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13 August 2004

PATENTS ACT 1977

APPLICANT Commonwealth Scientific and Industrial Research Organization

ISSUE Whether patent application number GB 0129486.7 complies with sections 1, 2(6), 4(2) and 14(5)(c)

HEARING OFFICER Mrs S E Chalmers

DECISION

1 Patent application GB 0129486.7 ("the application") entitled "Control of wool in sheep and related animals" was filed on 19 May 2000 by Commonwealth Scientific and Industrial Research Organization ("the applicant"). It is derived from international application PCT/AU00/00487 and published by WIPO as WO 00/71089 on 30 November 2000.

2 The Australian Patent Office acted as both the International Search Authority and the International Preliminary Examination Authority. In the International Search Report, six documents were cited for novelty and the claims were reported as lacking unity of invention. However, the subsequent International Preliminary Examination Report raised objection only to the lack of unity.

3 The application entered the national phase and was republished as GB 2368015 A on 24 April 2002.

4 The UK examiner issued an examination report under section 18(3) on 17 July 2003, in which he reported that the application was excluded from patentability under section 4(2) as a method of treatment of the animal body by therapy and that the claims lacked unity of invention. A lack of inventive step objection was also raised on the basis of the documents cited on the International Search Report.

5 The applicant responded to the first examination report with amendments to the claims, including claims in Swiss form, and observations. The examiner was satisfied that the application now related to a single inventive concept, but in a subsequent report maintained the inventive step objection. On further consideration, the examiner decided that the method claims as originally filed did not relate to a method of therapy and hence did relate to a patentable invention and suggested reinstatement of the method claims.

6 In response to the second examination report, the applicant submitted further observations relating to the patentability of the method claims and to the inventiveness of the application. The examiner accepted that the invention would be inventive were the claims addressed towards a method but was not persuaded that the invention related to a method of therapy as the applicant contended. The examiner therefore issued a further report objecting to the form and allowability of the claims which were in Swiss form. A novelty objection was also raised against these claims, using the documents cited previously, on the grounds that the claims were not entitled to the protection afforded by section 2(6).

7 The applicant responded with amended claims and further observations regarding the therapeutic nature and industrial applicability of the invention. An interview was suggested with a request that the examiner restate his major concerns before the interview. These concerns regarding the cosmetic/therapeutic nature of the invention were reiterated together with clarification of the novelty objection raised by the examiner.

8 In response, the applicant cancelled the interview and, on 8 July 2004, filed a new set of claims together with a request for a hearing should these claims not prove acceptable to the examiner. The examiner issued a further report on 20 July 2004 on these claims in which he maintained his objections and set out the outstanding issues. A hearing was appointed for 11 August 2004. However, the agent subsequently contacted the Office on 9 August 2004 saying that the applicant did not wish to attend or be represented at the hearing but requested a decision on the basis of the papers. He also filed further observations on the examiner's latest report.

9 In accordance with rule 34(1)(a) (ii) of the Patents Rules 1995, the normal period allowed for complying fully with the requirements of the Act expired on 19 July 2004. On 9 August, the applicant requested under Rule 110(3) a month extension of this period ie until 19 August 2004 to put the case in order.

10 When deciding the outstanding matters before me, I have given full and careful consideration to the written submissions made by the applicant's agent (Mr Perry of Gill Jennings & Every) as well as to the various authorities brought to my attention.

The application

11 The application relates to the control of wool growth in sheep and related animals by reducing or preventing wool growth in a selected area or areas in the animal. Specifically, the breech and/or pizzle area of sheep are treated with the aim of preventing the incidence of blow-fly strike and/or balanitis. As the application explains, current methods of containing blow-fly strike and balanitis comprise either surgery or the use of chemicals to remove or kill the cells (or "follicles") responsible for wool growth. In many cases, these operations cause the animal considerable pain and damage the skin which may also reduce the sale price of the hide. There is the further problem of the risk of injury to human operators through the use of toxic and irritant chemicals such as phenol. The application states that it seeks to overcome these disadvantages with a non-surgical method which is safe to use, causes little or no trauma to the animal and avoids damage to the skin.

