Miss Dunlow 3/60 41+ 01/129/93

PATENTS ACT 1977

IN THE MATTER OF Patent Application
No. 8912373.1 by Anne McManus

STATEMENT OF REASONS FOR DECISION

Application number 8912373 was filed on 30 May 1989, claiming priority from two earlier applications filed on 27 May 1988 and 16 June 1988. The application was published on 29 November 1989 under serial number 2218906A and is entitled "Medicament for various skin and ulcer disorders".

During the course of substantive examination, the examiner, Mrs S E Chalmers, raised objection under Sections 1(1)(a), 1(1)(b), 1(1)(c), 14(5)(c) and 14(5)(d). It is my understanding that - with one principal exception - the applicant has accepted the substance of all of these objections and the need to amend the application accordingly. However no amendments have been submitted to date. During the course of substantive examination the applicant expressed a wish to include a claim or claims to a medicament for oral use. Although, as indicated above, no such claim has actually been filed, the examiner raised objection that any such claim would be open to objection under Section 1(1)(a) and 14(5)(c). If I understand the position correctly, it is the adverse opinion of the examiner regarding the possibility of claiming a medicament for oral use, which is instrumental in causing the applicant to refuse to amend to meet any of the objections raised.

In the absence of agreement between the applicant and the examiner the matter came before me at a hearing on 27 July 1993. Having given careful consideration to all the points made by the applicant, both during the course of substantive examination and at the hearing itself, I gave an oral decision refusing to allow the application to proceed to grant. Below I set out the reasons for this decision.

The claims of the application as filed, which to date remain unamended, read as follows:

12 A pharmaceutical composition substantially as described with reference to the examples 1 and 2.

13. A method of obtaining a cosmetically beneficial improvement in a skin condition comprising applying eggshells as defined in claims 1 or 4 or a pharmaceutical composition as defined in any one of claims 7 to 12 to the affected skin area until a cosmetically beneficial improvement in appearance is obtained.

14. Use of paraffin in the preparation of a topical medicament.

15. Use of paraffin in the preparation of a topical medicament for use as a sun cream, skin moisturiser, anti-inflammatory, and for the treatment of arthritis, rheumatism, athletes foot and skin disorders.

16. Paraffin whenever used as a topical medicament.

17. A pharmaceutical composition comprising paraffin as a therapeutically active agent, and a pharmaceutically acceptable carrier.

18. A pharmaceutical composition as claimed in claim 17 wherein the paraffin is present in about 5% to 90% w/w, preferably 14% to 18% w/w of the total composition.

19. A pharmaceutical composition as claimed in claims 17 or 18 wherein the carrier includes at least petroleum jelly, wax, an oil based diluent, or glycerine.

20. A pharmaceutical composition as claimed in claim 19 wherein there is present olive oil at from 14% to 30%, sunflower oil at from 20% to 40%, wax at from 0.5% to 2%, and petroleum jelly at from 16% to 18% w/w, and glycerine at up to 8%, based on the pharmaceutical composition.

21. A pharmaceutical composition substantially as described with reference to example 3.

1. Use of eggshells in the preparation of a medicament.

2. Use of eggshells as claimed in claim 1 as in the preparation of a topical medicament.

3. Use of eggshells as claimed in claim 2 in the preparation of a medicament for the therapeutic treatment of skin complaints or ulcers.

4. Use of eggshells as claimed in claim 3 wherein the skin disorders are allergies and eczemas, and the ulcers are varicose ulcers, pre-varicose ulcer conditions, or rodent ulcers.

5. Use of eggshells as claimed in any one of claims 1 to 4 wherein the eggshells are in powder form.

6. Eggshells whenever used as a medicament.

7. A pharmaceutical composition comprising eggshells as a therapeutically active agent, and a pharmaceutically acceptable carrier.

8. A pharmaceutical composition as claimed in claim 7 wherein the pharmaceutical carrier includes at least petroleum jelly or wax.

9. A pharmaceutical composition as claimed in claim 8 wherein the carrier, expressed as w/w of the pharmaceutical composition includes paraffin at from 10% to 30%, other wax at 5% to 20% and petroleum jelly at 3% to 10%.

10. A pharmaceutical composition as claimed in any one of claims 7 to 9 and further including at least vinegar, essence of almond, or paraffin.

11. A pharmaceutical composition as claimed in claim 10 wherein, where there is vinegar, essence of almond, and liquid paraffin, it is present at respectively 3% to 10%, 3% to 12%, and 30% to 75%, preferably 45% to 65%.

