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PATENTS ACT 1977

APPLICANTS	Ajit Lalvani, Kartar Singh Lalvani and Robert Peter Taylor
ISSUE	Whether patent application GB1001877.8 complies with section 1(1)(b) of the Act
HEARING OFFICER	Dr Jim Houlihan

DECISION

Introduction

1 Patent application GB1001877.8, entitled '*Composition for the stimulation and regulation of the hair follicle',* was filed on 5 February 2010 and published as GB2477534 on 10 August 2011.

2 The first examination report was issued on 24 May 2016. After several rounds of examination and amendments the applicants requested a hearing in their letter dated 11 May 2017. The examiner issued a letter summarising the points to be addressed at the hearing, in line with conventional procedures on 7 July 2017. After this, the applicant asked the examiner to respond to some additional points in several letters. The examiner issued his final letter on 24th August.

3 The examiner's view is that there is no synergy between the substances listed in the independent claims. Therefore, he says that the claimed compositions amount to a collocation of substances. Because each substance has already been disclosed in the prior art to be of potential use to counter hair loss, the examiner considers there is no inventive step in the claims.

4 Further amendments to the claims and description were filed with the applicants' letter on 11 September 2017. The examiner confirmed in his letter dated 2 October 2017 that the sole issue to be decided was that of inventive step.

5 A telephone hearing was held on Monday 6 November 2017. Mr Robert Taylor of Vitabiotics Ltd. was assisted by the company's patent representative Mr Keith Bridgeman. I was assisted by Dr Graham Feeney.

6 The applicants opened the hearing with the complaint that the examiner had not responded to the points in their letter of 11 September and that they were unclear about the grounds for his objection. In my view, the examiner's final letter comprehensively and clearly lays out his objection. The applicants' 20 page letter of 11 September goes into considerable detail on the examiner's points and I explained that the purpose of the hearing is to give the applicants the opportunity to expand on their points and disagreements with the examiner. I consider that, on the basis of the applicants' correspondence and their submissions at the hearing, and the examiner's final letter, I can make this decision fairly in a manner that is proportionate to the issues before me, having regard to Rule 74 of the Patent Rules 2007, as amended.

Compliance date issues

7 An as-of-right extension to the compliance period was requested under Rule 108(2) which expired on 24 October 2017. After the hearing, the applicant filed a request for a discretionary extension of the compliance date which was accepted. The compliance date is now 24 December 2017.

The application

8 The application relates to the formulation of compositions to alleviate hair loss. Page 3 of the application lists seventeen ingredients (with ranges of percentages for each ingredient). At pages 4-5 the relevance of sixteen of these ingredients is briefly explained. The application goes on to explain how the composition may be topically applied to try to address hair loss in men and in women. Pages 7-12 describes a method to prepare a composition using the ingredients.

The Law

9 Section 1(1)(b) and Section 3 of the Act concern inventive step.

10 Section 1(1) of the Act sets out the requirements which need to be met for an invention to be granted. The relevant parts read as follows:

> *A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say –*
>
> *(a)….*
>
> *(b) it involves an inventive step*
>
> *(c)….*
>
> *(d)….*

11 Section 3 of the Act reads:

> *"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)."*

12 Section 2(2) of the Act reads:

> *"The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use or in any other way".*

13 In the UK, whether an invention defined by the claims involves an inventive step is assessed using the four-step test first formulated by the Court of Appeal in *Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd*[1] and restated by the court in *Pozzoli SPA v BDMO SA*[2]. This test is 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?"*

Preliminary issue - EPO vs. UK jurisprudence

14 Before considering the inventiveness of the claims, I will address an issue raised by the applicants regarding the jurisprudence of the UK national courts and that of the Boards of Appeal of the European Patent Office (EPO) with respect to the determination of the common general knowledge in the test for inventive step. I deal with the concept of the common general knowledge below where I consider there is not actually a disagreement between the applicant and the examiner's view with respect to the relevance of the citations and the common general knowledge. However, for completeness, I will address the applicants' point on this matter here as

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

they made substantial submissions on it both in written correspondence and in verbal submissions at the hearing.