12 The invention relates to a photodynamic method for the controlled destruction (or "ablation") of wool follicles within the skin of a wool bearing animal by treating the skin with a composition containing a follicle-ablating chemical and irradiating with electromagnetic radiation. The description provides details of suitable follicle-ablating chemicals, which may be either photosensitisers or substances that induce the formation and/or accumulation of endogenous photosensitisers. Preferred irradiation regimes are also described.

13 The latest set of amended claims filed on 8 July 2004 comprises two independent claims: claim 1, which seeks to protect the use of the follicle-ablating agent using the "Swiss- type" format and claim 27 which is for a method of photodynamic ablation of wool follicles.

14 Claim 1 reads:

Use of a follicle-ablating agent for the manufacture of a medicament for the treatment or prevention of blowfly strike or balanitis in a wool-bearing animal, wherein the medicament is to be applied to a selected area of the skin, the area then being irradiated with electromagnetic radiation to effect the controlled photodynamic ablation of wool follicles within the skin.

Claim 27 reads:

A method of photodynamic ablation of wool follicles within the skin of a wool-bearing animal, which comprises the steps of:

(a) applying a composition comprising a follicle-ablating agent to a selected areas of the skin; and

(b) irradiating the area with electromagnetic radiation

15 Claims 2-26 and 28-52 relate to detailed aspects of the invention and are appendent to claims 1 and 27 respectively.

Outstanding objections

16 The matters that remained unresolved at the time of writing the decision were:

(i) whether the method of photodynamic follicle ablation is patentable or is excluded from patentability under section 4(2) as a method of therapy of the animal body;

(ii) depending on my finding on (i), whether claims 1 and/or 27 are allowable under sections 1(1)(a) and 1(1)(b);

(iii) if I find the method of photodynamic follicle ablation to be a method of therapy –

a. whether claims 1-26 are patentable in the light of the decision in *Bristol-Myers Squibb v Baker Norton* [2001] RPC 1 (commonly known as *Taxol*)

b. whether claims 1-26 are supported by the description with regard to the treatment of balanitis in the light of the decision in *Prendergast's application* RPC [2000] 446

The law

17 Section 1(1) of the Patents Act 1977 provides:

> "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; (c) it is capable of industrial application; (d) the grant of a patent for it is not excluded by subsections (2) and (3) below; and references in this Act to a patentable invention shall be construed accordingly."

Section 4 deals with what is and what is not industrially applicable and provides:

> (1) Subject to subsection (2) below, an invention shall be taken to be capable of industrial application if it can be made or used in any kind of industry, including agriculture.
>
> (2) An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall not be taken to be capable of industrial application.

18 To alleviate the effects of the section 4(2) prohibition on claiming methods of therapy, section 2(6) states that:

> "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."

While section 2(6) only gives protection for the first medical use of a known substance, any further medical use can be protected by a claim to the use of the substance for the manufacture of a medicament for a specified medical use ie the so-called "Swiss-type" claim. Swiss-type claims only can only derive novelty from their intended use if that use is in a method excluded under section 4(2). This means that Swiss-type claims are not allowable for the new use of a known substance in a non-therapeutic method.

19 However, an application may include both claims to the second medical use of a compound for therapeutic purposes, and claims to non-therapeutic methods of using the compound, providing the therapeutic and non-therapeutic methods are distinguishable and both methods are fully supported by the application as filed. On the other hand, if the therapeutic and non-therapeutic aspects cannot be distinguished, or if the non-therapeutic effect is merely a secondary consequence of the therapy, then the invention is unpatentable, regardless of the wording used..

20 Section 14(5) provides:

The claim or claims shall –

(a) ….
(b) ….
(c) be supported by the description.

Is the method of photodynamic follicle ablation patentable?

