Opinion Number

OPINION UNDER SECTION 74A

Patent	GB 2493904
Proprietor(s)	Actegy Limited
Requester	Marks and Clerks (Manchester)
Observer(s)	N J Akers & Co
Date Opinion issued	21st January 2015.

The request

- 1. The Comptroller has been requested to issue an opinion as to whether GB 2493904 is valid. In particular, the requester has asked for an opinion on whether claims 1, 2 to 5 and 12 (when dependent on claims 1-5) are novel and/or inventive in the light of evidence they have provided as set out in paragraph 4 of their request.
- 2. More particularly, he has been requested to issue an opinion on whether claims 1, 2, 3 and 12 are novel and whether claims 1, 4, 5 and 12 are inventive.
- The request was received by the Office from Marks and Clerk on 24th October 2014. Observations were received from N J Akers & Co on behalf of the patentee on 24th November 2014. Further observations in response were received from Marks and Clerk on 9th December 2014.
- 4. I would like to thank both the requester and observer for the detailed request and their subsequent responses. These have proved very useful in coming to my opinion.

The Requester's Evidence

- 5. The requester has drawn my attention to a Chinese utility model patent, CN 200973920Y, published on 14th November 2007 of which they have helpfully provided a translation. The patentee has passed no comment on the accuracy of this translation and as such I will consider it a reliable indication of the content of the original document.
- 6. My attention has also been drawn to the patentee's acknowledged prior art, the Circulation Booster^{RTM} which is referred to on page 3 of the specification. In addition they provided a printout of an internet review of the Circulation Booster^{RTM} product containing a posting dated 5th February 2011. As far as I understand it, this is provided as evidence of the date the Circulation Booster^{RTM} was available. (I do not dispute this and nor does the observer so I will take it that this product was known at the priority date of the application.)

7. The requester has also provided the abstract to a paper in their initial request:

CHENG JS Effects of combining electrical stimulation with active ankle dorsiflexion while standing on a rocker board a pilot study for subjects with spastic foot after stroke

8. Following the observations of the Patentee, the requester provided three further documents:

US FDA 510(K) Submission for COMPEX^{RTM} SPORT US FDA 510(K) Submission for P4-Fitness US FDA 510(K) Submission for COMPEX^{RTM} REHAB

Claim construction

- 9. Before considering the documents put forward in the request I will need to construe the claims of the patent following the well known authority on claim construction which is *Kirin-Amgen and others v Hoechst Marion Roussel Limited and others* [2005] RPC 9. This requires that I put a purposive construction on the claims, interpret them in the light of the description and drawings as instructed by Section 125(1) and take account of the Protocol to Article 69 of the EPC. Simply put, I must decide what a person skilled in the art would have understood the patentee to have used the language of the claim to mean.
- 10. Section 125(1) of the Act states that:

For the purposes of this Act an invention for a patent for which an application has been made or for which a patent has been granted shall, unless the context otherwise requires, be taken to be that specified in a claim of the specification of the application or patent, as the case may be, as interpreted by the description and any drawings contained in that specification, and the extent of the protection conferred by a patent or application for a patent shall be determined accordingly.

11. And the Protocol on the Interpretation of Article 69 of the EPC (which corresponds to section 125(1)) states that:

Article 69 should not be interpreted in the sense that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Neither should it be interpreted in the sense that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patentee has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patentee with a reasonable degree of certainty for third parties.

 For the purposes of this opinion I need to come to a view on the construction of claims 1-5 and 12 of the patent. For ease of reading I have reproduced these claims below:

Claim 1

An apparatus for the electrical stimulation of a subject, the apparatus comprising:

A contact member having a contact surface for contacting the plantar surface of a foot of the subject; and

Means for providing an electrical stimulation cycle to the foot of the subject comprising supplying an electrical current to the contact surface for the electrical stimulation of the plantar muscles of the foot of the object;

Wherein the contact surface is movable so as to allow the angle of the joints of the foot and ankle of the subject to change during the electrical stimulation cycle

Claim 2

The apparatus according to claim 1, wherein the contact surface is elongate having a proximal end and a distal end

Claim 3

The apparatus according to Claim 2, wherein the contact surface can accommodate the major portion of the plantar surface of the foot of the subject

Claim 4

The apparatus according to any proceeding claim, wherein the contact surface is contoured to accommodate the contours of a foot of the subject

Claim 5

The apparatus according to any preceding claim, wherein the contact surface is movable about a pivot

Claim 12

The apparatus according to any preceding claim, wherein the apparatus comprises a first contact member having a first contact surface for one foot of the subject and a second contact member having a second contact surface for a second foot of the subject

13. Turning to Claim 1. Claim 1 is directed to a device for "electrical stimulation" of a subject. In particular, this is the plantar surface of a foot to which an electrical current is supplied through a contact surface as part of an electrical stimulation cycle. Importantly, the contact surface can move to allow the "angle of the joints of the foot

and ankle of the subject to change".