I shall deal firstly with the objection under Section 14(5)(d) that the claims do not relate to a single inventive concept, namely that the following inventions are claimed:

(i) that of claims 1 to 13

(ii) that of claims 14 to 21

The applicant did not contest this objection at the hearing; indeed I understood her to accept that this objection is well founded and that no further consideration need be directed to claims 14 to 21. However in the absence on file of any amendments making this concrete, I shall deal with the matter in more detail.

Claims 1 to 13 each include as an essential feature the use of eggshells as a medicament; claims 9 to 13 include paraffin in addition to eggshells. Claims 14 to 21 each include as an essential feature the use of paraffin as a medicament; none of claims 14 to 21 requires the use of eggshells. I find that there is no commonality of technical feature between claims 1 to 8 on the one hand and claims 14 to 21 on the other but that there is a technical feature common to claims 9 to 13 and claims 14 to 21, namely the use of paraffin as a medicament. I am satisfied however that such a use can properly be regarded as the application of common general knowledge - for instance liquid paraffin is well known as a medicament for treating constipation. In addition I note from page 354 of British National Formulary Number 12 (1986) (a document cited by the examiner against a number of claims) the statement that:

> "The most commonly used ointment bases consist of soft paraffin or a combination of soft paraffin with liquid paraffin and hard paraffin"

I find in consequence that in the terms of Rule 22, there are no "special technical features" common to claims 1 to 13 on the one hand and claims 14 to 21 on the other. It follows that the claims do not comply with Section 14(5)(d) and I therefore give no further consideration to claims 14 to 21.

It is convenient to deal next with claims 6 and 13. Claim 6 is a succinct claim which reads

"Eggshells whenever used as a medicament".

This I construe as a claim to a method of therapy using eggshells. By virtue of Section 4(2), such an invention cannot be taken to be capable of industrial application and I find in consequence that claim 6 does not comply with Section 1(1)(c). The applicant did not contest this objection at the hearing.

Claim 13 relates to a method of obtaining a cosmetically beneficial improvement in a skin condition by applying the medicaments of claims 1 to 4 or claims 7 to 12. Objection was raised by the examiner that claim 13 does not comply with Section 14(5)(c) in that it is not supported by the description. I find substance in this objection in that the application contains no description of a method of obtaining a cosmetic improvement; moreover I understood the applicant at the hearing to confirm that none of the examples in the application relates to a cosmetic preparation. I find therefore that claim 13 does not comply with Section 14(5)(c).

In addition the examiner has objected, correctly in my view, that insofar as claim 13 relates to a method of treatment using medicaments, it is open to the same objection as claim 6, namely that by virtue of Section 4(2) claim 13 does not relate to an invention capable of industrial application. In consequence I find that claim 13 does not comply with Section 1(1)(c) or with Section 14(5)(c). Again it is my understanding that this conclusion was not disputed by the applicant at the hearing.

I shall next consider the position under Sections 1(1)(a) and 1(1)(b). With the exception of the objection raised against claim 4, the applicant did not contest the objections below and I understand her to accept that these objections are well founded. Again however in the absence on file of any amendments to render this acknowledgement concrete, I shall deal with the matter in detail.

I find that the invention as claimed in claims 1, 2, 3, 5 and 7 is not new having regard to patent specifications GB 1251720, US 3624201, US 3559771 (all to Leslie Bolassa) and JP

59-137415 (Onada). Each of these specifications was published prior to 27 May 1988, the earliest priority date claimed for the present application and therefore forms part of the state of the art by virtue of Section 2(2). This point I shall examine in greater depth below when considering the question of a claim to a medicament for oral use. Each of these specifications describes the use of powdered eggshell in making a medicament, as required by claims 1 and 5; the GB and both US specifications describe the use of eggshell in making a topical medicament as required by claim 2; and GB 1251720 (at page 2 lines 36 to 39) and US 3558771 (at column 2, lines 61 to 64) each describe incorporation of eggshell into a suitable carrier as required by claim 7.

Claim 3 relates to the use of eggshell in the preparation of a medicament for the therapeutic treatment of "skin complaints or ulcers". Chambers Dictionary of Science and Technology defines an ulcer as

> "A localized destruction of an epithelial surface (eg of the skin or gastric mucous membrane) forming an open sore"

I conclude from this definition that an ulcer is a particular example of a skin complaint. Since GB 1251720 (at page 1 lines 13 to 16), US 3624201 (at column 1 lines 65 to 68) and US 3558771 (at column 2 lines 12 to 15) each describe the use of eggshell for the treatment of "open ulcers", I find that claim 3 is not new. Thus I find that claims 1, 2, 3, 5 and 7 do not comply with Section 1(1)(a).