21 I shall start by considering the patentability of the claims and specifically whether the method of photodynamic follicle ablation is a method of therapy

Examiner's argument

22 In the examiner's view, the method of follicle ablation claimed does not amount to a method of therapy as such and argues that the avoidance of blowfly strike or balanitis is an indirect consequence of the removal of wool from the animal, rather than the result of a direct treatment of these conditions. The follicle ablation results in the removal of wool in the relevant area of the wool-bearing animal, which in turn helps to reduce build-up of faecal matter and urea. This may then help to make infection resulting in balanitis less likely or may make blowfly strike less likely to occur but the examiner argues that prevention or treatment of these conditions is not a necessary consequence of this wool removal. He therefore considers that the follicle ablation method is "cosmetic" ie non-therapeutic, and the effect on balinitis and blowfly strike is a beneficial, but indirect, result of this wool removal.

Applicant's response

23 Mr Perry, the applicant's agent, argues that the examiner has ignored the nature of the invention by discounting the therapeutic aspect. He submits that the examiner's definition of the problem is artificial in that it has no reference to the reason for the need to remove/prevent re-growth of wool. Moreover, he says that the problem formulated by the examiner does not have reference to the wool-bearing animal treated in accordance with the invention. He argues that the appropriate test is whether the invention would have been obvious to a person skilled in the art. He submits that the examiner's definition of the problem is not the problem that would have been perceived by the skilled person working in the field relating to the present invention.

24 Mr Perry states that the present invention is directed to a method for the prevention of conditions such as blowfly strike and/or balanitis. He highlights page 1 lines 11-14 of the specification, which state that blowfly strike and balanitis are significant problems for sheep and wool growers. The prior art solutions adopted by the skilled persons in the art are specifically addressed to the treatment of blowfly strike and balanitis which are diseases that can cause injury to, or death of, wool-bearing animals: they would not see the problem to be solved as merely the removal and/or prevention of re-growth of wool. Apart from shearing/shaving, which only provides a temporary solution, the prior art solutions involve very severe treatments of the affected area as described on pages 1 and 2 of the specification which cause trauma to the animal and result in scarring of the skin

25 Mr Perry further submits that the prior art methods cannot be regarded as "cosmetic" in nature since shearing/shaving does not prevent the re-growth of wool and so cannot be regarded as a solution to the problem addressed by the invention. As for the prior art solutions that do remove/prevent re-growth, all involve aggressive treatments that cause varying degrees of skin damage. The word "cosmetic" in its ordinary meaning refers to something that serves to beautify or improve the beauty of something. The degree of skin damage caused by the prior art methods does not meet this description.

Assessment

26 Under UK law, it is well established that the definition of "therapy" includes not only curative treatment but also prevention of a disease. Moreover, therapy encompasses methods of alleviating symptoms and well as curative treatments for a disease. I must therefore decide whether a method of the invention constitutes a therapeutic or a non-therapeutic treatment. At the outset, I must state that I accept that balanitis and blowfly strike are both disease states.

27 Responding to the examiner's argument that the invention is a cosmetic method which has indirect therapeutic benefits, Mr Perry argues that the approach is to assess the nature of the invention underlying the claims, rather than the invention as embodied by the claims. An alternative approach is to look at the technical effect which the invention provides, and to ask whether that effect is itself patentable. Using the former approach, he says it is clear that the invention relates to a way in which to rid or prevent disease, in particular blowfly strike of balanitis ie the purpose of the treatment is therapeutic not cosmetic. Using the latter approach, he argues the technical effect provided is that it is an effective therapy of the afore-mentioned diseases. The inventive concept underlying the claims is primarily a therapeutic one and there is little or no technical effect in the cosmetic aspects that the examiner refers to. It is clear that the invention is primarily a method of treatment and it follows that it can only be claimed as a second medical use. Any other form of claim may bring into question the industrial applicability of the subject matter.

28 Looking first of all at the nature of the invention underlying the claims, the application as filed at page 1 lines 4-6, presents the invention in its broadest aspect as "a method for permanently reducing or preventing wool growth at a selected locality or localities in sheep and related animals". This is consistent with the Summary of the Invention at page 2 line 25 et seq and claim 1 as filed which are directed to "a method for the controlled ablation of wool follicles with skin of a wool bearing animal". The outcome of this method is the damage or death (ie ablation) of skin cells including cells of wool follicles (page 3 lines 30-31). As the passage at page 9 line 28 to page 10 line 4 states, this may affect the ability of the wool follicles to regenerate as well as the likelihood of the skin becoming inflamed and damaged in wet conditions that normally predispose to, or attract, blowfly strike".

