

12th February 2010**PATENTS ACT 1977**

APPLICANT Virulite Distribution Limited

ISSUE Whether patent application
N^o GB 2415387 is excluded as a method
of treatment by surgery or therapy

HEARING OFFICER Stephen Probert

DECISION**Introduction**

- 1 The invention in this patent concerns a method of cosmetically treating skin using light of a very specific, narrow wavelength (1072nm) to remove wrinkles. The applicant has an earlier patent, GB 2344532B (published several years before the present application was filed) which relates to a phototherapy system for treating a variety of conditions — eg. herpetic infections. The earlier system uses the same wavelength of light. The applicant has successfully marketed its phototherapy system in a device for treating cold sores around the mouth. After a while, the inventor noticed that using the phototherapy system around his eyes led to a reduction in wrinkles, and smoother skin in that area.

The Claims

- 2 There are two independent claims in the application:
 1. A method of cosmetically treating a superficial area of mammalian skin around, above or below an eye by reducing or alleviating or removing or diminishing wrinkles that occur as a result of natural aging, the method comprising irradiating the skin with a source of divergent electromagnetic radiation centred at 1072nm and having a bandwidth of between 10 to 120nm with an intensity of at least 500 μ Watts/cm² and up to 500mWatts/cm².
 13. Use of divergent electromagnetic radiation of a wavelength of 1072nm with an intensity of at least 500 μ Watts/cm² and up to 500mWatts/cm² for cosmetically treating an area of superficial skin around, above or below an eye by reducing wrinkles that have formed due to aging.

The Examiner's Objections

- 3 The examiner has maintained several objections against the application. They are conveniently summarised in his examination report dated 16 November 2009:

(a) The method of the invention is excluded from patentability under section 4A of the Patents Act as a method of treatment by surgery and/or therapy.

(b) The method does not involve an inventive step over the cited prior art GB2344532 and the common general knowledge.

(c) The description does not support the claims.

- 4 The applicant did not accept the examiner's objections, and the matter came before me at a hearing on 25th January 2010. The applicant was represented by Dr Lisa Brown of Harrison Goddard Foote. The inventor, Dr Gordon Dougal, and the examiner also attended the hearing. After hearing submissions from Dr Brown, and having read the official file and the precedent case law in the relevant areas, I have concluded that the objections should not be maintained for reasons which I will now explain.

Method of Treatment by Surgery or Therapy

- 5 This objection is based on section 4A(1) of the Act, which reads as follows:-

Methods of treatment or diagnosis

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

- (a) a method of treatment of the human or animal body by surgery or therapy, or
- (b) a method of diagnosis practised on the human or animal body.

- 6 Section 4A(1) replaces the previous section 4(2), now repealed, which stated that such methods "shall not be taken to be capable of industrial application". A corresponding amendment has been made to the European Patent Convention (EPC). It is well understood and widely recognised that the purpose of these provisions is to prevent medical or veterinary practitioners from being restrained or hampered by the prospect of patent infringement in their treatment of patients.

Surgery

- 7 The Boards of Appeal of the European Patent Office (EPO) have defined "surgery" as "a non-insignificant intentional physical intervention performed directly or indirectly by one human being on another by manual and instrumental procedures". See *Thermage*¹ and *General Hospital*². However, both of these decisions of the EPO Boards of Appeal give guidance as to the circumstances in which surgery for cosmetic purposes may fall outside the exclusion, notwithstanding the fact that it is a method of treatment by surgery. For example, in *General Hospital* the Board said (at paragraph 3.2(b)):

"Evidently the exclusion aims at protecting curative activities. As the BGH stated the doctor must be free to take the most suitable measure to treat his patient."

- 8 And again at paragraph 3.4:

¹ T1172/03 Thermage/"Apparatus for skin resurfacing" at paragraph 2.1

² T383/03 General Hospital Corporation/ "Hair removal method using optical pulses" at para 3.1

“Thus, treatments by surgery which are clearly neither suitable nor potentially suitable for maintaining or restoring the health, the physical integrity, or the physical well being of human beings or animals do not fall within the exclusion from patentability of Article 52(4) EPC.”

9 Thus it seems to me that in the EPO, there are two steps to determining whether a method is excluded as a treatment by surgery. The first step is to determine whether there is “a non-insignificant intentional physical intervention ...”, and if there is, one must then consider whether the treatment is suitable, or potentially suitable, for maintaining or restoring the health, the physical integrity, or the physical well being of human beings or animals. The exclusion only applies if the answer to both of these questions is ‘yes’.