- 14. There is little here that causes any real issue other than to determine what is meant by the supply of the electrical current. The patentee has, in paragraph 6 of their observations, observed that this is the application of an electrical current directly to the feet of the subject. I note that the requester has not disputed this in their response to the observations.
- 15. For the record I also agree on this construction. Page 4 Lines 26 33 make it very clear that the electrical current is provided to the foot through a conductive contact surface. Page 5 Lines 9-16 further describe the contact surface and properties that allow it to conduct electric current. Further details of the application of the electrical current can be found on Page 8 Lines 5-14 and in a specific embodiment at Page 12 Lines 8-10. Given that this is clearly what is intended by the drafter of the patent I have no reason to disagree with either the requester or the observer that this is the correct construction of term "electrical stimulation"
- 16. The remainder of the claim presents little difficulty in construction. However, I take the final clause of the claim to mean that the device can move so that the foot and ankle are not constrained in one position i.e. they can flex during any electrical stimulation. Beyond this, I see no reason to dwell on any further matters of construction.

Novelty

- 17. The major issue in determining novelty is what is disclosed in the Chinese Utility model, CN200973920Y which describes a "Foot training and Body Beautifying Machine with Electromagnetic Waves". At the heart of the invention defined in this Utility Model is the provision of "foot vibrating pedals", which have electromagnetic wave massage sheets disposed on them. The pedals and the massage sheets are both connected to power circuits. In operation the pedals can rock or rotate whilst the function of the sheets is specifically described such that "electromagnetic stimulation may be carried out on the feet of the human body resulting in massaging effect".
- 18. The requester, in the initial request, argues that this "electromagnetic stimulation of the foot" falls within the scope of the "electrical stimulation" required in claim 1 of the patent and consequently that the claim is not novel. Needless to say the patentee disagrees with this point. He argues that "The term 'massage' has a very clear meaning, that is the physical rubbing or kneading of muscles of the body of the user". He says that the "electrical stimulation massage" said to result from use of the device in the Utility Model should be interpreted accordingly; applying an electrical current to the massage sheets causes them to physically move and thus to apply a physical massage to the foot of the user. He says no electrical signal is applied directly to the foot of the user of the device in the Utility Model in contrast to the device in the patent. In one line of argument he suggests that the term "electromagnetic" refers to operating the massage sheets though "magnets movable in response to varying electrical current".
- 19. Further observations from the requester dispute this. He argues that the massage effect of the device disclosed in the Utility Model is more than just the physical rubbing or kneading of the body of the user. In support they have offered a number

of product applications to US Food and Drug Administration (USFDA) which they claim showed the term "massage" to encompass direct electrical stimulation. Thus in the requestor's view, the use of the term "massage" in the Utility Model does not just mean that the effect disclosed therein must result from the "physical, rubbing or kneading of the muscles of the body of the user" but can include electrical stimulation.