I turn next to consider claim 8 against the requirements of Section 1(1)(b). Claim 8 is appendant to claim 7 and introduces the additional limitation that the pharmaceutical carrier includes at least petroleum jelly or wax. I have already found that claim 7 is not new. I am also satisfied that the use of petroleum jelly and wax as carriers in pharmaceutical compositions is entirely conventional - this I conclude by reference to British National Formulary Number 12 (1986) page 354 which in the reference already quoted above states that

"The most commonly used ointment bases consist of soft paraffin or a combination of soft paraffin with liquid paraffin and hard paraffin"

Soft paraffin is otherwise known as petroleum jelly and hard paraffin as petroleum wax.

In consequence I find the invention as claimed in claim 8 to be no more than the incorporation of conventional carriers into a known pharmaceutical composition and, as such, not to involve an inventive step as required by Section 1(1)(b).

Finally under Section 1(1)(b) I turn to claim 4 which relates to the use of eggshell in the preparation of a topical medicament for the therapeutic treatment of allergic skin disorders and eczemas and of varicose ulcers, pre-varicose ulcer conditions and rodent ulcers.

Claims of this construction, so-called Swiss-type claims, have been allowed by both the enlarged Board of Appeal of the EPO (Decision Gr 05/83, OJEPO 3/85) and in the UK by the Patents Court (John Wyeth and Brother Ltd's Application; Schering A.G's Application 1985 RPC 545). Whilst claims to a product per se characterised by a medical application are precluded if that product has already been described for another medical use, it has been held that it is legitimate in principle to allow claims directed to the use of a substance for the manufacture of a medicament for a specified new and inventive therapeutic application, even if the process of manufacture does not differ from known processes using the same active ingredient. It follows, in the circumstances of the present application, that it is necessary to determine whether the use of eggshell for the therapeutic applications specified in claim 4 is new and inventive.

At the hearing the applicant argued that the eggshell medicament found particular application in the treatment of itchy skin conditions such as eczema and varicose ulcers and indeed this is fully consistent with page 1 paragraph 3 of the application as filed. However, as noted above, GB 1251720, US 3624201 and US 3558771 all refer to the use of eggshell medicaments for the treatment of "open ulcers". I am not persuaded, given these disclosures and in the absence of evidence to the contrary, that the use of such medicaments to treat particular, specified types of ulcer can be regarded as inventive; in other words I do not

regard the skilled man as having to exercise inventive ingenuity in treating a particular, specified type of ulcer with a medicament which is already known to be applicable to "promoting and assisting the healing of wounds, as for example, damaged mammalian tissue, open ulcers". I find therefore that claim 4 insofar as it relates to the treatment of ulcers does not comply with Section 1(1)(b).

On the other hand, I find nothing in any of the cited documents that would point the skilled man towards using the medicament for the treatment of allergic skin disorders and eczemas, any more than for the treatment of any other dermatological condition. I find therefore that insofar as claim 4 relates to the treatment of allergic skin disorders and eczemas, no objection lies under either Section 1(1)(a) or Section 1(1)(b).

I turn finally to what appears to be the main stumbling block to the grant of the present application, namely the applicant's wish to include a claim to a medicament for oral use. This wish appears to have been first expressed in a letter received in the Office on 25 June 1993. There is no claim to such a medicament in the application as filed and no such claim has subsequently been filed.

The application as filed does however contain two references to a medicament for oral use, namely:

> on page 1:
>
> "Although it is thought that the medicament may be taken orally for ulcers and the like, preferably it is used topically . . . . "
>
> and in the paragraph bridging pages 1 and 2:
>
> "The size of the eggshell particles depend on the intended treatment. Thus if taken orally, it is advisable to grind the eggshell to a fine powder for taking, for example, in tablet form."

Japanese specification 59-137415 cited by the examiner describes a medicament for oral use comprising powdered eggshells. In the search report issued under Section 17 the examiner referred to an abstract of the Japanese specification; a full translation of the specification was subsequently filed by the applicant at the Office on 29 May 1990. The specification describes the use of powdered eggshell for taking orally, either by the spoonful or in tablet form, with a view to reducing nutritional deficiencies responsible for a variety of ailments including tiredness and high blood pressure, but not, to use the terminology of the present application, for the treatment of "ulcers and the like".