15 The applicants' view is that in light of the judgment of the UK Supreme Court in *Human Genome Sciences v Eli Lilly*[3] *(*hereafter *HGS)*, the decisions of the EPO are now binding on me, even in preference to UK case law. Specifically, it was argued that I am bound to follow the so-called 'problem-solution' approach used by the EPO when addressing issues of inventive step and to view the common general knowledge in light of EPO practice.

16 The applicants' letter filed on 11 September 2017 states: "..*the Supreme Court stated in Human Genome Sciences…that EPO Boards of Appeal rulings should be followed where the Board has adopted a consistent approach to an issue in a number of decisions, and that it would require very unusual facts to justify a national court not following that approach. There has been a consistent approach in the EPO Boards of Appeal ruling concerning common general knowledge. There are also not any "very unusual facts" (in the present case) that would justify not following that approach*".

17 In *Re. HGS*, Lord Neuberger said, at paragraph 87:

> *"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."*

18 I disagree with Mr Bridgeman that this judgment means that EPO decisions are necessarily binding upon me. In my view, it is clear from Lord Neuberger's comment that this is not the intention of the Supreme Court. Rather, my view is that EPO decisions may be persuasive where there is similarity on the nature of the facts between a case in question and an EPO decision. I see no reason on the basis of Lord Neuberger's statement to depart from the *Windsurfing/Pozzoli* test, which has consistently been used by the UK courts to decide on inventive step.

[3] *Human Genome Sciences v Eli Lilly UKSC 51, [2012] RPC 6*

Claims

19 The final set of claims were filed on 11 September 2017 and consist of five independent claims and three dependent claims. Claim 1 reads:

> *A topically applied composition for combined, sequential or simultaneous administration, that includes Glucosamine and Chondroitin Sulphate, in which (a) the proportion according to weight of Glucosamine and Chondroitin Sulphate is not the greatest of the constituents, and which (b) the weight of Methyl Sulphonyl Methane exceeds the combined weight of Glucosamine and Chondroitin Sulphate, and that (c) also consists essentially of : L-Arginine, Oleoresin Capsicum and D-Panthenol, for the treatment of hair loss in humans.*

20 The opening part of independent claims 2-5 is identical to the part of claim 1 which reads "*A topically applied composition…. also consists essentially of L-Arginine, Oleoresin Capsicum and D-Pathenol*"; thereafter each of claims 2-5 list further ingredients.

21 The additional ingredients detailed in each of claims 2-5 are as follows:

> *Claim 2: "…and one or more of Vitamin A palmitate, thiamine hydrochloride, pyridoxine hydrochloride, niacinamide, ginger oil, cinnamon oil, magnesium, zinc, manganese, sodium glycerophosphate [or] L-lysine hydrochloride…*
>
> *Claim 3: "…and two or more of Vitamin A palmitate, thiamine hydrochloride, pyridoxine hydrochloride, niacinamide, ginger oil, cinnamon oil, magnesium, zinc, manganese, sodium glycerophosphate [or] L-lysine hydrochloride…*
>
> *Claim 4: "…and Vitamin A palmitate, thiamine hydrochloride, pyridoxine hydrochloride, niacinamide, ginger oil, cinnamon oil, magnesium, zinc, manganese, sodium glycerophosphate [and] L-lysine hydrochloride…*
>
> *Claim 5: "…and preservatives, co-solvent (propylene glycol), fragrances, anti-oidant, cooling-agent (menthol), emulsifier and vehicle (purified water)…*

22 Each of claims 2-5 has as the final phrase "…*for the treatment of hair loss in humans.*" as per claim 1.

23 Dependent claims 6-8 add further restrictions.

24 I will focus this decision on claim 1 and then consider if the additional components listed in claims 2-5 or the parameters detailed in the dependent claims affect my decision. I will deal with the construction of claim 1 in the context of identifying the inventive concept under step two of the *Pozzoli* test below.