29 Looking at the application as filed, I can find nothing to support Mr Perry's argument that the method is directed to the treatment of wool-bearing animals to rid them of balanitis and blowfly strike. Indeed the application specifically states at page 1 lines 8-9 that "sheep are treated to prevent the incidence of blowfly strike and/or balanitis" and at page 4 line 35 to page 5 line 1 that "the subsequent re-growth provided by the … follicles is insufficient for the

occurrence of blowfly strike".

30 Turning now to whether the method relates to prophylaxis ie a method of prevention. The *Examination Guidelines for Patent Applications relating to Medical Inventions in the UK Patent Office,* drawn to my attention by Mr Perry, indicates there is little UK case law on this issue. Since neither the examiner nor Mr Perry has cited any prior cases in support of their respective arguments, I am conscious that I should not introduce any at this stage unless they are well-established. However, *Unilever Limited (Davis's) Application* [1983] RPC 213, referred to in paragraph 15 of the *Guidelines,* gives some guidance on what is preventive treatment. This particular case concerned feeding poultry with an agent to immunise them against disease and it was held that such prophylactic treatment ie immunisation, fell within the broad definition of "therapy". For example, a vaccine will result in the generation of antibodies by the patient's immune system, the antibodies in turn destroying the pathogen when it infects the patient. However, the method claimed, differs from such a situation in that it merely results in the prevention of conditions favourable for blow strike and/or balanitis. The result ie the "technical effect", is a cleaner sheep's breach area but the method does not result in any agent or effect that will in turn actively prevent attack by blow flies or destroy the bacterium causing balanitis. In other words, the method may be viewed as essentially a matter of hygiene which is not the same thing as the treatment or prevention of balanitis and blow fly strike. The use of the term "cosmetic" rather than "non-therapeutic" is perhaps unfortunate given the method under consideration.

31 Mr Perry has also drawn my attention to paragraph 22 of the *Medical Guidelines*, which state that "it must be possible to distinguish between the therapeutic and non-therapeutic effects of a claimed method. If the non-therapeutic effect is inseparable from the therapeutic effect, or it is merely a secondary consequence of the therapy, then the invention is unpatentable, regardless of the wording used". However, he has not identified what these therapeutic and non-therapeutic effects are, so this does not assist me.

32 Although page 1 lines 6-8 mention a specific application of the treatment to prevent the incidence of blowfly and/or balanitis, I am satisfied that the invention lies in permanently or reducing wool growth in a selected locality or localities. I am therefore not convinced by Mr Perry's argument that the underlying inventive concept is therapeutic. It seems to me that for a treatment to constitute therapy, there must be a <u>direct</u> link between the treatment and the disease state to be cured, alleviated or prevented and I am not persuaded that the application demonstrates that this link is present. I therefore decide that the method of follicle ablation is not a method of therapy and is capable of industrial application as set out in section 4(1). It therefore complies with section 1(1)(c).

Are claims 1 and/or 27 allowable?

<u>Claim 1</u>

33 I have decided that the method of follicle ablation does not amount to a method of therapy ie for the prevention or treatment of blowfly strike and/or balanitis. Hence the provisions of

section 2(6) and, in particular, the "Swiss-type" form of claim, which are intended to protect the medical indication, are not applicable in this case. Hence claim 1 is not allowable. Likewise, claims 2-26 which are appendent to claim 1 are not allowable.

34 On the basis that the provisions of section 2(6) do not apply, I turn now to consider whether claims 1-26 are novel and involve an inventive step.

Examiner's argument

35 The examiner has objected that the documents cited on the International Search Report impugn the novelty of claims 1-13, 16 and 20-26 and render claims 14 and 17-19 non-inventive. Each of these prior art documents discloses a method of removing hair, or the reduction or prevention of hair regrowth involving application of a composition containing a photosensitiser to the skin and then irradiation to cause ablation of the hair follicles. Several suitable photosensitisers including benzoporphyrin and aminolevulinic acid are disclosed.