The applicant argued strongly at the hearing that the Japanese specification could not be cited against her for, if I understand her correctly, two reasons:

(1) it is not in English

(2) it is not a granted patent, or if it has been granted it has expired.

Section 2(1) states:

"An invention shall be taken to be new if it does not form part of the state of the art.

Section 2(2) states:

"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".

There is no restriction in Section 2(2) as to the language of such matter nor, if such matter be in the form of a patent specification, as to the granted status of the patent. JP 59-137415 was published on 7 August 1984, a date before 27 May 1988, which is the earliest date from

which the present application claims priority. In consequence I find that JP 59-137415 forms part of the state of the art by virtue of Section 2(2).

Also material to consideration of what is to be regarded as the state of the art is Section 2(6) which states

> "In the case of an invention consisting of a substance or composition for use in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body, 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".

Thus under Section 2(6) if a composition is known, it is not taken as forming part of the state of the art if it has no previous medical use. JP 59-137415, however, clearly describes the use of eggshells as an oral medicament and therefore is not excluded by Section 2(6) from forming part of the state of the art. It follows that any claim directed to an oral medicament or oral pharmaceutical composition comprising eggshells, or to eggshells for use as an oral medicament or oral pharmaceutical composition - whether or not for use in the treatment of "ulcers and the like" - I would refuse under Section 1(1)(a). Equally I would refuse a claim to the use of eggshells in the preparation of an oral medicament or oral pharmaceutical composition.

Finally it is necessary to consider the possibility of a Swiss-type claim, that is to say a claim to the use of eggshells in the preparation of an oral medicament for the treatment of "ulcers and the like". I have already found that a claim to the use of eggshells in the preparation of a medicament for the therapeutic treatment of skin complaints or ulcers (claim 3) lacks novelty. However I am satisfied that none of the cited documents describes eggshells in an oral medicament for the treatment of "ulcers and the like" and that, in consequence, a Swiss-type claim to the use of eggshells in the preparation of an oral medicament for the treatment of "ulcers and the like" would be free of objection under Section 1(1)(a) and Section 1(1)(b). However oral use forms part of the state of the art by virtue of JP 59-137415. It follows

therefore that the novelty of such an invention so claimed must necessarily reside, not in the composition of the medicament itself but in the particular treatment to which it is directed and in consequence a clear indication that such a treatment has been tried and tested is essential to provide the necessary support for the claim. I do not find the requisite support in the present application from the two brief references quoted above and indeed it is my understanding from the applicant at the hearing that she has in fact yet to put this area of her invention into effect. In consequence I would refuse such a claim under Section 14(5)(c).

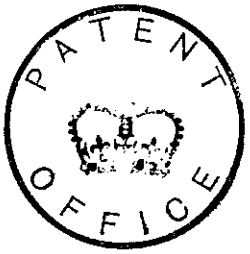
In summary I find that the invention as claimed in claims 1, 2, 3, 5 and 7 is not new as required by Section 1(1)(a), that the invention as claimed in claim 4, insofar as it relates to the treatment of ulcers, and as claimed in claim 8 does not involve an inventive step as required by Section 1(1)(b), that the invention as claimed in claims 6 and 13 is not capable of industrial application as required by Section 1(1)(c), that the invention as claimed in claim 13 is not supported by the description as required by Section 14(5)(c) and that the claims do not relate to one invention or to a group of inventions which are so linked as to form a single inventive concept as required by Section 14(5)(d).

Given that there are claims to which no objection has been taken, namely claims 9 to 12, or to which objection has been taken only in part, namely claim 4 insofar as it relates to the treatment of ulcers, it follows that, before refusing the application under Section 18(3) I should give the applicant an opportunity to amend the specification, with a view to meeting my findings. I should point out that I can foresee no circumstances under which a claim to oral use could be sustained.

Due to the particular circumstances of this application the period for placing the application in order has already been extended to 3 August 1993. However since the period during which an appeal may be filed against this decision is six weeks from the date of the oral decision that is to say six weeks from 27 July 1993, by virtue of Section 20(2) the period for putting the application in order is extended for that period. I therefore allow the applicant the same six week period in which to submit amendments ie until 7 September 1993. If no satisfactory amendment is submitted in that period, I shall refuse the application. I would observe that the applicant would be well advised to submit any amendments a sufficient time before the

end of that period to allow the examiner the opportunity to consider them and to agree any further amendments that may be necessary.

Dated this 5th day of August 1993



D J BARFORD

Principal Examiner, acting for the Comptroller