The notional person skilled in the art (step (1)(a))

25 In his final letter of 24 August 2017 at paragraph 7 the examiner summarises his view of the skilled person as *"The person skilled in the art is a team comprising a clinical trichologist or dermato-trichologist, a dermatologist, and a researcher working in the area of pharmaceutical preparations for skin and scalp disorders and hair loss."*

26 The application in suit concerns compositions of lotions for treating hair loss when applied topically. I note that the applicants have not disagreed on this point and consider that this is a reasonable definition of the skilled person.

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

27 During correspondence and at the hearing the applicants made strenuous submissions on the subject of the common general knowledge of the skilled person. Essentially the applicants contended that the documents cited by the examiner were not relevant, either singly or as a collection of documents. The applicants' submission on common general knowledge were intertwined with the issue of the 'state of the art' which is relevant to step 3 of the *Pozzoli* test below. For ease, I will deal with both of these issues at this stage.

The thrust of Mr Bridgeman's submissions was that none of the patent documents were common general knowledge and therefore I should disregard them. In their letter the applicants say "*the proposed prior art documents must come within the common general knowledge before the priority date in order to be able to challenge the inventiveness of an invention*". Mr Bridgeman referred me to the Manual of Patent Practice at 3.37.1 and said "*…examiners, [at the] IPO…,..everywhere don't get right the next section. The examiner must consider the common general knowledge of the skilled person and consequently be caused to disregard documents that are not the common general knowledge of the skilled person. This was not done in this instance."*

28 Mr Bridgeman then referred to case law cited in the Manual of Patent Practice in *Re. General Tire*[4], *Re. Sandoz*[5] and *Re. Raychem*[6] to substantiate his point.

29 In paragraph 8 of his final letter the examiner says "*It is not my contention that any of the patent documents cited in this report form part of the common general knowledge*". Mr Bridgeman submitted that case law and practice referred to in paragraphs 3.36 to 3.37 of the Manual of Patent Practice meant that "*the examiner must then consider the common general knowledge of the skilled person and consequently be caused to disregard prior art and document that are not common general knowledge*". Mr Bridgeman then went on to refer to *Re.* G*eneral Tire* where Sachs LJ stated that *"it is clear that individual patent specifications and their contents*

[4] *General Tire & Rubber Co v Firestone Tyre & Rubber Co Ltd [1972] RPC 457*

[5] *Sandoz Ltd (Frei's Application)* [1976] RPC 449

[6] *Raychem Corp's Patents* [1998] RPC 31

do not normally form part of the relevant common general knowledge". Later in the hearing, however, Mr Bridgeman referred to the Manual of Patent Practice paragraph 3.36 and said that a single document can be used to establish the state of the art even if it is not common general knowledge. However, Mr Bridgeman's submitted that only one document could be used to establish the state of the art and that several documents cannot be used to attack inventiveness by establishing the state of the art as the examiner has done.

30 I disagree with some of Mr Bridgeman's submissions about the common general knowledge. I agree with him that in order to establish the common general knowledge for the purposes of step 1(b) of the *Pozzoli* test it is necessary to prove that documents or the matter which they describe was common general knowledge before the priority date. However, there is an important distinction between the common general knowledge and the state of the art. It is clear from section 2(2) of the Act that the state of the art includes all matter which was known before the priority date of the application in suit. Such matter does not have to be common general knowledge, nor limited to one document. It is the state of the art that is relevant to step 3 of the *Pozzoli* test which I will deal with below.

31 Central to the claims are three ingredients: glucosamine, chondroitin sulphate and methyl sulphonyl methane (MSM). I do not see that the examiner is saying that these substances were part of the common general knowledge. I do not disagree with Mr Bridgeman that glucosamine, chondroitin sulphate and MSM were not common general knowledge in the field of the treatment of hair loss at the priority date. However, whether this is relevant to the determination of inventive step will become clear in step 3 of the *Pozzoli* test.