Applicant's response

36 Mr Perry has put forward no argument on this point.

Assessment

37 I must first of all construe the "Swiss-type" claims 1-26 to determine their scope. Since I have found the method of the invention is not therapeutic, the expression "for the treatment or prevention of blowfly strike or balanitis" is not limiting. In addition, in my view, the phrase "wherein the medicament is to be applied … within the skin" does not impose any restriction on the claims. Hence claim 1 may notionally be re-written as a "Method of manufacturing a composition using a follicle-ablating agent suitable for the treatment or prevention of blowfly strike or balanitis". On that basis, I have reviewed the citations and I agree that claims 1-13, 16 and 20-26 lack novelty and that claims 14 and 17-19 do not involve an inventive step.

Claim 27

38 I have decided that claim 27 is a patentable invention since it relates to a method which is non-therapeutic and therefore does not fall foul of section 4(2). It therefore follows that claim 27 is an industrially applicable invention as defined by section 4(1), (since section 4(1) is "subject to section 4(2)") and section 1(1)(c). Hence claim 27 is allowable. Likewise, claims 28-52 which are appendent to claim 27 are allowable. For avoidance of doubt, I confirm that claims 27-52 do comply with sections 1(1)(a) and 1(1)(b).

Patentability of claims 1-26 if the method of the invention is therapeutic

39 In the event that I am wrong and it is subsequently held on appeal that the method of the invention is a method of therapy, I shall now consider the patentability of claims 1-26.

Examiner's argument

40 In the examiner's view, should it be decided that the method of the invention constitutes therapy and second medical use claims are allowable, then claims 1-26 are defined in terms of the mode of administration of the "follicle ablating agent". He considers that these claims may be construed as an attempt to monopolise a new method of treatment and hence are excluded from patentability under section 4(2). These claims will therefore require amendment as the novelty of a second medical use claim must lie, not in the method of use, but in the new therapeutic purpose for which the substance is used as decided in *Bristol-Myers Squibb v Baker Norton* [2001] RPC 1 (commonly known as *Taxol*). If claims 1-26 are amended as a result of the above, then the phrase "follicle ablating agent" will require amendment to more appropriate wording reflecting the definition of "follicle ablating agents" as "photosensitisers and substances which induce the formation and/or accumulation of an endogenous photsensitiser" at page 3 lines 15-21. He argues this would appear necessary as claim 1 is at present only restricted to follicle ablating agents acting via photodynamic ablation by the wording relating to the mode of administration.

Applicant's response

41 Mr Perry agrees with the examiner that the novelty of a second medical use claim must lie, not in method of use, but in the new therapeutic purpose for which the substance is used. He submits that the applicant has never relied on the way in which the follicle ablating agent is to be applied, to establish novelty. Rather, novelty lies in the two disease states specified in claim 1, namely blowfly strike and balanitis.

Assessment

42 Again, I must first of all construe the "Swiss-type" claims 1-26 to determine their scope. Looking at the wording of claim 1, it says that "wherein the medicament is **to be applied** [my emphasis] to a selected area of the skin, the area then being irradiated with electromagnetic radiation to effect the controlled photodynamic ablation of wool follicles within the skin". In my view, the wording "is to be applied" is a statement of intent as to how the medicament is to be used and is not restricting, rather than a claim to a method of administering the "follicle-ablating agent" to the animal. I am therefore not persuaded that these claims may be construed as an attempt to monopolise a new method of treatment contrary to section 4(2). However, I agree that the phrase "follicle ablating agent" would require amendment to more appropriate wording reflecting the definition of "follicle ablating agents" as mentioned at page 3 lines 15-21. Since claims 1-26 clearly specify a new medical use as required by *Taxol*, I therefore find that the wording of claims 1-26, in principle, would be allowable.

Support for claims 1-26 if the method of the invention is therapeutic

43 Again, in the event that I am wrong and the method of the invention is therapeutic, I shall now turn to the issue of whether claims 1-26 are supported by the application as filed.