10 In *General Hospital* the invention concerned methods for hair-removal from a skin region by applying short bursts of light of a selected wavelength to the skin. Excess hair is a common dermatological problem and can be caused by heredity, malignancy or endocrinologic diseases. The Board of Appeal decided that the invention was surgery, because there was a non-insignificant intentional physical intervention — eg. the hair and follicles are damaged in the process. However, the Board decided that this particular method of treatment by surgery was not excluded. In other words, the answer to the first question was ‘yes’ (it’s surgery), but the answer to the second question was ‘no’. At paragraph 4.1 they said:

“While the underlying cause of excess hair may be malignancy or endocrinologic diseases, excess hair itself is not harmful and its removal does not treat the underlying cause of unwanted hair, nor is it relevant to the physical health of the treated person, the treatment merely results in an aesthetic improvement of the appearance of the person. The claims are directed to a “cosmetic method” in order to emphasise that the purpose of the claimed method is to improve the aesthetic appearance of the person treated rather than to cure the underlying malady.”

11 In *Thermage* the invention was a method of tightening the skin by directing electromagnetic energy through the skin surface to a collagen-containing tissue site in order to achieve controlled contraction of the collagen. The Board considered that there was a non-insignificant intervention because, in effect, the skin is burned. So the method in *Thermage* was found to be a treatment by surgery. (The answer to the first question was ‘yes’.)

12 However, in *Thermage*, the Board also found that the method was suitable for maintaining or restoring the health, the physical integrity, and the physical well being of a human being because it could be used for several therapeutic purposes including the application on the face or neck for reconstructive purposes. Thus the second question was also answered ‘yes’, and the invention was excluded.

13 There does not appear to have been much caselaw from UK courts in this area. The Examination Guidelines³ refer to the judgment of Falconer J in *Unilever*⁴ where he says (page 228 line 5):

³Examination Guidelines for Patent Applications relating to Medical Inventions in the UK Intellectual Property Office, August 2008. Available on the Office’s website.

⁴Unilever (Davis’s) Application [1983] RPC 219 at page 228

“Looking at surgery, surgery can be curative of the disease or diseased conditions, or prophylactic, that is, preventive of diseased conditions, as for example, where an appendix or tonsils may be removed before any diseased condition starts up, and surgery may even be cosmetic without being curative or preventive. So that the subsection it seems to me is saying that any method of surgical treatment, whether it is curative, prophylactic or cosmetic, is not patentable. It would be very strange if the non-surgical treatment, that is to say, the therapy covered by the subsection, should be restricted to curative and not extend to prophylactic, in other words, that while any method of surgery, whether curative, prophylactic or cosmetic, is not patentable, some methods of therapy, namely, the prophylactic ones, are.”

- 14 Even though strictly obiter, it might be suggested that Falconer J’s definition of “surgery” includes [all] cosmetic treatments, but that is not how I read the judgment. Some cosmetic treatments may involve surgery, but clearly not all cosmetic treatment is surgical. For example, a method of combing your hair might well be a cosmetic process or treatment, but no-one would seriously suggest that it should be regarded as surgical (or “treatment by surgery”). On the other hand, some cosmetic treatments will involve surgery; for example reconstructive surgery following a major injury or some serious illnesses. As I understand *Unilever*, what Falconer J is saying is that surgery, whether curative, prophylactic or cosmetic, is still surgery (and therefore excluded). He does not say that all cosmetic treatments fall within the definition of surgery. In this respect I consider that the definition of “surgery” in *Unilever* is not inconsistent with that of the EPO Boards of Appeal.
- 15 I have therefore been guided by the definitions and the reasoning in *Thermage* and *General Hospital*. In the present case, I am satisfied that the claimed method is not a treatment by surgery. There is not⁵ a “non-insignificant intentional physical intervention”. In particular, it does not burn the skin (as in *Thermage*), and neither is there any suggestion that the cells of the body are damaged or radically altered in the process (as in *General Hospital*). Thus if I adopt the EPO approach, then the answer to the first question is ‘no’, and the exclusion does not apply.
- 16 However, even if I am wrong about the “non-insignificant intentional physical intervention”, I consider that the answer to the second question would also be ‘no’. The invention is consistently claimed and described throughout the application as being for cosmetic purposes only. The method is manifestly not suitable for maintaining or restoring the health, the physical integrity, or the physical well being of human beings or animals.

Therapy

- 17 In *Unilever*, Falconer J defined “therapy” thus:

“In my judgment the word ‘therapy’ in section 4(2) is to be construed in its wide meaning as including preventive, that is to say, prophylactic, treatment as well as curative treatment of disease of the human body and the animal body.”