32 In my view the other substances in the claims, the minerals, amino acids, vitamin derivatives and oil extracts, namely those listed in the passage of claim 1 which reads "*L-Arginine, Oleoresin capsicum….L-Lysine HCL",* and the additional ingredients in claims 2-5 (as listed above in paragraph 21) would have been common general knowledge to the skilled person in this art at the time of filing of this application.

<u>Identify the inventive concept of the claim in question or if that cannot readily be done, construe it (step 2)</u>

33 In order to identify the inventive concepts to be tested I need to construe the claims. As the examiner's view is that the claims relate to a collocation of ingredients, in construing the inventive concept I will follow the guidance of Lord Hoffmann in the House of Lords judgment in *Re. Sabaf*[7] which is the leading authority on collocation. His Lordship said:

> "..*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*

[7] *Sabaf v MFI Furniture Centres Ltd* [2005] RPC 10

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."

34 Each independently claimed composition is formulated to be topically applied and must contain the following:

"Glucosamine and Chondroitin Sulphate, in which (a) the proportion according to weight of Glucosamine and Chondroitin Sulphate is not the greatest of the constituents, and which (b) the proportion of Glucosamine and Chondroitin Sulphate according to weight is exceeded by Methyl Sulphonyl Methane"

35 I take this to mean than in each claimed composition the amount of MSM must be greater than the combined amount of glucosamine and chondroitin sulphate, by weight.

36 The requirement for '*combined, sequential or simultaneous administration*' is unclear because it seems that only a single composition is defined in each instance. It is not clear what is combined or sequential. Is it the claimed composition with other compositions or parts of the claimed composition? Nonetheless, I do not think this is germane to the determination of the inventive concept which lies in the composition itself.

37 The closing phrase of claims 1-5 states *'for the treatment of hair loss in humans'*. In one sense this phrase imparts the characteristics of a second medical use claim, specifically afforded protection by section 4A(4) of the Act, on claims 1-5. On the other hand, it is generally considered that hair loss treatments are cosmetic rather than therapeutic. No submissions were made on the construction of this phrase in terms of section 4A(4). Thus, I consider this phrase means that the claimed compositions must be suitable for the treatment of hair loss in humans. In any event I do not think this has a bearing on the relevance of the cited prior art as all of the cited prior art relates to hair loss compositions.

38 Having arrived at a view as to the construction for each of the claims to be tested, I must next identify or construe the inventive concept(s) for each claim. Whilst ordinarily patent claims are considered in their entirety such that the inventive concept might be taken to concern each and every technical feature working together, this is not true if a claim merely defines an aggregation or mere collocation of features rather than a true combination.

39 For the purpose of assessing inventiveness, I must therefore consider whether each one of claims 1-5 relates to a single invention or to two or more inventions as per *Re. Sabaf.*

40 The applicants argued that the *'SABAF ruling is irrelevant to the present invention. They merely judged a case in which it was pointed out that it was not inventive to add together two obviously effective inventions in their entirety to get a third invention. The example they gave was a machine for producing sausages, which consists of a known mincing machine and a known filling machine disposed side by*

side...a mere collocation of two known concepts that are very effective for the purpose they are being used for…..What you [the examiner] have done is to take one or a few substances out of as many as a thousand constituents from different patents without any logic, reason or rationale as to why those few elements have been selected. This is not complying with the SABAF ruling at all."

41 The applicants referred to the "*EPO Guidelines for Substantive Examination" (December 2003) which state that:*

> *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."*

42 Hoffmann LJ referred to these guidelines in *Re. Sabaf* where he said:

> "*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*"

43 It is clear to me the approach to collocation adopted in *Re. Sabaf* was intended to be consistent with EPO practice in this area and is clearly good law in the UK.

44 The applicants, both in correspondence and at the hearing, made significant submissions on the issue of synergy which I will now look at in detail.

