider them in the interests of consistency.

142 At the second hearing Mr. Bridgeman elaborated that consistency in the Office's decisions was not a good enough reason for me to follow a decision that was in his opinion 'nonsense'. Unfortunately, Mr. Bridgeman did not expand on the reasons behind this assessment of the decision in *Hoffman*[25] other than to assert that there are 1,000's of granted first medical use patents 'out there' which do not contain any *Prendergast* style support, so clearly the hearing officer must be wrong.

143 I am afraid that I do not agree with this assessment. I find the hearing officer's arguments in *Hoffman*[25] persuasive and logical. On balance, I do not think that Mr Bridgeman's assertions provide me with sufficient reasons to depart from this position. I therefore agree with the reasoning in *Hoffman*[25] and likewise conclude that first medical use claims require *Prendergast* style support.

144 Alternatively, *if* the claims of either application were to be construed as relating to second medical use, due to each of the ingredients being known to have existing individual therapeutic effects, then the decision in *Prendergast*[24] itself would apply. That decision is binding on me.

145 As explained above, *Prendergast*[24] requires evidence in the application as filed that the claimed composition does actually treat the stated condition. Considering the specifications of both applications carefully, I cannot see any evidence, however rudimentary, that could support medical use claims. Thus, if I had concluded that "lactation" was a medical use, the claims of GB0807735.6 would not be supported by its' description. There is no evidence in the application as filed supporting such a therapeutic use. Similarly, if the claims of GB0804968.6 were amended so as to be clearly directed towards a medical use, such as "the prevention of osteoporosis", they too would not be supported by their description.

146 Consequently, I can see no possible saving amendment for either application that might circumvent the issue of lack of inventive step by limiting the claims to medical use. Even if this was possible, and I am not sure that it is, any such amended claims would lack support.

5. Added matter

147 For the sake of completeness, I shall now briefly turn to the issue of added matter. The examiner objected that claims 2, 6 and 7 of both applications contain matter not present in the applications as filed.

148 In particular, claim 2 of the lactation patent specifies that calcium, DHA, and EPA "form 70%-85% by weight of the composition". This range was not specified in the original application. Claims 6 and 7 of the same case specify that certain constituents of the composition are optional, whereas the application as filed specified that they were essential features of the invention.

149 Similarly, claim 2 of the bone health patent specifies that omega-3 fatty acids derived from fish oil, calcium, soy isoflavone and boron "form 70% to 80% by weight of the composition". Again, this range was not specified in the original application. Claims 6 and 7 also specify that certain constituents are optional, where the application as filed did not disclose these options.

5.1 The law

150 Section 76(2) of the Patents Act states:

> *76.-(1)...*
>
> *(2) No amendment of an application for a patent shall be allowed under section 15A(6), 18(3) or 19(1) if it results in the application disclosing matter extending beyond that disclosed in the application as filed.*

5.2 Arguments and analysis

151 Dealing first with the 'lactation patent', the applicants argue that the 70 to 85% range in claim 2 is based on the 'optimal' composition specified on page 3 of the description. This, they submit, equates to DHA, EPA and calcium forming 77% of the total weight of the composition. Further, they argue that the skilled person would know that it is possible to make compositions other than the optimal one, with efficacy dropping off the further away from optimal a composition is. Thus the skilled person would appreciate that the application is implicitly disclosing a small range of effective compositions 'centred' around the optimal one described on page 3. Thus, they argue, the 70 to 85% range is fully consistent with the description as filed and therefore not added matter.

152 Even if I accept all of the above submissions, I am afraid that I cannot reach the same conclusion as the applicants. While the skilled reader may realise that there is some leeway around the exact composition used, this is very different from disclosing the precise range specified in claim 2. There is simply no disclosure anywhere in the application as-filed of any range either side of the

optimal composition. Thus claim 2 of this application must contain added matter.

153 Similarly, for the 'bone health patent' the applicants argue that the optimal composition specified in the description discloses that soy isoflavone, boron, omega-3 fatty acids and calcium are present at 75% by weight. Again, I am afraid that this provides no basis for a subsequent claim to a range of 70-80% since the range itself was not present in the application as-filed. I therefore conclude that claim 2 of this application also adds subject matter.

154 Turning to claims 6 and 7 of the 'lactation patent', I cannot see any suggestion in the specification as filed that any of the constituents specified in these claims were intended to be optional.

155 The applicants, however, argue that the description sets out the "optimal" formulation and a skilled person would appreciate that less optimal compositions were also possible. Furthermore, they argue that "any lessening of the number of the constituents, as occurs in Claims 6 and 7, is less than optimal and does not provide a technical advantage". Thus they are allowable following the EPO decision in G1/93[26]. This decision states that:

> *a feature which has not been disclosed in the application as filed but which has been added to the application during examination and which, without providing a technical contribution to the subject-matter of the claimed invention, merely limits the protection conferred by the patent as granted by excluding protection for part of the subject-matter of the claimed invention as covered by the application as filed, is not to be considered as subject-matter which extends beyond the content of the application as filed...".*

156 I am afraid that I do not agree with these arguments. The decision referred to by the applicants concerns the EPO practice of limiting a claim by reference to prior art. It is not at all relevant to the present situation, where claims have been broadened by removing constituents originally stated as being essential to the working of the invention. Thus I conclude that claims 6 and 7 of the 'lactation patent' add matter.

157 Finally, I note that a number of the original claims of the 'bone health patent' did specify compositions comprising different combinations of constituents. For instance, original independent claim 16 was to a composition comprising just soy isoflavones, omega-3 fatty acids, vitamin D3 and calcium. However, I still can find no basis anywhere in the original application for the subject matter of amended claims 6 and 7. Those specific variations were not present in the application as filed. I thus conclude that they too add subject matter.

[26] G1/93 (OJ 1994, 541)

6. Decision

158 I have found that all of the claims of GB0804968.6 and GB0807735.6 lack an inventive step. I have also found that amended claims 2, 6 and 7 of each application add subject matter not present at the filing date.

159 I have read the specification of each application carefully and can find nothing that could reasonably form the basis of a valid claim. I therefore refuse both applications under section 18(3).

7. Appeal

160 Any appeal must be lodged within 28 days.

Dr. Stephen Brown
Deputy Director, acting for the Comptroller