- 20. So what would the skilled person have understood the disclosure of the Utility Model to have meant when it was published? I consider he would have construed it as disclosing "electrical stimulation" as per claim 1 of the patent for the following reasons:
- 21. First I am inclined to agree with the requester on the meaning of massage. Clearly, a massaging effect can be induced by the physical manipulation of the body through any number of techniques such as more traditional forms like rubbing or kneading using the hand or other tools like bamboo. However, to my mind it also includes more high tech methods such as electrical stimulation and ultrasound to induce a massaging effect. It is therefore appropriate to consider it as covering both physical and electrical stimulation. Thus in my view the skilled person would not have considered use of the term "massage" in the Utility Model to limit the device to one where the sheets move.
- 22. Second, whilst it is a relatively brief disclosure, the Utility Model uses very specific terminology to describe the effect it is seeking to achieve electrical stimulation massage. Indeed that terminology is consistently used throughout the Utility Model when describing the effect produced by not only the massage sheets located on the pedals but also the handles and stick on pads used to cause the effect on other parts of the user's body as shown in figure 3. In one instance when discussing the massage sheets it is made clear that "changing the current and frequency may produce various electrical stimulation massage modes such as tapping, kneading or produce shiatsu massage".
- 23. That the same wording electrical stimulation is used to describe the effect achieved in the patent and in the earlier Utility Model is in my view no coincidence. Furthermore I also think it is significant that the various pads are provided in pairs in the Utility Model. This is particularly so for the small pads that are attached to other parts of the user's body, such as acupuncture points, but which generate the same electrical stimulation massage effect. If they are operated by vibration as the patentee seems to suggest there is no reason why they would need to be deployed in pairs. In my view the skilled person would understand the device of the Utility Model to create the electrical stimulation massage effect directly from the electrical signals applied to the pads. There is nothing in the disclosure that would lead him or her to conclude that those signals are converted to any other form as the patentee suggests
- 24. Furthermore, in its introduction, the Utility Model discusses the existing state of the art of fitness and massage machines. These are said to include foot vibrating massage pedals which are controlled to rock or rotate. Their function is however said to be simplistic since "The machine massages or exercises the leg muscles mainly through vibrating. There are no other functions."

- 25. The invention in the Utility Model is said to solve this problem in that it "provides a foot training and body beautifying machine with electromagnetic waves. It may carry out electromagnetic stimulation on the feet of a human body, resulting in massaging effect to further achieve effects of health and fitness".
- 26. If the device of the Utility Model works as the patentee suggests an applied electric current causing the massage sheet to move then the resulting massage effect would still be caused by vibration. I do not consider that the skilled person would construe the Utility Model in that way. He (or she) would not consider that to be a "foot training and body beautifying machine with <u>electromagnetic waves</u>". To my mind the skilled person would see that the Utility Model provides additional functionality over and above a vibrating massage device.
- 27. Although the information provided by the utility model is not very comprehensive it does in my opinion provide enough information to come to the view that on the balance of probabilities the massage sheets disposed on the pedals do provide electrical stimulation of the feet as required in claim 1. The final part of the claim concerns whether the contact surface is movable during the electrical stimulation cycle. The Utility model makes it very clear that the pedals rock or rotate and since the massage sheets are disposed on the pedal and both are connected to the control unit in the body of the machine they are considered to allow the users foot an ankle to move during the electrical stimulation cycle.
- 28. On that basis it is my opinion that claim 1 is not novel over CN 200973920Y,
- 29. It is also my opinion claims 2, 3 & 12 also lack novelty over CN 200973920Y. Figure 2 shows clearly two foot shaped pads. These are clearly elongate, have a proximal and a distal end to accommodate the plantar surface of the foot.

Inventive Step

- 30. The requester has also asked for an opinion on whether claim 1 & 4-5 & 12 lack an inventive step in the light of the Circulation Booster^{RTM} product when considered alongside CN 200973920Y or the document attributed to CHENG. The requestor's argument is that the Circulation Booster^{RTM} is indicative of the state of the art, a point they reinforce in paragraph 13 of their observations in reply. They further argue that the Chinese Utility Model and CHENG document are indicative of the common general knowledge of the skilled person and that in view of that common general knowledge (s)he would consider the differences between the invention and the Circulation Booster^{RTM} device to be obvious.
- 31. To determine whether or not an invention defined in a particular claim is inventive over the prior art, I will rely on the principles established in Pozzoli SPA v BDMO SA [2007] EWCA Civ 588, in which the well known Windsurfing steps were reformulated:

(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, determine whether those differences constitute steps which would have been obvious to the person skilled in the art.