45 The examiner said in paragraph 12 of his final letter that *'each substance [of the inventions] performs its own function independently of any of the others'.*

46 A passage in the description at pages 12-13 under the header of *'Industrial applicability'* says *'there is a synergistic composition, or the use of that composition in the manufacture of a medicament, for the stimulation and regulation of the hair follicle, for combined, sequential or simultaneous administration, in any form, via any biological route.'* The only other reference to synergy in the description, either explicit or implicit, is on page 1 which simply states "*the invention concerns a synergistic composition for the stimulation and regulation of the hair follicle*".

47 A passage in the applicants' written submissions on page 17 says "*Hair growth goes through a sequence of entirely interdependent biochemical reactions without which healthy hair could not grow. Scalp blood flow and circulation facilitates the availability of hormones and nutrients to the scalp. An increase in IGF-1 production then promotes the stimulation of hair follicles. Dermal papilla cells develop in to hair matrix cells when hair growth is stimulated. Keratin, the hair protein is then formed via a sequence of enzymes involved in protein biosynthesis necessary for hair growth that require mineral cofactors used in the present invention in several consecutive steps, and certain amino acids. Sebum secretion is required for the proper secretion of hair. Pigment is added to the hair via melanin biosynthesis. Without each of these biochemical reactions functioning optimally the hair would not properly be formed. The constituents are included in order to promote each of these stages of healthy hair growth : the facilitation of follicle stimulation (glucosamine, chondroitin sulphate), sebum secretion (vitamin A), melanin biosynthesis (Pyridoxine, D panthenol), niacinamide (scalp circulation), L-arginine, L-lysine (scalp hair growth), hair growth (manganese, magnesium works with calcium), keratin and collagen formation (Methyl Sulphonyl Methane), scalp blood flow (Oleoresin Capsicum), increasing IGF-1 production in hair follicles (Capsaicin). The constituents are therefore very much part of an interactive process, as are virtually all sequences of biochemical reactions."*

48 The applicants' letter goes on to say *"Under the present circumstances, there is no obligation to provide evidence that clinically proves that the constituents have a greater synergistic effect".* During the hearing Mr Bridgeman expanded on this, for example by saying *"All of human biochemistry: every substance acts synergistically; we cannot think of one substance that doesn't."*

49 Mr Bridgeman discussed the biochemistry of chondroitin sulphate and glucosamine in the context of L-dopa and L-tyrosine and made the point that the same pathways can take place in different tissues, for example muscular tissue, skin cells and the retina. He went on to say that "*In the case of glucosamine and chondroitin sulphate they are commonly used for connective tissues…because they are found in synovial fluid and cartilage, it was considered by the medical team at Vitabiotics that the dermal papilla and connective tissue share certain properties enabling the possibility that glucosamine and chondroitin sulphate may facilitate follicle stimulation even though biochemically these are entirely different functions*". On this basis, Mr Bridgeman submitted that this made the use of glucosamine and chondroitin sulphate to treat hair loss a non-obvious thing to do.

50 From these submissions I understand that the nub of the applicants' assertion is that a combination of the factors necessary for a biochemical reaction to proceed is inherently synergistic. Furthermore, the applicants' view is that the ingredients of the compositions of the present inventions (in particular glucosamine and chondroitin sulphate) were only present in the prior art in multi-component formulations, and these ingredients were not specifically combined. I do not see the relevance of this. In my view the test for synergy set out in *Re. Sabaf* is based on the relationship of the different integers that make up the claimed invention, and not the interrelationship between the claimed invention and the state of the art.

51 The question to my mind is whether the ingredients in the instant case have a synergistic effect or an additive one and whether evidence of synergy has to be disclosed in the application as filed. The distinction between synergy and additive effects has been addressed in *Glaxo Group Ltd's Patent*[8] which refers to an earlier authority, *Richardson Vicks' Patent*[9]. Moreover, these authorities also address the issue of whether synergy has to be disclosed in the application as filed.