⁵The triple negative, however unpleasant to the mind, is (regrettably) unavoidable here.

18 The EPO Boards of Appeal have developed a more detailed definition. In *Salminen*⁶, the Board agreed that:

“... the word ‘therapy’ covers any non-surgical treatment which is designed to cure, alleviate, remove or lessen the symptom of, or prevent or reduce the possibility of contracting any malfunction of the animal body;

and also relates to the treatment of a disease in general or to a curative treatment in the narrow sense as well as the alleviation of the symptoms of pain and suffering”

19 Later, in *Thompson*⁷, the Board refined the definition thus:

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

20 The invention described in the present application claims to alleviate or lessen one of the symptoms of natural ageing - ie. wrinkles. To many of us, ageing is a disease or disorder or malfunction of the body; however, I don’t think Parliament would have regarded it as such when the Act was passed, and I don’t think the Court or the EPO Boards of Appeal had it in mind when they defined ‘therapy’ as set out above. Consequently I do not consider that a method of cosmetically treating skin to reduce wrinkles that occur as a result of natural ageing is a method of therapy for the purposes of patent law. In the present application, the limitation in the claims to treating age-related wrinkles is sufficient to distinguish the method from any therapeutic method.

21 Dr Brown drew my attention to witness statements by Dr Gordon Dougal (a medical doctor) and Professor Julia Bishop. Dr Dougal says:

“To the best of my knowledge there are no medical conditions that would benefit from wrinkle reduction and the cosmetic effect of electromagnetic radiation of between 900 to 1500nm and especially 1072nm light.”

22 Professor Bishop is professor of Dermatology at the University of Leeds. She is an expert in melanoma and pigmented lesions and leads a research group which is addressed to understanding the epidemiology and genetics of skin cancer. She says she is experienced in dermatology and the effects of ageing and sun exposure on the skin. Professor Bishop’s evidence is that facial wrinkles are:

“... cosmetically troubling for some patients and many seek cosmetic treatment for them. The presence of facial wrinkling may have medical implications, most commonly in terms of assessing skin cancer risk. So, if an individual has many wrinkles then this implies a significant exposure to the sun and therefore some increased risk of skin cancer. The treatment of facial wrinkling per se however is a cosmetic exercise, because any reduction in those wrinkles as a result of treatment will not impact on the skin cancer risk, which results from the sun exposure not the development of wrinkles.”

⁶T 58/87 Salminen / Pigs III [1989] EPOR 125, at paragraph 2.1

⁷T 24/91 Thompson / Cornea [1996] EPOR 19 at paragraph 2.7

- 23 Dr Brown also drew my attention to an email from Mr Dhruvi Patel of the Medical and Healthcare Products Regulatory Agency (MHRA). In his email, Mr Patel says that the MHRA do not regard a device for treating wrinkles around the eyes as a medical device, and such a device would therefore not be within their remit.
- 24 Lastly, and I suggest most importantly, before confirming that the method claimed in this application is not a method of treatment by surgery or therapy, I have considered the well established purpose of this exclusion — ie. to prevent medical or veterinary practitioners from being restrained or hampered by the prospect of patent infringement in their treatment of patients. As this is the purpose of the exclusion, then in my view this should be the fundamental, overriding test — ie. would this patent, if granted, interfere with the work of a medical or veterinary practitioner in their treatment of patients? The definitions and multiple step tests identified above will often be useful in helping to answer this fundamental question, but ultimately if granting this patent application would restrain or hamper a medical or veterinary practitioner in their treatment of patients, then I must reject the application. I believe the converse is equally true; that is, if granting this patent application would not restrain or hamper a medical or veterinary practitioner in their treatment of patients, then section 4A(1) does not preclude grant.
- 25 Having read the entire patent application carefully, I concluded that if this patent were to be granted, it would not, on any construction of its claims, interfere with the work of a medical or veterinary practitioner in their treatment of patients. As Dr Brown submitted, wrinkles caused by natural ageing are not a pathological condition.

Inventive Step

- 26 Section 1(1)(b) and section 3 of the Patents Act 1977 set out the statute law on inventive step in the UK:

Patentable Inventions

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

- (a) the invention is new;
- (b) it involves an inventive step;
- (c)

and references in this Act to a patentable invention shall be construed accordingly.