Examiner's argument

44 The examiner has objected that claim 1 is not adequately supported insofar as it relates to balanitis in that it is not clear how the specification provides by way of description enough

material to enable the relevantly skilled worker to way that this medicament treats the condition alleged (see in *Prendergast's Application* [2000] RPC 446). He argues that the data included in the description would appear to relate purely to blowfly strike with no data provided to demonstrate that balanitis may be treated by a similar method. In his view, these two conditions would not appear to be sufficiently linked for the blowfly strike tests to provide support for the aspect of the claim relating to balanitis.

Applicant's response

45 In reply, Mr Perry acknowledges that the Examples in the specification do not specifically refer to the therapy of balanitis, but submits that the key step in preventing balanitis, ie the removal of wool follicles from the skin, is satisfactorily demonstrated by the Example. He asserts that this is quite different to *Prendergast's Applications*, where Dr Prendergast submitted no test results to show that the invention actually worked. Mr Perry submits that the specification provides enough information to enable the skilled man to say that the invention can be used to prevent balanitis. Further, since this therapeutic effect is based on the reasonable scientific belief of one skilled in the art, he argues that this cannot be disputed by the examiner in the absence of objective technical evidence to the contrary.

Assessment

46 I have carefully considered Mr Perry's argument but I am not persuaded that claims 1-26 are adequately supported insofar as they relate to balanitis. The tests included in the application relates solely to blowfly strike with no data provided to demonstrate that balanitis may be treated by a similar method. It was held in *Prendergast's Applications*, that where there is a claim for the use of a substance in the preparation of a medicament for the treatment of a particular condition, the specification had to provide, by way of description, enough material to enable the relevantly skilled man to say that this medicament did treat the condition alleged. Although the tests can be very rudimentary, the law does require that some data is needed and that pure assertion is insufficient. Although Mr Perry has filed evidence that blowfly strike and balanitis are diseases, and has asserted that the relevantly skilled person would consider that the method of the invention would prevent balanitis, I can find nothing in the application as filed to back up his assertion. I therefore find that there is no support for the aspect of the claim relating to balanitis. Since section 76(2) precludes amendment to include such tests, the application does not contain enough information to support any "Swiss type" claims relating to balanitis.

47 Although not addressed in the papers before me, I also note that claim 1 refers to "the **treatment** [my emphasis] or prevention of blowfly strike or balanitis". I have already indicated that I can find nothing in the application as filed to support the treatment of wool-bearing animals to rid them of balanitis or blowfly strike. I therefore find that claims 1-26 do not comply with section 14(5)(c) and are supported only to the extent that they relate to the prevention of blowfly strike. I do not believe that this is a controversial step to take since, on the basis of his arguments made elsewhere, it would appear that Mr Perry accepts that the method of the invention relates only to prophylaxis, and not to the treatment or alleviation of balanitis or blowfly strike.

Patentability of the method claims if the invention is deemed therapeutic

48 Finally, I turn to the patentability of claims 27-52. If I am wrong and the method of the invention does constitute therapy, then method claims 27-52 should be deleted as they would relate to a method of treatment of the animal body by therapy as such and hence are unpatentable under section 4(2).

Summary of findings

49 I have found that:

(i) Claims 1-26 are not allowable under sections 1(1)(a), 1(1)(b) and 2(6);
(ii) Claims 27-52 are allowable under section 4(2) and section 1(1)(c).

I therefore refuse the application under section 18(3).

Possible amendments

50 As noted above, I have decided that the method of photodynamic follicle ablation is patentable and there is therefore scope for amendment. Since the applicant has applied under rule 110(3) for a retrospective extension of one month to the normal rule 34 period, he will then benefit from the provisions of section 20(2) which provide for an automatic extension until the end of the period for appeal against this decision. If the applicant chooses to take this opportunity to file further amendments, the application would be remitted to the examiner for further examination.

Appeal

51 Under the Practice Direction to Part 52 of the Civil Procedure Rules, any appeal must be lodged within 28 days.

MRS S E CHALMERS
Deputy Director acting for the Comptroller