52 I will summarise *Re. Glaxo* briefly. Glaxo's patent related to an anti-asthma formulation consisting of two different drugs, a ß-agonist which treated bronchospasm, and a corticosteroid which treated bronchial inflammation. It was common ground that bronchial inflammation and bronchospasm were two aspects of asthma. In *Re. Glaxo* the late Pumfrey J said at page 882:

> *It is sometimes thought that a patent may be saved from a finding of obviousness if a combination otherwise obvious has some unexpected advantage, and, in particular, an advantage caused by an unpredictable cooperation between the elements of the combination. I do not consider that such an approach is in general justified. There is a limited class of cases in which the patentee has identified an advantageous feature possessed by some members only of a class otherwise old or obvious, has described the advantageous effect in his specification and has limited his claim to the members of the class possessing this advantageous feature. Such a claim may be justified on the basis of what is called selection. Unexpected bonus effects not described in the specification cannot form the basis for a valid claim of this kind. I think that the matter is described with complete correctness by Jacob J in Richardson-Vicks' Patent...:*
>
> *'Whether or not there was a synergy demonstrated by experiments conducted after the date of the patent cannot help show obviousness or non-obviousness. Nor can the amended claim be better if only the components of the amended claim (as opposed to the unamended claim) can be shown to demonstrate synergy. The patent does not draw any such distinction and it would be quite wrong for later-acquired knowledge to be used to justify the amended claim'*
>
> *If a synergistic effect is to be relied on, it must be possessed by everything covered by the claim, and it must be described in the specification."*

53 The applicants submitted that the precedents of *Re. Richardson-Vicks* and *Re. Glaxo Group* are not relevant to their case because they believe these cases

[8] Glaxo Group Ltd's Patent [2004] RPC 43
[9] Richardson Vicks' Patent [1995] RPC 568

concern “selection inventions”. In correspondence, the applicants’ submitted that *“It is a fundamental requirement of case law that it matches the specific circumstances. However as the present invention is not a “selection invention” it clearly does not”.* I disagree with this view because both *Re. Richardson Vicks* and *Re. Glaxo Group* relate to a similar scenario to the present case - the activity of multiple components in a single formulation. Accordingly, I consider both authorities as relevant precedents to the instant case.

54 In my view both *Richardson Vicks* and *Glaxo Group* make it clear that evidence for synergy must be in the application as filed. A particularly important aspect of the applicant’s submissions both at the hearing and in the correspondence is their suggestion that the MSM interacts with the chondroitin sulphate and glucosamine, by providing sulphur for keratin production in the follicle stimulated by the chondroitin sulphate and glucosamine. The reactions Mr Bridgeman described appear to concern a series of co-operative factors such as co-enzymes, co-factors and substrates rather than synergistic effects within the meaning used in *Re. Sabaf*.

55 On the point of the distinction between additive and synergistic effects, Mr Taylor said at the hearing that, in contrast to synergy, if multiple components merely have additive effects, then a reaction will still continue to operate when only one component is present and, by implication, submitted that the claimed formulation would not function as effectively if one of the components was absent. In turn, he submitted that the claimed composition was therefore synergistic. However, the description does not provide any information to support this. There is nothing in it which compares the relative functional effects of the claimed composition over individual ingredients or a mixture of a subset of ingredients.

56 Having read the application thoroughly with all of the applicants’ submissions in mind, I cannot find any indication of synergy between the ingredients listed in the independent claims. Also I do not believe there are any grounds to support the notion that synergy between the ingredients, particularly glucosamine, chondroitin sulphate and MSM, would be regarded as implicit by the person skilled in this art. I therefore conclude that each component of the compositions defined by claims 1-5 acts independently of the other components. Accordingly, it is my view that claims 1-5 each relate to a separate inventive concept for each ingredient listed.