Inventive Step

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

- 27 The examiner's objection is based on GB2344532; it is clearly part of the state of the art by virtue of section 2(2). In my opinion, it discloses an apparatus that could be used to perform the method that is now claimed in this later application. According to Dr Dougal, that is how the invention was made — ie. while experimenting with the apparatus of the prior art, he stumbled upon a new, albeit cosmetic, benefit from using the apparatus for a longer period of time on a region of "looser, more mobile skin" around the eyes.

28 Although the method of the invention can be performed using known apparatus, the question of novelty does not arise in this case. The Manual of Patent Practice explains why, at paragraph 2.17:

A claim for a method of using a known apparatus may be regarded as novel provided that the method of use is new. Parker J stated in *Flour Oxidizing Co Ltd v Carr and Co Ltd*, 25 RPC 428 at page 457, "But when the question is solely a question of prior publication, it is not, in my opinion, enough to prove that an apparatus described in an earlier specification could have been used to produce this or that result. It must also be shown that the specification contains clear and unmistakable directions so to use it."

29 The specification of GB2344532 (the prior art) does not contain clear and unmistakable directions to use the known apparatus for reducing wrinkles around the eyes caused by natural ageing. So the method is novel; but does it involve an inventive step? Would a person skilled in the art realise, without any degree of invention, that the apparatus disclosed in GB2344532 could be used to treat wrinkles around the eyes? Is there a hint or suggestion that might point the reader in the direction of this new method of cosmetic treatment? There is a structured approach for assessing inventive step, as set out in *Windsurfing*⁸ and reformulated by the Court of Appeal in *Pozzoli*⁹. In the specific circumstances of this case, I can go straight to the crucial, fourth question:

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

30 Dr Brown developed her argument in favour of inventive step along two distinct tracks. I found both of them quite compelling at the hearing. After giving them further thought after the hearing, I have found them to be irrefutable.

31 The first argument is that the earlier patent is concerned with treating pathological conditions — most notably herpetic infections. It doesn't matter whether the person skilled in the art is reading the patent specification, or actually using one of the applicant's devices, they would have no reason to suppose that a device intended for treating a genuine medical illness could also have a secondary, purely cosmetic, use. According to Dr Dougal, even if someone had used one of the applicant's devices to treat an infection near the eyes, they would not notice any cosmetic improvement (in relation to wrinkle reduction) within the typical timescales associated with treatment of herpetic infections or any other pathological condition. He said it takes many weeks of regular use to achieve a noticeable reduction in wrinkles; and that is only because the skin around the eyes is looser and more mobile than, for example, the skin around the mouth where the device of the prior art would typically be used.

32 Dr Brown's second line of argument was that this new use of 1072nm light is completely counter-intuitive. Most people would accept that one of the most common causes of wrinkled skin is prolonged exposure to sun light. Who then

⁸ *Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd*, [1985] RPC 59

⁹ *Pozzoli SPA v BDMO SA* [2007] EWCA Civ 588

would think of shining more light at wrinkles in order to reduce them? It would be like prescribing cigarettes to treat lung cancer.

- 33 For these reasons I think that the method claimed in the present application is not one which would have been obvious to the person skilled in the art. The objection to lack of inventive step therefore fails.

Support

- 34 The examiner has objected that the claims as amended during the examination process are no longer supported by the description. This objection is founded on section 14(5)(c), reproduced below:

- (5) The claim or claims shall -
- (a) define the matter for which the applicant seeks protection;
 - (b) be clear and concise;
 - (c) be supported by the description;

- 35 During the examination stage the applicant restricted the claims to treating skin “around, above or below an eye” and “wrinkles that occur as a result of natural aging”. The examiner objected that both of these limitations lack clear support in the originally filed description.

- 36 The first sentence of the description, as filed, reads as follows:

“The present invention relates to the cosmetic use of electromagnetic radiation for the reduction or alleviation or removal or diminishing of wrinkles or fine lines, especially but not exclusively facial and neck wrinkles and other signs of aging.”

- 37 There are other references to cosmetically treating facial skin, but in particular the last paragraph on page 6 mentions “reducing skin volume above the eyes and under the eyes”. Lastly, describing some human studies that were undertaken, the specification says on page 14 that:

“The skin around the eyes was chosen as it is more mobile and more likely to demonstrate an improvement in the elasticity of the skin.”

- 38 Having regard to the description as a whole, and particularly the extracts quoted here, I am satisfied that the claims as amended are supported by the description.

Next steps

- 39 The objections raised against this application cannot be sustained, and I am therefore remitting the case back to the examiner to conclude the examination process.

S J PROBERT

Deputy Director acting for the Comptroller