- 32. Identifying the skilled person in this case does not present a great deal of difficulty. Both parties appear to agree that they are healthcare professional who would have an understanding of the use of electrical stimulation in treating a subject and specifically for treatments to improve venous blood flow.
- 33. In terms of common general knowledge I believe they would be aware of the techniques and equipment that can be used to achieve improved circulation by electrical stimulation.
- 34. It is suggested that the Chinese Utility model CN 200973920Y is part of the common general knowledge. A single patent document can in some cases be illustrative of the common general knowledge but I do not believe that is the situation here. The observer in his observations make this exact point referring to *General Tire & Rubber Co v Firestone Tyre & Rubber & Co Ltd [1972] RPC 457* stating that "individual patent specifications do not normally form part of the relevant common general knowledge". I feel confident in saying that this is most definitely the case here as I am sure a single Chinese Utility model clearly does not form part of the relevant common general knowledge. Furthermore, the requester has not provided any evidence that this document is indicative of the state of the art it is single very obscure document.
- 35. The requester has also directed me to the abstract of a paper by JS CHENG which concerns some research into the use of electrical stimulation in the treatment of "spastic foot" in stroke patients. I am also grateful to the patentee for providing a full copy of the paper.
- 36. Having now had an opportunity to read the paper I am of the opinion that this experiment was designed for a different set of circumstances. In particular, it appears to lie in treatment of stroke victims and assisting them to redevelop walking skills through treating ankle spasticity. The conclusions presented in column 1 of the report make it very clear that this is the case. Also importantly were the locations of the electrodes in this experiment. These are detailed in the second paragraph of column 1 on page 507 of the paper and are located on the "motor points of the tibialis anterior muscle and common peroneal nerve". As I understand the paper the rocker board used was used to monitor the position and weight bearing characteristics of the subject. At no point in the paper is it suggested that electrical current is applied to the plantar surface of the foot. Given the disclosures of the paper I do not believe it would form part of the common general knowledge in the area of improving the circulation of a subject.
- 37. The inventive concept of the invention is to allow the foot of the subject to move about the ankle whilst undergoing electrical stimulation through the plantar surface of the foot.
- 38. It is known in the prior art to provide an electric current to the foot. This is clearly seen in the Circulation Booster ^{RTM} product where static pads are provided on which

the subject's feet are placed. It is also known that by applying electrical stimulation to the lower leg muscles of the subject it is possible to improve blood flow to the subject's foot. This much is clear from the prior art recited by the patentee in the specification.

- 39. On this basis the difference between the inventive concept and the state of the art appears to lie in allowing the foot to move about the ankle during electrical stimulation.
- 40. The final step is to determine if it would be obvious to the person skilled in the art. Given that neither the Utility model nor the CHENG paper are part of the common general knowledge it follows that any inventive step argument is based entirely on whether it would be inventive to modify the Circulation Booster ^{RTM} to allow the subjects foot to move during the electrical stimulation cycle.
- 41. The requester has asserted that this is the case and that the skilled professional would require no inventive ingenuity to provide the device of claim 1 considering the common general knowledge that moving the foot and ankle is well known as a means of improving circulation
- 42. In my opinion this is not the case. The Circulation Booster^{RTM} clearly shows a device where electrical stimulation of the foot is undertaken. The question is whether the skilled person would consider it obvious to amend this product to allow the foot to move at the same time. To my mind, the skilled person would not consider it obvious to modify the Circulation Booster^{RTM} device to allow the contact surface to move during the electrical stimulation cycle. Specifically, there is some difference between the knowing that moving the foot and ankle during stimulation can help circulation to adapting the system seen in the Booster to move without the benefit of hindsight. In my opinion it is this adaptation that forms the inventive element of the claim. As such, I am of the opinion that claim 1 of the patent provides an inventive step over the Circulation Booster^{RTM}. It follows that claims 4, 5 and 12 also demonstrate the an inventive step

Conclusion

43. The requestor has asked me for an opinion on whether claims 1-5 and 12 of the patent GB 2493904 are novel and/or inventive over Chinese Utility Model CN200973920Y, the CHENG paper and the Cirucaltion Booster^{RTM}. It is my opinion that:-

Claims 1-3 & 12 are not novel in the light of the Chinese Utility Model CN 200973920Y.

And

That neither the Chinese Utility model and CHENG document form part of the common general knowledge and on this basis claims 1, 4, 5 and 12 demonstrate an inventive step over the Circulation Booster^{RTM}.

Application for review

44. Under section 74B and rule 98, the proprietor may, within three months of the date of issue of this opinion, apply to the comptroller for a review of the opinion.

Nigel Hanley Examiner

NOTE

This opinion is not based on the outcome of fully litigated proceedings. Rather, it is based on whatever material the persons requesting the opinion and filing observations have chosen to put before the Office.