<u>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; (step 3)</u>

57 Before considering each of the prior art documents cited by the examiner as examples of the state of the art of each ingredient, I am minded of the applicants’ strenuous submissions at the hearing that these prior art documents cannot be relevant as they require the skilled person to make a selection of a single ingredient from a long list. This point was stated in their written submissions as *“If 3 out of 20 constituents of a composition are in a [cited] patent [specification] that consists of over 1000 substances it certainly is not obvious to use only those three substances. Such a contention would have no logical validity. If an invention consists of A, B, C and a prior art document consists of A, B, C, and 20 other substances it could*

reasonably be argued that the choice of A, B, C, is obvious if that prior art documents states that A, B, C are of primary importance and that the other 20 constituents are only optional. However none of the proposed prior art documents made any suggestion of this kind."

58 The applicants' point is that because the citations disclosed "laundry lists" of every conceivable option, the skilled person is taught nothing of any use. Mr Bridgeman submitted that it was not appropriate to merely pluck ingredients from a long list without motivation to do so and that there was no disclosure of the separate use of chondroitin sulphate, glucosamine or MSM. I disagree that the disclosure of separate use is necessary (I note in any case that these three substances are not referred to separately in the claims). I return to the point which I have made above concerning the state of the art: in order for something to form the state of the art it is sufficient that it is disclosed anywhere in any form before the priority date of the application that is suitable for the purpose claimed. It is the state of the art, not the common general knowledge, which is determinative to step 3 of the *Pozzoli* test.

59 The cited prior art GB2461021 ('021) discloses every component except for the glucosamine and the chondroitin sulphate, as disclosed in claims 1-5 for the treatment of hair loss, namely Vitamin A Palmitate, Thiamine Hydrochloride, Pyridoxine Hydrochloride, Niacinamide, D-Panthenol, L-Arginine, Methyl Sulphonyl Methane, Ginger Oil, Cinnamon Oil, Oleoresin Capsicum, Magnesium, Zinc, Manganese, Sodium Glycerophosphate, L-Lysine HCl, Preservatives, Co-solvent (Propylene Glycol), Fragrances, Anti-Oxidant Cooling agent (Menthol), Emulsifier Vehicle (Purified water). The embodiment in '021 describes the use of these ingredients in a lotion, the same type of composition as the embodiment in the present application. Thus, there are no differences between these components recited in the instant claims and the state of the art with respect to their use in a topical composition for the treatment of hair loss.

60 US2004/0191202 ('202) discloses methods of promoting hair growth by administering '*a sugar that is metabolised to a glycosaminoglycan'*. An example is shown which *inter alia* includes 6.5% w/w glucosamine sulphate (though glucosamine itself may be used see [0033]) and 6.1% w/w chondroitin sulphate. '202 clearly envisages topical formulations for the treatment of hair loss (see paragraphs 47 and 61). There is no substantive difference between the disclosure of '202 and the inventive concept of claims 1-5 with respect to the topical application of either glucosamine and chondroitin sulphate for the treatment of hair loss.

61 WO2009/053163 discloses a topical hair treatment comprising a *'synergistic mixture of a….glycosamino production agent, a cell nutrition regulator, a microcirculation promoter…'*. At claim 4, the '*glycosamino production agent*' is selected from a group of nine ingredients including glucosamine and glucosamine sulphate. To me, the disclosure of this document shows there is no difference between the inventive concept with respect to glucosamine and the state of the art.

62 In JP2007262094 the skilled person is taught a hair growth enhancing agent for topical application which, at claim 2, preferably comprises chondroitin sulphate. JP2007176956 discloses a topical composition comprising chondroitin sulphate, specifically a *'trichogenous agent containing one or more material selected from the following material group is provided: bamboo grass extracts, Panax notoginseng*

extracts, keratan sulfate, and hyaluronic acid and chondroitin sulphate…'. JP2006298857 discloses an oral agent for hair restoration which *'comprises pine bark extracts and at least one selected from a group consisting of ascorbic acid, its derivatives, chondroitin sulfate and chondroitin sulfate protein conjugates.'* (The applicant's indicated they were content with the fact that the examiner had relied on machine translations of these Japanese documents and were familiar themselves with the EPOs translation tools).

63 On account of these Japanese documents in my view there is no difference between the inventive concept with respect to chondroitin sulphate and the state of the art.

64 In concluding comments, Mr Taylor submitted that the lists of ingredients in the prior art seem to be "cut and paste" as for example some of them are incorrectly spelt. However, I remain of the view that MSM, chondroitin sulphate and glucosamine are each featured adequately enough in each of the cited prior art documents for each of them to be regarded as state of the art in relation to the treatment of hair loss.

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?" (step 4)

65 I have found there is no synergy between the ingredients claimed in claims 1-5 - they are a collocation. I have also not found any differences between the state of the art and the inventive concepts in claims 1-5. On these grounds there is no degree of invention in these claims.

66 However, I need to consider whether there is an invention in the particular proportions claimed for MSM, glucosamine and chondroitin sulphate claimed as it is possible that a patentable invention can arise from a selection of different components if that selection affords a technical advantage, as per *Glaxo Group's patent* referred to above.

67 The applicants made significant submissions on this point, focussing on the part of claim 1 which reads

> "..*the proportion according to weight of Glucosamine and Chondroitin Sulphate is not the greatest of the constituents, and which (b) the weight of Methyl Sulphonyl Methane exceeds the combined weight of Glucosamine and Chondroitin Sulphate".*

68 The kernel of the applicants' submissions is that these proportions are technically significant.

69 Their letter states on page 18 "*…MSM contains sulphur which is required for the production of keratin and collagen. It has also been explained why glucosamine and chondroitin sulphate can facilitate follicle stimulation. The capacity to stimulate the follicle using glucosamine and chondroitin sulphate becomes worthless if the precursors of keratin, including sulphur provided by Methyl Sulphonyl Methane is not supplied in more abundant quantities. It is a basic principle of human biochemistry*

that the precursor of any biochemical reaction of biosynthesis must at least match or exceed the capacity of the biochemical reaction. If the quantity of Methyl Sulphonyl Methane was significantly less than that of glucosamine or chondroitin sulphate, they would lack sufficient quantity of the precursor with which to enable keratin biosynthesis. The proportions in claim 1 are therefore advantageous. This proportion of Methyl Sulphonyl Methane is a fundamental restriction that has purposefully been included in the claims from the outset".

70 The application says on page 4 that "G*lucosamine is commonly used for joint connective tissues. However, dermal papilla and connective tissue sheath share certain properties, enabling the possibility that glucosamine may facilitate follicle stimulation".* The application says exactly the same thing with respect to chondroitin sulphate. On the following page the application says "*MSM contains sulphur, which is required for the production of keratin and collagen. Both are important constituents of hair"*. The application provides no more detail about the properties of the three ingredients in question.

71 At the hearing Mr Bridgeman emphasised that the proportions of glucosamine, chondroitin sulphate and MSM are not present in the prior art. I agree. However, the question to my mind is whether the specification, implicitly or explicitly, teaches a technical advantage of the relative proportions of these three ingredients. As stated in *Re. Glaxo Group* referred to above, unexpected bonus effects which are not described in the specification cannot form the basis of an inventive selection.

72 Having considered the specification in light of the applicants' submissions I do not find a sufficient level of information in the specification that supports the applicants' contention that the claimed proportions of MSM, glucosamine and chondroitin sulphate provide a technical advantage.

73 For this reason and for the reasons given in paragraph 69 above, I consider that the independent claims 1-5 do not have an inventive step.

74 I have considered claims 6-8 and do not see that they add anything inventive to the claims upon which they are dependent. No submissions were made on the inventiveness of claims 6-8.

Conclusions

75 I hold that claims 1-8 do not have an inventive step and, as such, they do not meet the requirement of section 1(1)(b) of the Act.

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

Appeal

77 Any appeal must be lodged within 28 days after the date of this decision.

Dr Jim Houlihan

Deputy Director, acting for the Comptroller